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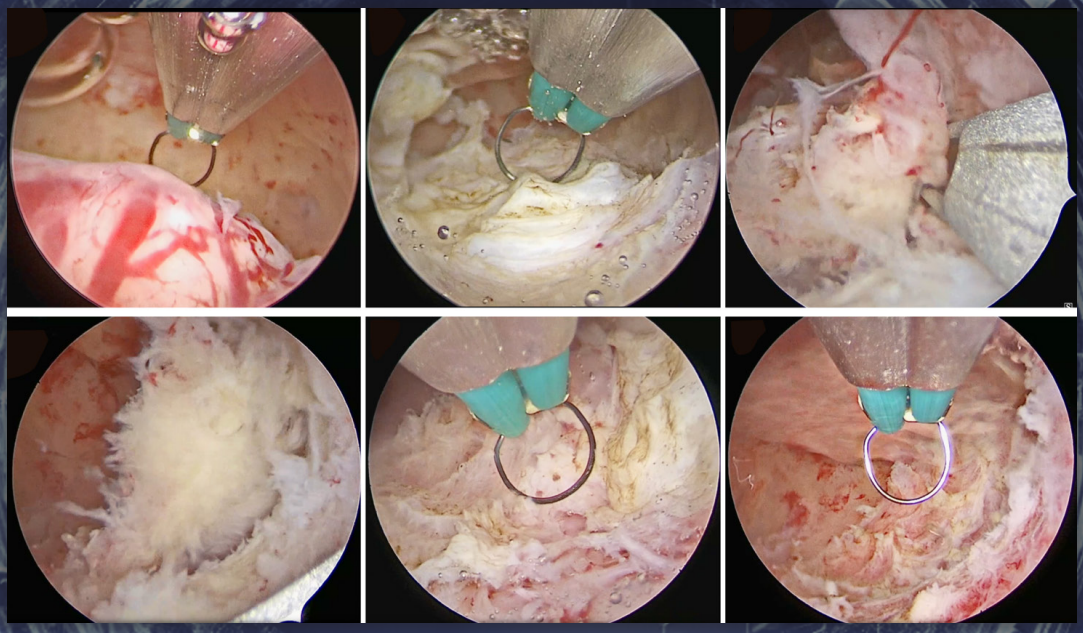

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EDITORIAL

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Virtual reality for pain relief in gynaecological care

Josep Estadella-Tarriel

Hospital de la Santa Creu i Sant Pau, Department of Obstetrics and Gynecology, Universitat Autonoma de Barcelona, Institut d'Investigació Biomèdica Sant Pau (IIB Sant Pau), Barcelona, Spain

Keywords: Hysteroscopy, virtual reality, pain

Hysteroscopy is integral to optimising the diagnosis and treatment of intrauterine pathologies in contemporary gynaecology. Indeed, the landscape of surgical practice has been transformed by advances in hysteroscopic surgical technologies. Common interventions that were previously performed in the operating room are now conducted in an outpatient setting. This change in practice reduces the costs and utilisation of scarce health care resources and enhances safety, convenience, and efficiency of clinical management.[1] However, despite these benefits, procedures may fail and need to be discontinued because of pain.

Pain transmission pathways are inherently complex and susceptible to modulation through various mechanisms. One such modulator is anxiety, which can significantly alter the pain experience through the activation of the amygdala. Extensive evidence highlights the direct correlation between pre-procedural anxiety and heightened pain perception, as well as increased analgesic consumption. Consequently, implementing relaxation strategies aimed at reducing pre-procedural anxiety has been shown to effectively mitigate perceived pain levels. Additionally, targeted focus on specific tasks can direct cerebral activity away from brain regions implicated in pain processing, such as the thalamus and insula. This approach, known as distraction, enables a reduction in perceived pain intensity despite the constancy of the nociceptive stimulus.[2] The use of virtual reality (VR) has emerged as a valuable tool in this context, offering both relaxation and distraction mechanisms that can effectively decrease patient discomfort during gynaecological and obstetric procedures. By immersing patients in controlled, engaging virtual environments, VR not only fosters relaxation but also provides cognitive distraction, thereby diminishing the overall pain experience without pharmacological intervention.[3]

A systematic review and meta-analysis evaluated the efficacy of VR in reducing acute procedural pain across various clinical settings.[4] The study synthesised data from 20 studies involving 776 participants undergoing various painful procedures, including burn wound care, physiotherapy for burns, needle-related interventions, and minor surgical procedures. The findings indicated that VR was particularly effective in reducing pain during needle-related procedures and physical therapy for burns, with a standardised mean difference (MD) in pain score reduction of -0.49 [95% confidence interval (CI): -0.83 to -0.14, *P*=0.006]. However, the effect of VR on other surgical procedures was less pronounced, with high statistical heterogeneity observed across studies. The authors concluded that while VR showed potential as a non-pharmacological intervention for pain management,

Corresponding Author: Josep Estadella-Tarriel, MD, Hospital de la Santa Creu i Sant Pau, Department of Obstetrics and Gynecology, Universitat Autonoma de Barcelona, Institut d'Investigació Biomèdica Sant Pau (IIB Sant Pau), Barcelona, Spain
E-mail: jestadella@santpau.cat **ORCID ID:** orcid.org/0000-0001-7140-3091
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further methodologically robust studies were needed to confirm its efficacy and explore its cost-effectiveness in clinical practice.[4]

A recent systematic review and meta-analysis has evaluated the use of VR during hysteroscopy.[5] The study synthesised data from six randomised controlled trials (RCTs) involving a total of 457 patients. The primary outcomes included pain and anxiety levels during and after the hysteroscopy, assessed using the visual analogue scale. The findings indicated a significant reduction in pain scores during the procedure for the VR group compared to standard care [MD: -1.43, 95% CI (-1.69, -1.16), $P<0.001$]. Additionally, anxiety levels were significantly lower among patients receiving VR intervention ($P=0.01$). Post-procedure pain scores also decreased significantly in the VR group [MD: -1.52, 95% CI (-1.78, -1.26), $P<0.001$]. Despite these promising findings, the authors highlighted some limitations, including heterogeneity in VR content, device types and procedure duration and stated that further research with a higher number of patients was needed to standardise VR protocols and confirm its efficacy in broader clinical settings.[5]

In this issue of Facts, Views & Vision, we publish two studies evaluating the efficacy and acceptability of VR in outpatient hysteroscopy. An RCT from Italy showed that the use of VR environments during outpatient hysteroscopic procedures significantly reduced perceived pain and anxiety levels amongst the VR group compared to controls,[6] in keeping with earlier RCTs.[5] A real-world observational series also showed potential efficacy, but uptake was relatively low, with only a third of women offered VR willing to use it.[6] Thus, the place for VR within modern, outpatient hysteroscopic practice needs defining, which procedures and which patients. It seems clear that much remains to be done in pain perception during outpatient hysteroscopy. Recent guidelines state that information about treatment for pain should be addressed with patients before the procedure.[7] VR technologies provide patients with more options for pain management during outpatient hysteroscopy.

We should also broaden our perspective beyond outpatient hysteroscopy, considering the implementation of VR in other areas of obstetrics and gynaecology. Satisfactory outcomes have already been documented in using VR for pain relief during the first stage of labour[8] or in procedures such as amniocentesis[9] albeit not during intrauterine device placement.[10] Thus, VR could potentially complement existing pain control options used in certain gynaecological and obstetric procedures, widening its impact and utility within women's health care.

We are aware that technology is transforming our daily lives, and the medical field is no exception. We have already normalised the use of telemedicine tools and the presence of surgical robots in our hospitals, maybe it is time to embrace other technologies, such as VR, to enhance patient care during outpatient, interventional procedures.

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Ethical approval: Not required.

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ORIGINAL ARTICLE

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Pre-operative GnRH agonist use and surgical outcomes in rectovaginal/colorectal endometriosis: an international multicentre prospective cohort study

Munazzah Rafique[1], Christian Becker[1,2], Jonathan Lewin[3], Arvind Vashisht[3], Ertan Sarıdoğan[3], Martin Hirsch[1,2]

[1]Department of Obstetrics and Gynaecology, John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom
[2]Oxford Endometriosis CaRe Centre, Nuffield Department of Women's & Reproductive Health, University of Oxford, Oxford, United Kingdom
[3]Department of Gynaecology, University College London Hospitals NHS Foundation Trust, London, United Kingdom

ABSTRACT

Background: Rectovaginal/colorectal endometriosis is severe form of endometriosis requiring complex surgery, where pre-operative gonadotrophin releasing hormone agonists (GnRHa) are used to improve the surgical outcomes but the evidence supporting this is limited.

Objectives: To evaluate the association between pre-operative use of GnRHa and perioperative and postoperative complications in patients undergoing surgery for rectovaginal or colorectal endometriosis.

Methods: We analysed prospectively collected data from British Society for Gynaecological Endoscopy-accredited endometriosis centres between 2009 and 2021. Multivariable logistic regression analysis was performed to model the odds of each complication by pre-operative GnRHa use, controlling for patient age, body mass index, smoking status, whether a hysterectomy was performed, history of previous endometriosis surgery and surgical complexity.

Main Outcome Measures: The association of GnRHa use with perioperative and postoperative complications.

Results: We included 9,433 patients aged 18-55 years from 101 specialist endometriosis centres from six countries including UK, USA, Sri Lanka, Saudi Arabia, Turkey and Iran. Patients receiving pre-operative GnRHa were associated with higher rate of perioperative complications [odds ratio (OR): 1.31, 95% confidence interval (CI): 1.08-1.59, *P*=0.007], late complications (OR: 1.477, 95% CI: 1.15-1.9, *P*=0.002) and pelvic haematoma (OR: 2.251, 95% CI: 1.41-3.64, *P*<0.001). After controlling for confounding factors, GnRHa use remained significantly associated with colostomy (aOR: 4.05: 95% CI: 1.51-12.7, *P*=<0.001] pelvic haematoma (aOR: 3.08, 95% CI: 1.72-5.75, *P*<0.001) and abscess (aOR: 2.25, 95% CI: 1.10-4.79, *P*=0.029). Health related quality of life (HR-QOL) improved in the Pre-GnRHa group at 12 months and 24 months (mean difference 2.09/100, 95% CI, 0.27-3.92, *P*=0.025) and (mean difference 2.85/100, 95% CI 0.55-5.16, *P*=0.015).

Conclusions: Pre-operative use of GnRHa has been associated with a higher incidence of perioperative and late complications, including significantly increased odds of colostomy, pelvic hematoma and abcess formation. There is need of careful patient counselling and further prospective research to clarify the pre-operative use of GnRHa in rectovaginal/colorectal endometriosis.

What is New? There is need of caution use of pre-operative GnRHa in deep rectovaginal/colorectal endometriosis surgery due to increased association of the risks of complications such as colostomy, pelvic haematoma and abcess. Despite long-term improvement in HR-QOL, there is need for careful patient selection and counselling.

Keywords: Endometriosis, rectovaginal, colorectal, GnRHa, surgical complications

Corresponding Author: Munazzah Rafique, MD, Department of Obstetrics and Gynaecology, John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom
E-mail: munazzah.rafique@ouh.nhs.uk **ORCID ID:** orcid.org/0000-0002-1751-6287
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Introduction

Deep endometriosis (such as rectovaginal/colorectal endometriosis) is a severe form of endometriosis that commonly presents with pelvic pain, deep dyspareunia, dysmenorrhea, and dyschezia. Treatment options include both medical and surgical approaches with both believed to have benefits of reducing pain and improving health related quality of life (HR-QOL).[1] In the United Kingdom the use of medical therapies including gonadotrophin releasing hormone analogues (GnRHa) as a pre-operative adjunct to surgical therapy is recommended for severe endometriosis.[2] Surgery for rectovaginal endometriosis is challenging and commonly associated with complications.[3] Pre-operative GnRHa is believed to facilitate surgery by reducing inflammation, vascularisation, and adhesions, however, there is limited data to support this.[4]

International guidance is currently divided with discrepancies between the National Institute for Health and Care Excellence and European Society of Human Reproduction and Embryology (ESHRE) in the recommended role of pre-operative GnRHa. The updated ESHRE guidelines highlighted less certainty of its pre-operative role.[1] British Society for Gynaecological Endoscopy (BSGE) has one of the largest pools of prospectively collected data from patients undergoing deep rectovaginal/colorectal endometriosis surgery, including information about pre-operative GnRHa use.[5]

The aim of this study is to evaluate the association between pre-operative GnRHa use with perioperative and postoperative complications following deep rectovaginal/colorectal endometriosis surgery. Moreover, we assessed the HR-QOL in patients who received pre-operative GnRHa and had deep rectovaginal/colorectal endometriosis surgery, with follow-up periods extending up to two years postoperatively

Methods

Data Collection

The BSGE database is a comprehensive database which is used to capture data on large international multicentre cohort of patients undergoing complex endometriosis surgery (defined by endometriosis surgery requiring dissection of the para-rectal space). These patients are prospectively registered on the BSGE database from 101 specialist endometriosis centres from six countries including UK, USA, Sri Lanka, Saudi Arabia, Turkey and Iran. The BSGE surgical information collection system is reliable cloud-based database system for gynaecological procedures. More detailed information on how the data is collected can be found on the BSGE website.[6]

The database allows collection of information related to patient symptoms and HR-QOL data collected pre-operatively, 6-, 12- and 24-months post-operatively, as well as surgical findings, details of the procedure and any intraoperative/perioperative and postoperative complications. The intraoperative complications are defined as procedure related injury or harm recognized during the procedure. Postoperative complications are defined as procedure-related complications, categorised as either early complications (when reported within 48 hours) or late complications (this includes complications reported up to 6-12 week following the primary procedure). BSGE has defined criteria and classification of specific postoperative complications that are entered in the database by individual clinicians at their respective centres. To prevent the diversion from primary outcomes to investigate the rate of perioperative and postoperative complications, we have not included the detailed information on pain scores, bladder and bowel symptoms. Similarly, for HR-QOL although BSGE questionnaire incorporates the EQ-5D-3L questionnaire in conjunction with EuroQol-visual analogue scales (EQVAS) scores, we limited the information to EQVAS scores which is a standard visual analogue scale, used in recording an individual's rating of their HR-QOL by paper questionnaire.

The study was approved by the BSGE Scientific Advisory Group. All patients entered onto the BSGE database provided informed consent for their anonymised data to be included in research.

Patient Population

We included all patients on the BSGE database undergoing surgery for deep rectovaginal/colorectal endometriosis from 2009-2021. All the patients that were included, had dissection of the para-rectal space with either a rectal shave, disc, or segmental resection of rectovaginal or colorectal endometriosis. The patients included had intra or postoperative complication records and had a pre-operative and at least one post-operative questionnaire response for the analysis of HR-QOL scores. For the primary analysis, the patients were divided into two groups based on either having pre-operative GnRHa or not. In the manuscript, patients who had received pre-

operative GnRHa are described as Pre-GnRHa whereas the patient who did not receive any form of pre-operative GnRHa are described as the nPre-GnRHa. We gathered data on the patient's age, body mass index (BMI), smoking status, hysterectomy, prior endometriosis surgery, and surgical complexity. High surgical complexity was defined as involving bladder nodule excision, ureteric nodule excision or bowel resection (disc or segmental). Some of the important information like menopausal status, adenomyosis, fibromyalgia and mental health problems are not captured in the BSGE database.

Statistical Analysis

All data manipulation, graph production and statistical analysis was performed in R Studio using R version 4.2.3 for Windows (Copyright 2023, the R Foundation for Statistical Computing). Demographic differences between groups were compared using independent samples t-tests and chi-squared test of proportions. *P*-value of <0.05 were considered to be statistically significant throughout. The raw differences in complication rates between patients receiving vs not receiving pre-operative GnRHa were compared using odds ratios (OR) and tested for statistical significance using the chi squared difference of proportions test, or Fisher's exact test where any group size was <5. As these groups differed in demographics and surgical complexity, multivariable analysis was performed using logistic regression to model the odds of each complication by pre-operative GnRHa use, controlling patient age, BMI and smoking status, whether a hysterectomy was performed, history of previous endometriosis surgery and surgical complexity.

We analysed the effect of treatment on HR-QOL using mixed-effects linear regression, modelling the score at each timepoint by GnRH analogue use pre-operatively, controlling for age, BMI and smoking, surgical approach (laparoscopic vs. laparotomy), hysterectomy, and a random intercept for each patient, using a time x treatment group interaction term as the measure of the difference in outcome. As age and the type of bowel surgery performed were predictive of symptom improvement, this effect was also controlled for with a timepoint interaction term.

Results

Patients' Cohort and Demographics

Our analysis included 9,433 surgical cases, of these 3,275 (34.7%) patients received pre-operative GnRHa (Pre-GnRHa), 6,158 patients did not receive Pre-operative GnRHa (nPre-GnRHa). Age and BMI were assessed graphically for normality and were described as mean (Figures 1, 2). The data exhibit negligible skewness, and relatively symmetrical distribution with mild tails. The descriptive statistics for the age revealed a mean age 36.4 and range between 18-55 years. Similarly, the mean BMI was 26.4, with a range between 15-45. The mean BMI and age were similar for both groups, however large numbers of patients allowed for statistical significance even when this may not necessarily be a clinically significant difference.

Overall, the type of bowel surgery performed were shaving 8,399 (89.1%), disc resection 272 (2.9%) and segmental resection in 762 (8%) cases. Of these, 2,461 (26.1%) patients underwent a hysterectomy. The differences in the demographics of the patients who received Pre-GnRHa and those who did not receive the nPre-GnRHa can be seen in Table 1.

Overall Complication Rate

Overall, the perioperative complication rates for the whole cohort were as follows: haemorrhage (≥1 L)

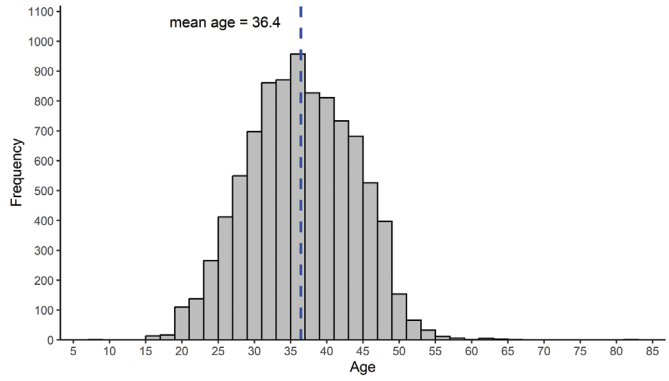

Figure 1. Age histogram.

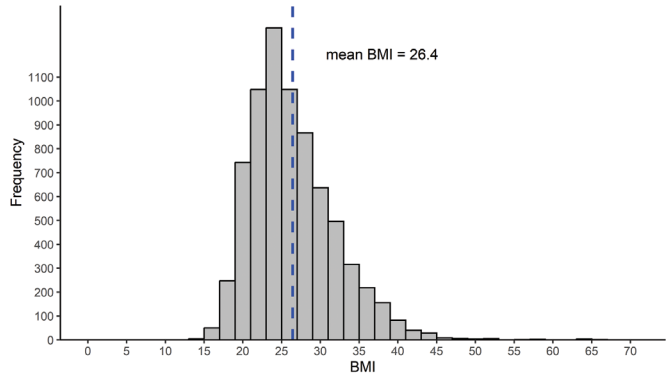

Figure 2. BMI histogram.

BMI: Body mass index.

Table 1. Demographic and operative difference in Pre-GnRHa vs. nPre-GnRHa groups (n=9433).

Characteristics	Pre-GnRHa group (n=3275)	n (pre-GnRHa) group (n=6158)	*P*-value
Age	36.9 (SD: 7.31)	36.2 (SD: 7.31)	<0.001*
BMI	26.7 (SD: 5.52)	26.2 (SD: 5.52)	<0.001*
Smoking	308 (9.4%)	584 (9.5%)	0.041*
Hysterectomy	1061 (32.4%)	1400 (22.7%)	<0.001*
Bowel surgery			
- Shaving	2796 (85.4%)	5603 (91%)	<0.001*
- Disc resection	97 (3%)	175 (2.8%)	
- Segmental resection	382 (11.7%)	380 (6.2%)	
Surgical complexity			
High	772 (23.6%)	1201 (19.5%)	<0.001*
Low	2503 (76.4%)	4957 (80.5%)	

*Statistically significant *P*<0.05, BMI: Body mass index, Pre-GnRHa: Group received pre-operative gonadotrophin releasing hormone analogues, nPre-GnRHa: Group with no pre-operative GnRH analogues, SD: Standard deviation.

97 (1.3%); unexpected bowel injury 90 (1.2%); and conversion to laparotomy in 87 (1.2%) cases. Whereas the postoperative complication for the whole cohort included: pelvic haematoma 72 (1.3%); pelvic abscess 39 (0.7%); and bowel leak in 35 (0.6%) case (Table 2).

Perioperative Complications

Compared to the nPre-GnRHa group, the patients in the Pre-GnRHa having any form of deep rectovaginal/colorectal endometriosis surgery demonstrated significantly greater odds of any perioperative complications [OR: 1.31, 95% confidence interval (CI): 1.08-1.59, *P*=0.007]. The odds of colostomy and ileostomy were higher in the Pre-GnRHa group, (OR: 2.677, 95% CI: 1.16-6.5, *P*=0.016 and OR: 2.076, 95% CI: 1.14-3.81, *P*=0.014) respectively when compared to the nPre-GnRHa group (Table 2). When multivariable regression analysis was done to control for confounding factors including age, BMI, smoking, hysterectomy, surgical complexity and previous endometriosis surgery, the result showed that the patients in the Pre-GnRHa group had increased odds of colostomy (OR: 3.953, 95% CI: 1.48-12.4, *P*=0.008). However, there was no statistically significant difference in the rates of bleeding or surrounding organ injury including bowel, bladder, blood vessels and ureter. There was no significant difference in odds of conversion to laparotomy between the nPre-GnRHa and the Pre-GnRHa groups (Table 3).

Postoperative Complications

In patients having any form deep rectovaginal/colorectal endometriosis surgery, Pre-GnRHa had significantly greater odds of any late postoperative complications compared to the nPre-GnRHa (OR: 1.477, 95% CI: 1.15-1.9, *P*=0.002). The odds of pelvic haematoma was higher with Pre-GnRHa compared to the nPre-GnRHa group (aOR: 2.251, 95% CI: 1.41-3.64, *P*=0.001) (Table 2). After controlling confounding factors including age, BMI, smoking, hysterectomy, surgical complexity and previous endometriosis surgery, the patients receiving Pre-GnRHa had increased odds of pelvic haematoma (aOR: 3.08, 95% CI: 1.72-5.75, *P*<0.001). The odds of having a pelvic abscess were also higher with Pre-GnRHa (aOR: 2.25, 95% CI: 1.10-4.79, *P*=0.029). However, there were no statistically significant difference in urinary or bowel leak or fistula formation, the odds of sepsis in the Pre-GnRHa group and the nPre-GnRHa group was not statistically significantly different (Table 3).

Health Related Quality of Life EuroQol-visual Analogue Scales

The follow-up rates were 86.7% at 6 months (4832), 60.1% (3351) at 12 months and 33.9% (1891) at 24 months. Postoperative HR-QOL scores showed statistically significant improvement in the Pre-GnRHa group at 12 months (mean difference: 2.09/100, 95% CI: 0.27-3.92, *P*=0.025*) and 24 months (mean difference: 2.85/100, 95% CI: 0.55-5.16, *P*=0.015*). However, no statistically significant difference was seen for HR-QOL pre-operatively and at 6 months postoperatively between Pre-GnRHa and nPre-GnRHa groups (Tables 4, 5, Figure 3).

Table 2. Complications rate nPre-GnRHa vs. Pre-GnRHa group.

Complication	Pre-GnRHa (%)	nPre-GnRHa (%)	Odds ratio (95% CI)	*P*-value (chi²)
Overall perioperative complications	176 (6.3)	266 (4.9)	1.31 (1.08-1.59)	<0.001*
Haemorrhage litre	40 (1.4)	57 (1)	1.38 (0.91-2.06)	0.124
Ureteric injury	21 (0.8)	26 (0.5)	1.58 (0.88-2.82)	0.117
Unexpected bowel injury	28 (1)	62 (1.1)	0.88 (0.56-1.37)	0.575
Unexpected bladder injury	12 (0.4)	30 (0.6)	0.79 (0.38-1.5)	0.465
Unexpected vascular injury	11 (0.4)	12 (0.2)	1.79 (0.77-4.13)	0.158
Epigastric injury	2 (0.1)	3 (0.1)	1.33 (0.16-8.75)	0.773
Conversion to laparotomy	35 (1.3)	52 (1)	1.32 (0.85-2.02)	0.210
Colostomy	14 (0.5)	9 (0.2)	3.02 (1.31-7.34)	<0.001*
Ileostomy	24 (0.9)	20 (0.4)	2.35 (1.29-4.32)	<0.001*
Death	1 (0)	2 (0)	1.04 (0.03-12.82)	0.984
Overall late complications	116 (5.3)	142 (3.7)	1.48 (1.15-1.9)	<0.001*
Pelvic haematoma	42 (1.9)	30 (0.8)	2.51 (1.57-4.07)	<0.001*
Pelvic abscess	20 (0.9)	19 (0.5)	1.88 (0.99-3.57)	0.046 *
Urinary tract leak	6 (0.3)	15 (0.4)	0.72 (0.25-1.79)	0.477
Bowel leak	13 (0.6)	22 (0.6)	1.06 (0.51-2.08)	0.888
Urinary tract fistula	1 (0)	5 (0.1)	0.4 (0.02-2.57)	0.323
Bowel fistula	8 (0.4)	7 (0.2)	2.03 (0.72-5.9)	0.162
Severe sepsis	12 (0.6)	14 (0.4)	1.53 (0.69-3.34)	0.28
Pulmonary embolism	1 (0.0)	6 (0.2)	0.33 (0.01-2.01)	0.231

*Statistically significant *P*<0.05, Total cases: 9,433, Missing data for perioperative complications: Cases 1,187 (12.6%), Missing data for postoperative complications: Cases 3,396 (36%).
Pre-GnRHa: Group received pre-operative gonadotrophin releasing hormone analogues, nPre-GnRHa: Group with no pre-operative GnRH analogues, CI: Confidence interval.

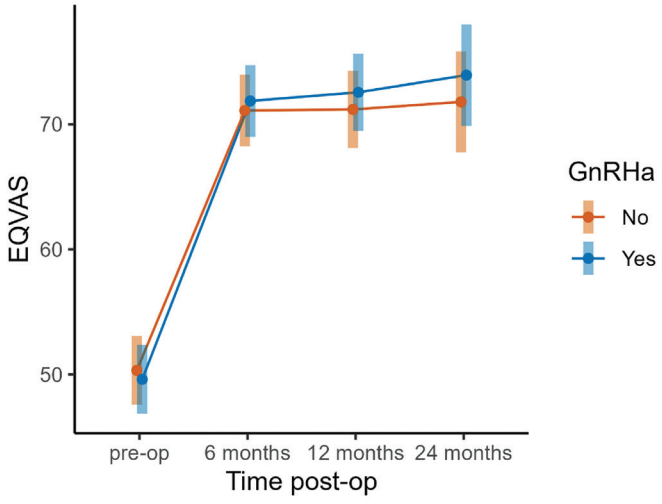

Figure 3. EQVAS scoring.

EQVAS: EuroQol-visual analogue scales, GnRHa: Gonadotrophin releasing hormone analogues.

Death

Overall, there were 3 cases of death reported in the database of the cohort of patients having surgical treatment for deep rectovaginal/colorectal endometriosis. There was no statistically significant difference in odds of death between groups, including after controlling for confounding factors with *P*=0.897, OR: 0.85 (95% CI: 0.04-9.0) (Tables 2, 3). We could not explore this serious complication in detail as the relevant information is not routinely collected by the BSGE database and are held locally by the individual hospital.

Missing Data

There was total 9,433 patients that fulfil the inclusion criteria to be considered in the analysis. However, there was missing data for perioperative complications in 1,187 (12.6%) patients and for postoperative complications the missing data was more for about 3,396 (36%) of patients (Table 6). The information on the possible reasons for missing data for perioperative and late complications was not captured by individual centers and therefore was not available to analysis.

Table 3. Multivariable logistic regression, controlling for age, BMI, smoking, hysterectomy, surgical complexity and previous endometriosis surgery.

Complication	Odds ratio (95% CI) Pre-GnRHa vs. nPre-GnRHa group	*P*-value
Overall perioperative complications	1.22 (0.97-1.54)	0.091
Haemorrhage litre	1.15 (0.70-1.86)	0.586
Ureteric injury	1.46 (0.76-2.79)	0.254
Unexpected bowel injury	0.78 (0.46-1.28)	0.335
Unexpected bladder injury	0.67 (0.29-1.44)	0.322
Unexpected vascular injury	1.61 (0.62-4.14)	0.319
Epigastric injury	3.64 (0.34-79.87)	0.298
Conversion to laparotomy	1.05 (0.63-1.75)	0.841
Colostomy	4.05 (1.51-12.7)	<0.001*
Ileostomy	1.67 (0.85-3.33)	0.135
Death	0.85 (0.04-9.07)	0.897
Overall late complications	1.51 (1.13-2.00)	<0.001*
Pelvic haematoma	3.08 (1.72-5.75)	<0.001*
Pelvic abscess	2.25 (1.10-4.79)	0.029*
Urinary tract leak	0.64 (0.20-1.8)	0.412
Bowel leak	1.38 (0.61-3.06)	0.431
Urinary tract fistula	0.28 (0.02-1.78)	0.252
Bowel fistula	1.97 (0.56-7.76)	0.299
Severe sepsis	1.47 (0.57-3.81)	0.414
Pulmonary embolism	Data insufficient for analysis	

*Statistically significant *P*<0.05, Total cases: 9,433, Missing data for perioperative complications: Cases 1,187 (12.6%), Missing data for postoperative complications: Cases 3,396 (36%).
Pre-GnRHa: Group received pre-operative gonadotrophin releasing hormone analogues, nPre-GnRHa: Group with no pre-operative GnRH analogues, CI: Confidence interval.

Table 4. Pre-operative mean difference in HR-QOL between Pre-GnRHa vs. nPre-GnRHa group.

	Pre-GnRHa (mean)	nPre-GnRHa (mean)	*P*-value
EQVAS	53.5	53.9	0.4

Pre-GnRHa: Group received pre-operative gonadotrophin releasing hormone analogues, nPre-GnRHa: Group with no pre-operative GnRH analogues, EQVAS: EuroQol-visual analogue scales.

Table 5. Postoperative mean differences in HR-QOL between Pre-GnRHa vs. nPre-GnRHa groups.

	6 months (95% CI, *P*-value)	12 months (95% CI, *P*-value)	24 months (95% CI, *P*-value)
EQVAS	1.48/100 (-0.13-3.1, *P*=0.072)	2.092/100 (0.27-3.92, *P*=0.025)*	2.85/100 (0.55-5.16, *P*=0.015)*

*Statistically significant *P*<0.05. Pre-GnRHa: Group received pre-operative gonadotrophin releasing hormone analogues, nPre-GnRHa: Group with no pre-operative GnRH analogues, EQVAS: EuroQol-visual analogue scales, HR-QOL: Health related quality of life, CI: Confidence interval.

Table 6. Missing data for perioperative and late complications.

Total cases	Missing cases no perioperative	Missing cases % perioperative	Missing cases no late complication	Missing cases % late complications
9,433	1,187	12.58%	3,396	36%

Discussion

Key Findings

The result of our study provides evidence of an association between pre-operative GnRHa use with higher complication rates at the time of surgery for deep rectovaginal/colorectal endometriosis with increased odds of colostomy, pelvic haematoma and abcess, although the HR-QOL outcomes appear to be better in the postoperative years in patients who received pre-operative GnRHa. The recent ESHRE guidelines found insufficient evidence to recommend pre-operative medical therapies to improve outcome.[1] Cochrane reviews by Chen et al.[4], 2020 and Yap et al.[7], had evaluated the role of pre and post-surgical medical therapy for endometriosis surgery and highlighting inconclusive efficacy of medical therapy as an adjunct for endometriosis surgery, however, it had not evaluated the complication rates. There are no previous studies evaluating the role of pre-operative GnRHa and postoperative complication rate with which we can compare our study findings.

It is important to acknowledge that surgical complexity may represent the greatest predictor of major intraoperative complications rather than disease severity. The data we have available does not allow for a granular view of the complexity of surgery. The use of pre-operative GnRHa is not believed to influence these wider complexities.[8,9] There are previous studies evaluating the ways in which pre-operative GnRHa may provide benefit through reduced inflammation, reduced vascularisation of endometriosis lesions, reduced adhesions and reduced risk of recurrence.[10,11] However, there is evidence of GnRHa induced vaginal atrophy in patients undergoing hysterectomy that can negatively influence wound healing and increase the risk of vaginal cuff dehiscence.[8] A cases series described the increased risks of vaginal cuff dehiscence with the use of pre-operative GnRHa, however, the evidence was weak.[12]

Laparoscopic segmental colorectal resection increases the risk of major complication including rectovaginal fistula and pelvic abscesses.[13] Previous studies by Benbara et al.[14], 2008 and Kondo et al.[15], reported increased risk of major complications and digestive fistulas with vaginal opening and ileocaecal resection. The overall complications rate after conservative surgery were lower and the risk of complications increased if additional surgery, such as ureterolysis, uterosacral ligament resection, and hysterectomy were required.[16] Opening of the vagina and extensive electro coagulation can lead to necrosis of the posterior vaginal cuff with a higher risk for rectovaginal fistulae and abscess.[17]

Angioni et al.[18], had evaluated the effect of GnRHa as a post-surgical medical treatment in patients with rectovaginal endometriosis and the result showed improvement of symptoms in those patients in whom total eradication of the pathology was not feasible. Our findings suggest that there may be a benefit of using pre-operative GnRHa to improve HR-QOL, although this needs to balance against the greater complication rates.

Strengths and Limitations of the Study

The BSGE database represents the largest prospective dataset of surgically managed deep rectovaginal/colorectal endometriosis. This includes about 9,433 cases of deep rectovaginal/colorectal endometriosis surgery, together with comprehensive information on demographics, surgical technique, perioperative and postoperative complications. The large sample size enabled a multivariable analysis controlling for demographic and clinical variations among the groups. This multicentre study reduces bias arising from systemic variation in practice and enables confidence that the results reflect the real value of complications. There are annual governance measures for each endometriosis centre to ensure validity and comparability of data from multiple centres.

The primary limitation of this research is the study design and lack of randomization. We cannot rule out the possibility that the higher complication rates in the Pre-GnRHa group that may be due to more complex endometriosis in this group compared to the nPre-GnRHa group, hence they were more likely to be given this medication pre-operatively. This may give rise to bias negatively influencing the results against GnRHa use. There is missing data in our study making it challenging to determine the complication rate with accuracy. There were challenges controlling for the variation in the clinical characteristics like severity of adhesions, size of bowel nodule, distance from the anal verge, adenomyosis, fibromyalgia, depression/anxiety, menopausal status, postoperative GnRHa use that were not captured on the BSGE database during multivariate analysis.

Clinical Implications and Future Research

We recommend future randomised controlled trials (RCT's) evaluating pre-operative medical management as an adjunct to deep rectovaginal/colorectal

endometriosis surgery. We were able to control for a number of potential confounding factors including age, BMI, smoking, hysterectomy, surgical complexity and previous endometriosis surgeries however, there may be other factors mentioned above, that we were not able to control yet may influence the risk of complication. To mitigate against this, we suggest future RCT include the #ENZIAN classification.

Moreover, other causes that can affect HR-QOL such as adenomyosis, fibromyalgia, depression/anxiety, menopausal status could not be adjusted for multivariable analysis as the information about these conditions are not routinely collected in the BSGE database. Future RCT's would provide greater clarity on the role of GnRHa as a pre-operative adjunct to surgery.

Conclusion

This is the largest prospective international study evaluating the role of pre-operative GnRHa use for surgical treatment of deep rectovaginal/colorectal endometriosis including shaving, disc resection or segmental resection. The results suggest an increased risk of perioperative complications with risk of colostomy being significant. Moreover, there is increased risk of overall late complication with association of pelvic haematoma being significantly high with pre-operative GnRHa use. There is significant long term improvement post-operatively in HR-QOL up to two years for the patient who used pre-operative GnRHa. The results of our study suggest cautious use of pre-operative GnRHa balancing the increased risk of perioperative and postoperative complications against improvement in HR-QOL. When counselling patients ahead of surgery for rectovaginal/colorectal endometriosis adequate discussion is needed of the increased risk of complication yet greater improvement in HR-QOL.

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Informed consent: The BSGE Scientific Advisory Group approval was taken for this study. All patients in the BSGE database gave written consent for the use of the anonymised data in research. All included patients gave written consent for their anonymised data to be used in research.

Data sharing: Data supporting the results in the paper are archived in the Institutional electronic system. Additional data and related information are available from the corresponding author upon request.

Transparency: The authors affirm that the manuscript is an honest, accurate, and transparent account of the studies assessed. There are no important aspects of the studies omitted.

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ORIGINAL ARTICLE

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Feasibility of single step hysteroscopic myomectomy: fibroid size is the most significant factor based on data from a single centre and surgeon

Ursula Catena[1], Eleonora La Fera[1], Diana Giannarelli[2], Andrea Scalera[3], Emma Bonetti[4], Federica Bernardini[1], Federica Campolo[1], Francesco Fanfani[1,5], Giovanni Scambia[1,5]

[1]Unit of Gynecologic Oncology, Department for Women's and Children's Health and Public Health, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy
[2]Biostatistics Unit, Scientific Directorate, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy
[3]Department of Women's, Children's, General and Specialist Surgery, University of Campania "Luigi Vanvitelli", Naples, Italy
[4]Department of Clinical and Experimental Sciences, University of Brescia, Brescia, Italy
[5]Università Cattolica del Sacro Cuore, Rome, Italy

ABSTRACT

Background: Uterine fibroids are the most common benign solid neoplasms of the uterus. Hysteroscopy represents the gold standard treatment for submucosal fibroids.

Objectives: The aim of this study was to retrospectively analyse all consecutive symptomatic patients diagnosed with the International Federation of Gynecology and Obstetrics G0-G3 fibroids who underwent hysteroscopic myomectomy, to identify factors that may influence the feasibility of single step myomectomy.

Methods: The study included all consecutive symptomatic patients, diagnosed with G0-G3 fibroid. Surgical procedure was performed by a single experienced surgeon. All patients underwent postoperative hysteroscopic control 30-40 days after the procedure.

Main Outcomes Measures: Evaluation of feasibility of hysteroscopic myomectomy in a single surgical step.

Results: One hundred and twenty-five patients were included. In 97 women (77.6%) the fibroid was removed in one single step; 28 patients (22.4%) had a residual fibroid. Of these patients, in 10 cases (35.7%) the residual fibroid was removed during the office hysteroscopic control, 16 (57.2%) and 2 (7.1%) patients required II- and III-time myomectomy, respectively. 85.6% of patients did not need a second time surgery under general anaesthesia. At univariate and multivariate analysis, diameter was found to be the parameter most related to single-step fibroid removal with P=0.001 and P<0.001 respectively. For G0-3 fibroids <3 cm in 72% (66/92) of cases the 15 Fr mini-resectoscope was used with one step myomectomy in 89.4% of cases.

Conclusions: In expert hands, single step hysteroscopic myomectomy is feasible for G0-3 fibroids. The possibility to use miniaturized instruments for myomectomy may improve the surgical outcomes and prevent intra- and post-operative complications, in particular uterine perforation by avoiding cervical dilation. Further studies are needed to evaluate the true efficacy of 15 Fr mini-resectoscope in the removal of G0-G3 fibroids <3 cm.

What is New? Hysteroscopic myomectomy in a single surgical step is feasible for G0-G3 fibroids, with diameter being the only independent factor influencing the success of the procedure. In expert hands, the success rate of single step myomectomy by using miniaturized instruments in fibroids ≤3 cm, is 89.4%.

Keywords: Fibroid, myoma, hysteroscopy, myomectomy

This study was presented as an abstract at the 2024 Hartus Congress.

Corresponding Author: Eleonora La Fera, MD, Unit of Gynecologic Oncology, Department for Women's and Children's Health and Public Health, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy
E-mail: laferaeleonora@gmail.com **ORCID ID:** orcid.org/0000-0002-2572-0886
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Introduction

Uterine fibroids (leiomyomas) are the most common benign solid neoplasms of the uterus.[1]

The prevalence varies widely (4.5%-68.6%) due to factors such as ethnicity; it may be underestimated because they can be asymptomatic.[2,3]

The most widely used classification system is the 2011 classification of the International Federation of Gynecology and Obstetrics (FIGO). This classification was updated in 2018, with G3 fibroids now being classified as submucosal myomas.[4]

Submucosal fibroids are typically the most symptomatic and are often associated with abnormal uterine bleeding (AUB). They can also cause pelvic pain or subfertility.[5]

Advancements in technology have made direct visualization of the uterine cavity essential for the diagnosis and treatment of intrauterine pathologies. Hysteroscopy is currently considered the gold standard for the treatment of submucosal fibroids.[6]

According to the Consensus of the Global Community of Hysteroscopy (GCH) Scientific Committee, type 0-1 fibroids are more likely to be removed in a single surgical step, while type 2 fibroids may require multiple steps.[7] The optimal surgical approach for type 3 fibroids has not yet been definitively established.[5]

Therefore, clinicians should be encouraged to publish their findings until prospective studies are available. In this context, our study seeks to identify the key factors influencing the feasibility of performing hysteroscopic myomectomy as a single-step procedure. We present our data, which includes a standardized diagnostic and therapeutic approach, as well as an analysis of patient characteristics and the conditions that determine the success of a one-step procedure in patients with symptomatic submucosal fibroids (G0-3), all of whom consecutively underwent hysteroscopic myomectomy under the care of a single surgeon.

Methods

Study Design and Population

This was a retrospective review of consecutive symptomatic patients diagnosed with FIGO G0-G3 fibroids who underwent surgical treatment by a single operator (U.C.) during the period between January 2021 and November 2023, in the Digital Hysteroscopic Clinic (DHC) Class Hysteroscopy of Rome. Patients were identified from hospital DHC records. Prior to starting patient enrolment, the study protocol obtained the approval from the Fondazione Policlinico Universitario Agostino Gemelli IRCCS Ethics Committee (approval no: 6659, date: 11.04.2024).

Patients' records were checked individually, and data were collected. Only patients who underwent pre- and post-operative evaluation at our DHC were included. Exclusion criteria included asymptomatic patients; preoperative positive pregnancy test; severe comorbidity or concomitant uterine malformation.

All patients underwent pre-operative work-up, including ultrasound and hysteroscopy simultaneously followed by sonohysterography to reliably attribute the fibroid FIGO grade.[4]

Oral progestin therapy or gonadotrophin-releasing hormone analogues (GnRH-a) were considered for all patients based on the fibroid size, from 1 to 3 months before surgery. Fibroids <4 cm underwent oral progestin therapy (acetate norethisterone 5 mg or desogestrel 75 mcg/day). Fibroids >4 cm underwent GnRH-a (acetate leuprorelin 3.75 mg every 28 days). Some patients did not receive pre-operative hormonal therapy due to comorbidities that made its use infeasible or because of the caregiver's decision.

The surgical procedures were carried out by a single experienced surgeon (U.C.) under general anaesthesia, according to an ambulatory model of care.[8] The surgeon selected the instrument to use based on the patients' (previous deliveries or uterine surgeries, fertility desire, access to the uterine cavity) and the fibroids' characteristics (grade, site and dimension of the lesion). Instruments used included Bipolar 26 and 15 Fr Resectoscopes, 5 mm Bettocchi hysteroscope (Karl Storz, Tuttlingen, Germany) with 5 Fr instruments and/or tissue removal device (TRD) (Truclear Elite Mini, Medtronic). The uterine cavity was distended with saline solution (0.9% NaCl) provided through an electronic irrigation system (Endomat, Karl Storz, Tuttlingen, Germany). The parameters used were continuous flow between 200 and 400 mL/min; intrauterine pressure between 100 and 140 mmHg. Strict intraoperative monitoring of fluid balance was performed. Antibiotic prophylaxis was never administered. Surgical techniques included slicing and enucleation, used alone or in combination.[6]

Type 0 fibroids were resected using the classical slicing technique using a bipolar diathermic loop of a 26 Fr (Figure 1) or 15 Fr resectoscope, progressively excising the lesion from the free surface to the base.

Types 1-3 fibroids were resected with a bipolar loop of a 26 Fr or 15 Fr resectoscope (Figure 2), using the slicing technique for the intracavitary component, followed by cold loop mobilization and enucleation of the intramural component using Mazzon cold loop technique.[9] Mazzon et al.[9], and completing resection with the slicing technique. In patients of reproductive age with G2-3 fibroids and minimal intracavitary involvement, a technique was employed to minimize the loss of the overlying endometrium. This approach involved making a small incision in the endometrium covering the fibroid to expose the cleavage plane between the pseudo capsule

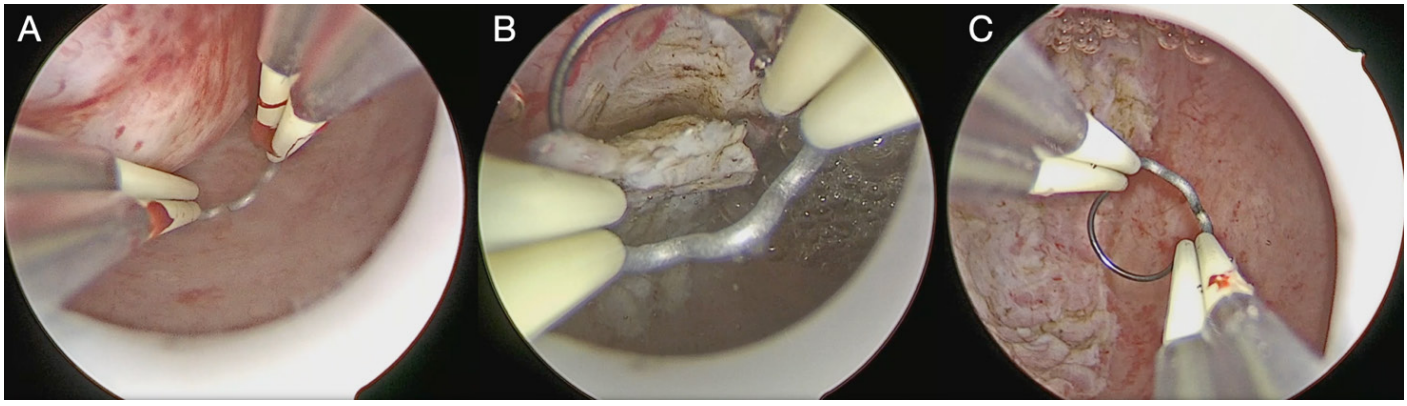

Figure 1. Myomectomy of a 3 cm G0 fibroid using a bipolar diathermic loop of a 26 Fr resectoscope. A and B) Slicing technique using the 90° loop. C) Fibroid fovea after its complete removal.

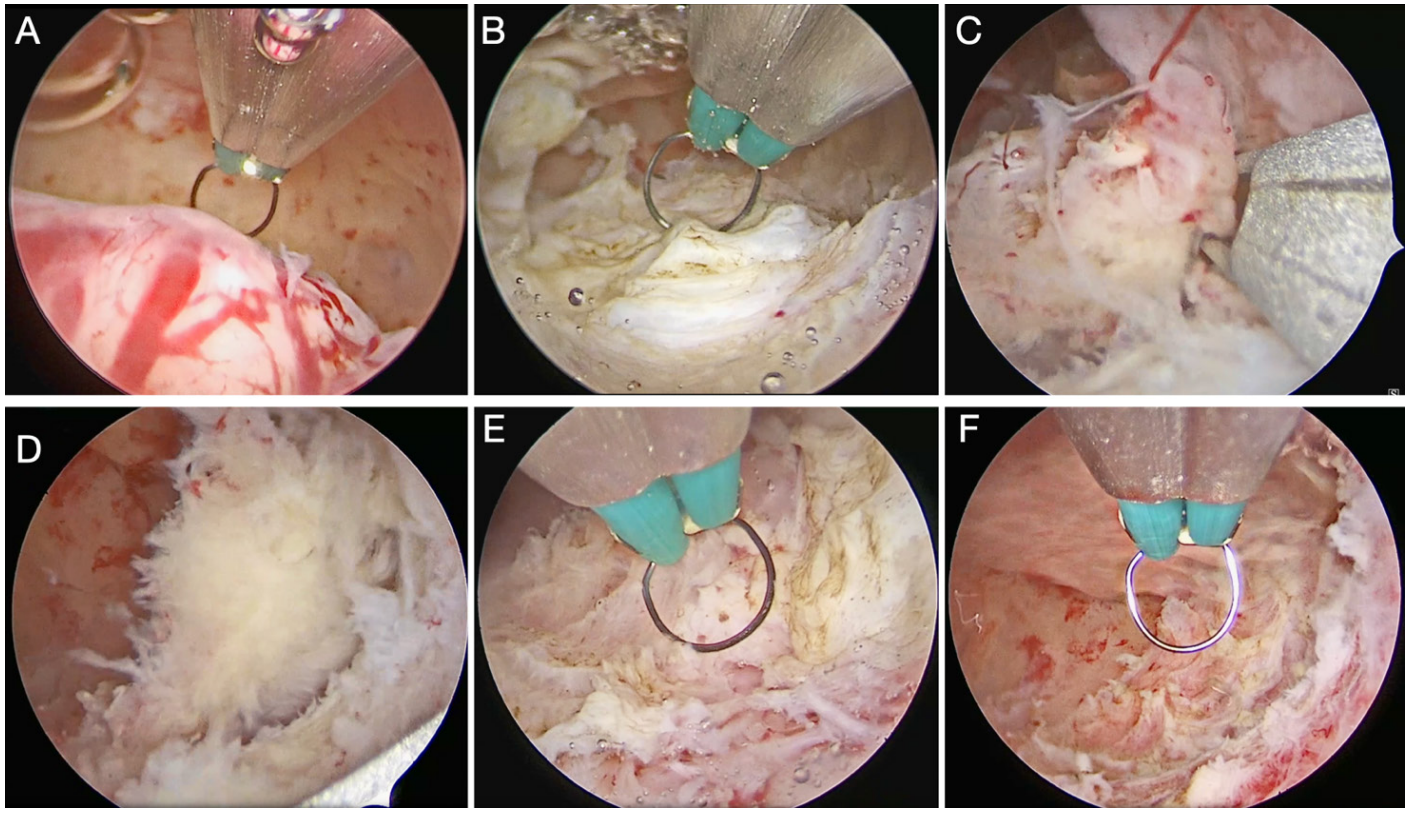

Figure 2. Myomectomy of a 2 cm G1 fibroid using a 15 Fr bipolar mini-resectoscope. A and B) Removal of the intracavitary portion using the slicing technique with a 90° loop. C) Cold loop mobilization and enucleation of the intramural component using Mazzon cold loop technique. D) Vision of the intramural portion of the fibroid exteriorized in the uterine cavity. E) Completion of the resection with 90° loop. F) Fibroid fovea after its complete removal.

and the myometrium, thereby preserving the surrounding healthy endometrium.[10]

In case of fundal fibroid, the Collins loop of the 15 Fr mini-resectoscope was used, modifying the technique described by Lasmar et al.[6] to enucleate the fibroid and then dissect it once almost completely in the uterine cavity (Figure 3).

In a minority of cases, removal of the fibroid was performed using a Bettocchi hysteroscope and a TRD. This technique was used in patients motivated to perform the procedure without anaesthesia. Miniaturized 5 Fr instruments were used to separate the fibroid from the surrounding myometrium. TRD was used to "morcellate" the fibroid from the uterine cavity (Figure 4). Moreover, this technique was limited to small fibroids ≤20 mm.

All patients underwent an office hysteroscopic control 30-40 days after the procedure.

Statistical Analysis

Data analysis was mainly descriptive. Categorical items were summarized by absolute counts and percentages while quantitative variables were reported as median and range. A logistic regression model was implemented to analyse associations between patients, fibroids and therapy features and the need for multiple steps procedures; odds ratios (OR) and their 95% confidence intervals were reported.

Results

One hundred and fifty-two patients underwent hysteroscopic myomectomy by the same surgeon (U.C.). Twenty-seven patients were excluded for missing pre- and/or post-operative evaluation at our DHC. One hundred and twenty-five patients were included in our analysis.

The median age was 43 years old. The most frequent symptoms were AUB in 66.4% (83/125) and infertility in 30.4% (38/125) of patients.

Of the 38 patients with infertility, 6 (15.8%) had previous miscarriages of which 4 were recurrent. The median diameter of fibroids (considering the largest one in cases of multiple fibroids) was 20 mm (5-65) and the median number of fibroids was 1 (1-6).

Patients' characteristics were reported in Table 1.

In 97 women (77.6%) the fibroid has been removed in one single step; 28 patients (22.4%) had a residual fibroid at hysteroscopic control. Of these patients, in 10 cases (35.7%) the residual fibroid has been removed during the office hysteroscopic control. No intrauterine adhesions

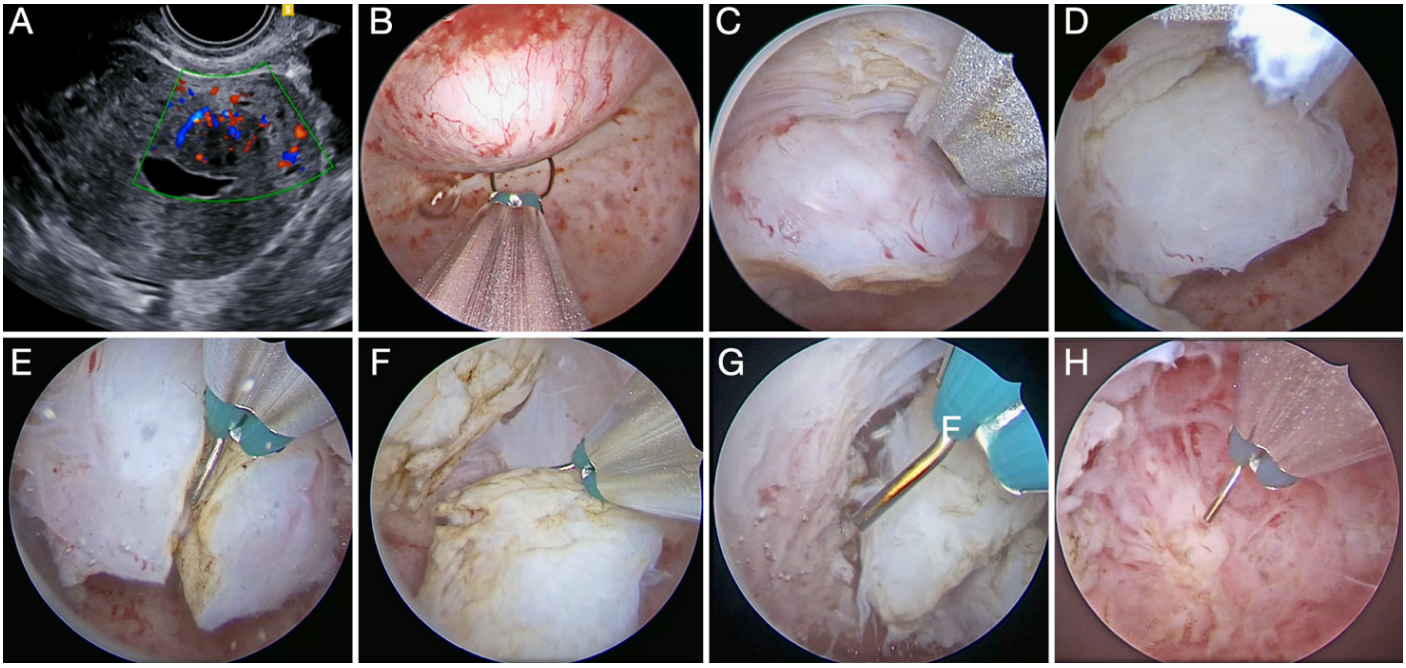

Figure 3. Myomectomy of a 2 cm G2 antero-fundal fibroid using a 15 Fr bipolar mini-resectoscope. A) Ultrasonographic vision of the intramural component of thefibroid. B) Removal of the intracavitary portion using the slicing technique with a 90° loop. C) Cold loop mobilization and enucleation of the intramural component using Mazzon cold loop technique. D) Vision of the intramural portion of the fibroid exteriorized in the uterine cavity. E-G) Use of Collins loop to cut and dissect the fundal part of the fibroid from the surrounding myometrium. H) Fibroid fovea after its complete removal.

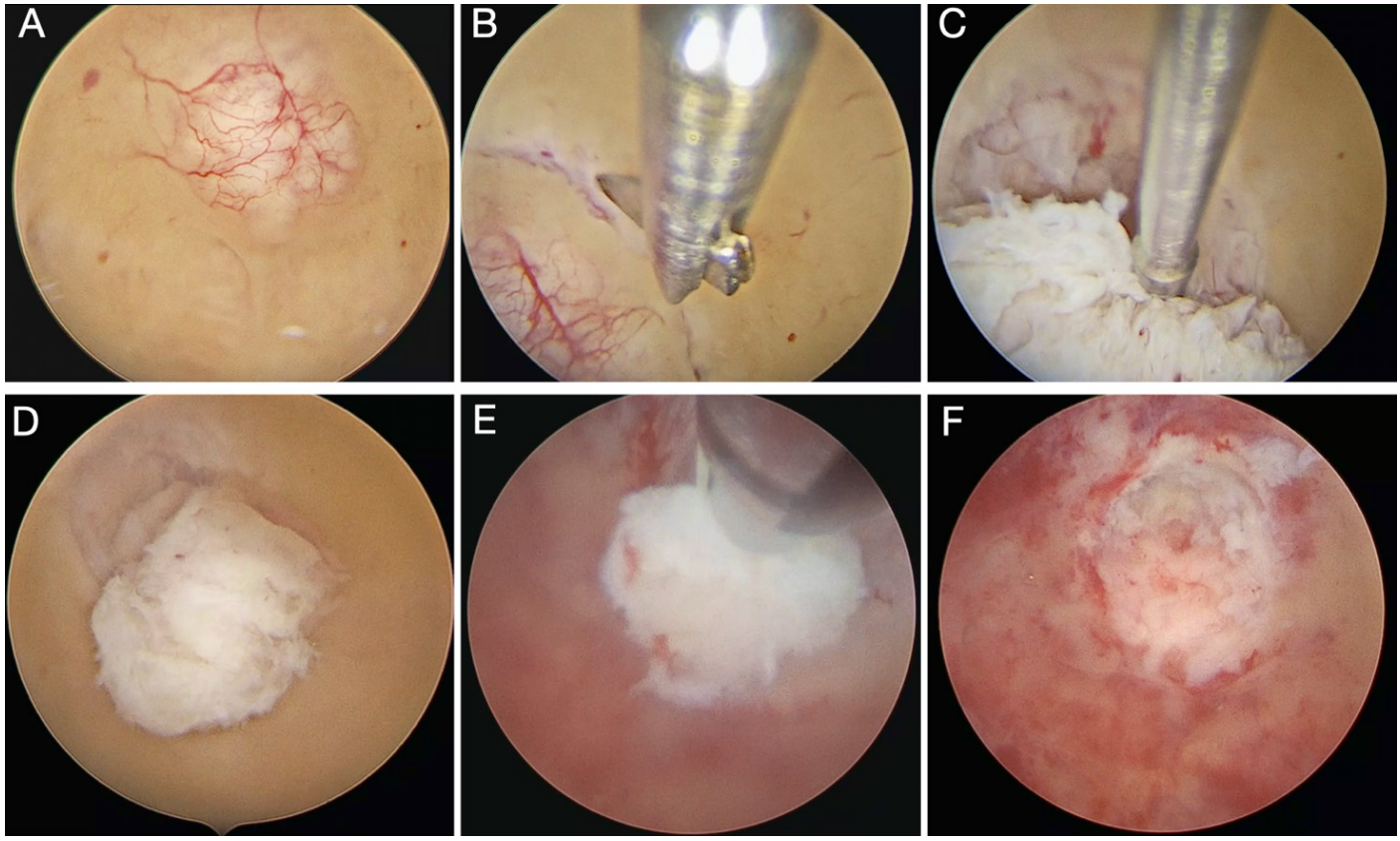

Figure 4. Myomectomy of a 1 cm G3 fundal fibroid using a 5 mm hysteroscope and a TRD. A) Visualization of the fundal lesion. B and C) Use of 5 Fr scissors to separate the fibroid from the surrounding myometrium. D) Vision of fibroid completely exteriorized in the uterine cavity. E) Use of dense tissue blade of TRD to "morcellate" the fibroid from the uterine cavity. F) Fibroid fovea after its complete removal.

TRD: Tissue removal device.

were found to office hysteroscopic controls. Sixteen/28 (57.2%) and 2/28 (7.1%) patients required II- and III-surgical step, respectively. Consequently, 85.6% (107/125) of patients did not need a second surgical time, but the fibroid was removed in one single step (97/125) or the residual fibroid was removed the office hysteroscopic control (10/125). Only 14.4% of patients (18/125) needed a second surgical step under anaesthesia. The median size of fibroid removed in one single step was 20 mm (5-65 mm) whereas fibroids that needed multiple step procedures measured 30 mm (15-52 mm) (Table 1).

To identify factors that may influence the feasibility of hysteroscopic myomectomy in one-step, our population was stratified according to the variables that may affect the surgical outcomes (Table 2).

The number of fibroids did not seem to affect the removal in one or multiple steps. The size (maximum diameter of the larger fibroid), the FIGO grade and the site seem to influence the possibility to perform multiple steps procedures. In particular, the 93.75% (15/16) of patients who needed a second time surgery and the 100% (2/2) who needed a third time surgery, presented with fibroid >2 cm. For the FIGO grade, the 37.1% (36/97) of patients were affected by G2 fibroids in case of single step myomectomy, which increased to 80% (8/10), 62.5% (10/16) and 100% (2/2) for residual fibroids removed during office hysteroscopic control, second step surgery and third step surgery, respectively. Regarding fibroids' site, patients who underwent single step procedures had more frequently anterior or posterior fibroids: the fibroid was anterior in 33% (32/97) of cases and posterior in the 38,1% (37/97). Patients who underwent 2 and 3 steps myomectomy had fundal localization in 31.3% (5/16) and 50% (1/1) respectively. The pre-operative pharmacological preparation affects the surgical outcomes: the 43.8% (7/16) of patients who underwent second step surgery was not under hormonal therapy prior to the hysteroscopic myomectomy.

Table 1. Characteristics of: all patients (n=125); patients who underwent myomectomy in a single surgical step (n=97); patients in which the residual fibroid was removed during the office hysteroscopic control (n=10); patients who underwent two steps hysteroscopic myomectomy (n=16); patients who underwent three steps hysteroscopic myomectomy (n=2).

Characteristics	All n=125	One step n=97	Office n=10	Two steps n=16	Three steps n=2
Age (years) median (range)	43 (25-68)	45 (27-68)	40.5 (49-25)	41 (49-34)	40.5 (40-41)
Parity					
Nulliparous	64 (51.2%)	45 (46.4%)	6 (60.0%)	12 (75.0%)	1 (50.0%)
Spontaneous abortion	11 (12.8%)	8 (8.2%)	1 (10.0%)	1 (6.2%)	1 (50.0%)
TOP	1 (2.4%)	-	-	1 (6.2%)	-
Spontaneous delivery	29 (23.2%)	25 (25.8%)	2 (20.0%)	2 (12.6%)	-
Caesarean section	20 (15.2%)	19 (19.6%)	1 (10.0%)	-	-
Previous surgery					
None	77 (61.6%)	55 (56.7%)	7 (70.0%)	14 (87.5%)	1 (50.0%)
Yes, at least one surgery	48 (38.4%)	42 (43.3%)	3 (30.0%)	2 (12.5%)	1 (50.0%)
Caesarean section	20	19	1	-	-
HSC myomectomy	17	14	-	2	1
LPS/LPT myomectomy	9	6	3	-	-
Other	6	6	-	-	-
Symptoms					
AUB	83 (66.4%)	67 (69%)	5 (50.0%)	11 (68.7)	-
Pelvic pain	2 (1.6%)	2 (2.1%)	-	-	-
Infertility	38 (30.4%)	26 (26.8%)	5 (50.0%)	5 (31.3)	2 (100.0%)
Multiple miscarriages	2 (1.6%)	2 (2.1%)	-	-	-
Therapy					
None	57 (45.6%)	48 (49.5%)	2 (20.0%)	7 (43.7%)	-
Yes	68 (54.4%)	49 (50.5%)	8 (80.0%)	9 (56.3%)	2 (100.0%)
Oral EP	61 (89.7%)	48 (97.9%)	6 (75.0%)	6 (66.7%)	1 (50.0%)
GnRH-a	7 (10.3%)	1 (2.1%)	2 (25.0%)	3 (33.3%)	1 (50.0%)
Instrument					
5 mm hysteroscope	7 (5.6%)	7 (7.2%)	-	-	-
15 Fr bipolar miniresectoscope	70 (56.0%)	60 (61.9%)	4 (40.0%)	6 (37.5%)	-
26 Fr bipolar resectoscope	44 (35.2%)	26 (26.8)	6 (60.0%)	10 (62.5%)	2 (100%)
Tissue removal device	4 (3.2%)	4 (4.1%)	-	-	-
Number of fibroids					
1	95 (76.0%)	73 (75.3%)	8 (80.0%)	12 (75.0%)	2 (100%)
>1	30 (24.0%)	24 (24.7%)	2 (20.0%)	4 (25.0%)	-
Maximum diameter (mm) (median, range)	20 (5-65)	20 (5-65)	26 (15-40)	30 (15-52)	39 (30-48)
FIGO grade					
0	25 (20.0%)	24 (24.7%)	-	1 (6.3%)	-
1	37 (29.6%)	31 (32.0%)	1 (10.0%)	5 (31.2%)	-
2	56 (44.8%)	36 (37.1%)	8 (80.0%)	10 (62.5%)	2 (100%)
3	7 (5.6%)	6 (6.2%)	1 (10.0%)	-	-
Site					
Anterior	38 (30.4%)	32 (33.0%)	3 (30.0%)	3 (18.8%)	-
Lateral	16 (12.8%)	13 (13.4%)	-	3 (18.8%)	-
Posterior	47 (37.6%)	37 (38.2%)	5 (50.0%)	4 (25.0%)	1 (50.0%)
Fundal	21 (16.8%)	13 (13.4%)	2 (20.0%)	5 (31.2%)	1 (50.0%)
Isthmic	3 (2.4%)	2 (2.0%)	-	1 (6.2%)	-

TOP: Termination of pregnancy, HSC: Hysteroscopic, LPS: Laparoscopic, LPT: Laparotomic, AUB: Abnormal uterine bleeding, EP: Estro-progestins, GnRH-a: Gonadotrophin-releasing hormone analogues, FIGO: The International Federation of Gynecology and Obstetrics.

Table 2. Patients' stratification according to the fibroids' characteristics: number, size, site, FIGO grade, pre-operative pharmacological preparation.

n=125	One step myomectomy n=97	Office hysteroscopy n=10	Two steps myomectomy n=16	Three steps myomectomy n=2
No of fibroids				
=1	73 (75.3 %)	8 (80.0%)	12 (75.0%)	2 (100.0%)
=2	18 (18.5%)	1 (10.0%)	2 (12.5%)	-
=3	6 (6.2%)	-	2 (12.5%)	-
=4	-	-	-	-
=5	-	-	-	-
=6	-	1 (10.0%)	-	-
Maximum diameter (mm)				
<20	34 (35.0%)	1 (10.0%)	1 (6.2%)	-
≥20	63 (65.0%)	9 (90.0%)	15 (93.8%)	2 (100.0%)
Site*				
Lateral right	6 (6.2%)	-	2 (12.5%)	-
Lateral left	7 (7.2%)	-	1 (6.2%)	-
Anterior	32 (33.0%)	3 (30.0%)	3 (18.8%)	-
Fundal	13 (13.4%)	2 (20.0%)	5 (31.3%)	1 (50.0%)
Isthmus	2 (2.1%)	-	1 (6.2%)	-
Posterior	37 (38.1%)	5 (50.0%)	4 (25.0%)	1 (50.0%)
FIGO grade*				
0	24 (24.7%)	-	1 (6.2%)	-
1	31 (32.0%)	1 (10.0%)	5 (31.3%)	-
2	36 (37.1%)	8 (80.0%)	10 (62.5%)	2 (100.0%)
3	6 (6.2%)	1 (10.0%)	-	-
No therapy	48 (49.5%)	2 (20.0%)	7 (43.8%)	-
Oral	48 (49.5%)	6 (60.0%)	6 (37.5%)	1 (50.0%)
GnRH-a	1 (1.0%)	2 (20.0%)	3 (18.7%)	1 (50.0%)

*Of the largest fibroid, FIGO: International Federation of Gynecology and Obstetrics, GnRH-a: Gonadotrophin-releasing hormone analogues.

Table 3 stratifies patient's population according to the instruments used during surgery, describing for each category interesting and potential influencing factors.

The 26 Fr bipolar resectoscope was used in the 35.2% (44/125) of total cases. In the 93.2% (41/44) of cases in which a 26 Fr resectoscope was used, the fibroid was >2 cm and the localization of the fibroid was posterior in the 43.2% (19/44) of cases, with grade G2 fibroid in the 45.5% (20/44) of patients. The median fibroid maximum diameter treated with 26Fr resectoscope was 33.7 (range 15-65) mm. The median procedure time was 33.3 (range 17-67) minutes. A residual fibroid was found in the 41% (18/44) of cases.

The 15 Fr bipolar mini-resectoscope was used in the 56% (70/125) of total cases. In the 64.3% (45/70) of cases in which a 15 Fr mini-resectoscope was used, the fibroid was >2 cm and the localization of the fibroid was anterior and posterior in the 38.6% (27/70) and 35.7% (25/70) of cases respectively, with grade G2 fibroid in the 48.6% (34/70) of patients. The median fibroid maximum diameter treated with 15Fr mini-resectoscope was 19.5 (range 9-32) mm. The median procedure time was 28.8 (range 6-64) minutes. A residual fibroid was found in the 14.3% (10/70) of cases.

According to our findings about the fibroid size, we decided to perform a sub-analysis in which the instruments used for the removal of fibroids ≤3 cm were evaluated, excluding the ones >3 cm. The fibroids ≤3 cm were 92/125. In 72% (66/92) of cases of fibroids ≤3 cm, a 15Fr mini-resectoscope was used; in 16% (15/92) of cases, a 26Fr resectoscope was used; in 12% (11/92), a 5 mm hysteroscope with 5 Fr instruments and/or a TRD were

Table 3. Instruments used during surgery accordingly to the main variables.

	5 mm hysteroscope 7/125 (5.6%)	15 Fr mini-resectoscope 70/125 (56%)	26 Fr resectoscope 44/125 (35.2%)	Tissue removal device 4/125 (3.2%)
No of fibroids				
=1	7 (100.0%)	48 (68.6%)	36 (81.8%)	4 (100.0%)
>1	-	22 (31.4%)	8 (18.2%)	-
Maximum diameter				
<20	6 (85.7%)	25 (35.7%)	3 (6.8%)	2 (50.0%)
≥20	1 (14.3%)	45 (64.3%)	41 (93.2%)	2 (50.0%)
Site*				
Lateral right	-	4 (5.7%)	4 (9.1%)	-
Lateral left	2 (28.6%)	6 (8.6%)	-	-
Anterior	2 (28.6%)	27 (38.6%)	7 (15.9%)	2 (50.0%)
Fundal	2 (28.6%)	8 (11.4%)	11 (25.0%)	-
Isthmus	-	-	3 (6.8%)	-
Posterior	1 (14.2%)	25 (35.7%)	19 (43.2%)	2 (50.0%)
FIGO grade**				
0	3 (42.9%)	10 (14.3%)	10 (22.7%)	2 (50.0%)
1	3 (42.9%)	18 (25.7%)	14 (31.8%)	1 (25.0%)
2	1 (14.2%)	34 (48.6%)	20 (45.5%)	1 (25.0%)
3	-	8 (11.4%)	-	-
Residual myoma				
No	7 (100.0%)	60 (85.7%)	26 (59.0%)	4 (100.0%)
Yes	-	10 (14.3%)	18 (41.0%)	-
Maximum diameter				
Median (range)	11.6 (6-20)	19.5 (9-32)	33.7 (15-65)	16.2 (10-20)
Time of procedure (minutes)				
Median, range	13.1 (6-21)	28.8 (6-64)	33.3 (17-67)	25.2 (10-38)

**Of the largest fibroid, FIGO: International Federation of Gynecology and Obstetrics.

used. In this population, when a 15 Fr mini-resectoscope was used, the fibroid was removed in one single surgical step in the 89.4% (59/66).

The fibroids >3 cm were 33/125. In the 97% (32/33) of these cases, the 26 Fr resectoscope was used.

In our population, no intraoperative (fluid overload or perforation) and postoperative complications were described.

Univariate analysis showed that diameter and pre-operative hormonal therapy are the parameters most related to single-step fibroid removal, with P=0.001 and P=0.019, respectively. Diameter is the only parameter that is confirmed also on multivariate analysis (P<0.001) (Table 4).

Discussion

In our cohort 85.6% of patients did not require a second-step myomectomy under anaesthesia. In 77.6% of cases the myomectomy was completed during the first surgical step and in 8% of cases during the office hysteroscopic control. Only 14.4% of patients needed a second surgical step. The need of multiple steps is more frequent in fibroids >2 cm, in FIGO grade 2 fibroids and in fundal location. In case of fibroids ≤3 cm, a 15Fr mini-resectoscope was used in the 72% of cases. In these patients, the myomectomy was completed in one surgical step in 89.4% of cases.

Our findings align with the GCH Scientific Committee Consensus, emphasizing the need of a thorough preoperative assessment using combined approach with transvaginal ultrasound and hysteroscopy.[7] This permits

Table 4. Factors associated with multiple steps procedures.

	Univariate OR (95% CI)	Multivariate OR (95% CI)
Therapy	*P*=0.019	-
No	Ref.	-
Oral	0.93 (0.30-2.83)	-
GnRH-a	9.52 (1.75-51.77)	-
Number of fibroids	*P*=0.85	-
1	Ref.	-
>1	0.89 (0.27-2.94)	-
Maximum diameter (mm)	*P*=0.001	*P*<0.001
	1.08 (1.03-1.13)	1.08 (1.03-1.13)
Maximum FIGO grade	*P*=0.14	
0-1	Ref.	
2-3	2.20 (0.77-6.28)	
Time of surgery (min)	*P*=0.075	-
	1.03 (1.00-1.07)	-

GnRH-a: Gonadotrophin-releasing hormone analogues, FIGO: International Federation of Gynecology and Obstetrics, OR: Odds ratio, CI: Confidence interval.

to perform also sonohysterography during the same step. The water distension allows to accurately evaluate the fibroid's extent in the uterine wall.

These findings highlight the importance of performing an office hysteroscopy 30-40 days after the main procedure to evaluate the uterine cavity and to eventually remove residual fibroid during this step.

The fibroids' number did not significantly affect the removal in one or multiple steps. The size, the FIGO grade and the site influenced the possibility to perform multiple steps procedures, but fibroid diameter was the only statistically significant parameter, even in multivariate analysis, related to single-step fibroid removal (*P*<0.001).

Regarding preoperative therapy, univariate analysis suggests that the use of GnRH-a negatively impacts the feasibility of performing surgery in a single step. However, when stratified by fibroid diameter, it is evident that patients treated with GnRH-a tend to have larger fibroids. Specifically, patients who did not receive preoperative hormonal therapy had fibroids with a median diameter of 21.1 mm at the time of surgery, those treated with oral therapy had a median diameter of 24.8 mm, and those treated with GnRH-a had fibroids with a median diameter of 40.3 mm. Therefore, although patients treated with GnRH-a appear more likely to require a multi-step procedure, these same patients also have larger fibroids. Since fibroid diameter is the only independent factor, influencing our primary outcome in this case series, it is not possible to definitively assess the true efficacy of presurgical GnRH-a treatment.

In the literature, different studies suggest that GnRH-a can facilitate surgery by reducing operative time, endometrial thickness, and fluid absorption,[11] but recent systematic reviews and meta-analyses indicate that GnRH-a does not significantly improve surgical outcomes.[12] In our study, the efficacy of GnRH-a is influenced by the bias of fibroid size, the most significant prognostic factor impacting the primary outcome.

Based on our experience and published data, pharmacological preparation, even with progestin alone, is essential in reducing endometrial thickness, improving intrauterine vision, reducing bleeding, and operative time.[13]

Our data described the possibility to remove the 72% of submucosal fibroids ≤3 cm with a 15 Fr mini-resectoscope, completing the procedure in one surgical step in 89.4% of cases. Previous studies showed one step complete resection rate with mini-resectoscope of 39.5%.[14] The technique standardization in our set-up offers a high success rate. The 97% of fibroids >3 cm were removed with a 26 Fr bipolar resectoscope.

Although the average fibroid volume in the 26 Fr group is significantly larger compared to the 15 Fr group (with diameters of 33.7 mm versus 19.5 mm), the operative time was only 4.5 minutes longer. While cervical dilation adds extra time, one advantage of the 26 Fr resectoscope is its larger loop. However, we acknowledge that the experienced operator using the 15 Fr mini-resectoscope is able to maintain a relatively short operative time due to their familiarity with the technique. This, however, may not be the case for less experienced operators, which could lead to longer procedure times. We recommend reserving the use of the 26 Fr resectoscope for fibroids larger than 3 cm. As also noted by Clark et al.[15], smaller-diameter operative hysteroscopes should be used whenever possible to minimize cervical trauma.

Our data shows no intraoperative and postoperative complications.

It is essential for all women of childbearing age to preserve the endometrial surface as much as possible by using surgical techniques[10] and instruments that minimize thermal damage to the greatest extent.[15]

The cold loop technique is critical for deeply intramural fibroids (G2-G3) with a thin myometrial free margin. This technique prevents uterine perforation, reduces thermal damage and the risk of intrauterine adhesions formation.[7,16]

To our knowledge, this is the first paper, in which the use of 15 Fr mini-resectoscope Collins loop was described to treat fundal fibroids. This technique was described by Lasmar et al.[6] using a 26 Fr resectoscope. This technique enhances the possibility to remove G2-3 fundal fibroids with few millimetres free myometrial margin, lowering the possibility of perforation.

Study Limitations

All the procedures were performed by the same surgeon. On one hand, this eliminate the variability seen in other studies where multiple operators are involved especially of non-comparable experience. On the other hand, this is a limit because the surgeon experience may affect the study reproducibility.

Another limit is the retrospective nature, resulted in some missing data or not perfectly standardized procedures, as the missing hormonal pre-operative therapy in a group of patients. Additionally, the sample size could affect the results' statistical significance, as the power was limited.

Hysteroscopic myomectomy is one of the most complex intrauterine surgeries, with potentially serious complications. In expert hands, it may be considered an effective and safe procedure.

Safety in myomectomy is made by a good preoperative evaluation and a correct operative act.

Further studies are needed to better understand the importance of preoperative hormonal preparation and which instrument use in relation with fibroid size, position and grade.

Conclusion

Hysteroscopic myomectomy in a single surgical step is feasible and should be the goal to reduce complications and increase patient satisfaction. Our data shows that fibroid diameter is the only independent factor determining the feasibility of performing the procedure in a single surgical step. Preoperative progestin therapy reduces endometrial thickness, enhancing intrauterine vision and facilitating complete fibroid removal. More studies are needed to evaluate the effectiveness of GnRH-a.

The ability to perform myomectomy with miniaturized instruments is crucial to avoid cervical dilation and reduce uterine perforation, minimizing damage to the surrounding endometrium, a key objective in patients of childbearing age. Further studies are needed to evaluate the true efficacy of 15 Fr mini-resectoscope in the removal of G0-G3 fibroids <3 cm.

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Data sharing: The dataset used and analyzed durng the current study is not publicly available but can be made available from the corrisponding author upon reasonable request.

Transparency: The manuscript is an hoest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted.

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ORIGINAL ARTICLE

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The impact of virtual reality technology in the era of See & Treat hysteroscopy: a randomised controlled trial

Brunella Zizolfi[1], Virginia Foreste[1], Maria Giuseppina Trinchillo[1], Danilo Borrelli[1], Alessandra Gallo[2], Maria Chiara De Angelis[3], Fabiola Nardelli[1], Attilio Di Spiezio Sardo[1]

[1]Department of Public Health, University of Naples Federico II Faculty of Medicine, Naples, Italy
[2]Unit of Obstetrics and Gynecology, University Hospital "San Giovanni di Dio e Ruggi d'Aragona", Salerno, Italy
[3]Department of Neuroscience, Reproductive Sciences and Dentistry, University of Naples Federico II Faculty of Medicine, Naples, Italy

ABSTRACT

Background: In the context of outpatient hysteroscopy (OPH), performing a single procedure integrating the operative and diagnostic part is known as "See & Treat hysteroscopy". The virtual reality (VR) technology provides an immersive virtual environment that can provide a non-invasive analgesic. To date, there is limited evidence regarding its use in the OPH setting.

Objectives: To evaluate the feasibility and effectiveness of VR technology for pain and anxiety management in OPH.

Methods: Unblinded, prospective, randomised controlled trial, conducted at the Hysteroscopy Unit of the University of Naples "Federico II" between May and July 2024. Women aged 18-70 years, indicated for OPH, were randomised into a control group (standard OPH care) and an intervention group (OPH care with the addition of a VR headset).

Main Outcome Measures: Pain and anxiety were assessed through subjective measures: numerical rating scale (NRS) scores before and after the procedure, and objective measures: heart and respiratory rate pre- and during the procedure. Satisfaction, time, and success rates were also evaluated.

Results: Overall, 116 women were enrolled. The VR group compared to the control group reported significantly lower mean standard deviation NRS scores for pain [3.9 (2.7) vs. 5.4 (3.0); mean difference 1.5, 95% confidence interval (CI) 0.4 to 2.5] and anxiety [3.2 (2.1) vs. 4.8 (2.8); mean difference 1.6, 95% CI 0.7 to 2.5] respectively. Regarding satisfaction, 96.5% of the VR group would use the headset again, whereas 3.5% requested its removal. All women in the control group desired a distraction. No serious adverse events were reported.

Conclusions: VR technology proved feasible and effective for pain and anxiety management in OPH, particularly during operative procedures.

What is New? Its use can support the implementation of the See & Treat philosophy.

Keywords: Outpatient hysteroscopy, virtual reality technology, pain and anxiety

Introduction

Hysteroscopy is a minimally invasive endoscopic technique that is considered the gold standard for diagnosing and treating intracavitary lesions.[1]

Technological advancements, including the introduction of miniaturised instruments and the vaginoscopic approach, have led to an increase in the number of diagnostic and operative hysteroscopic procedures performed in an outpatient hysteroscopy

Corresponding Author: Brunella Zizolfi, MD, Ph.D., Department of Public Health, University of Naples Federico II Faculty of Medicine, Naples, Italy
E-mail: brunellazizolfi@hotmail.it **ORCID ID:** orcid.org/0000-0002-3409-7504
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(OPH). In this context, the "See & Treat hysteroscopy"[2] approach, which integrates the operative part into the diagnostic work-up in a single procedure, has several advantages, such as reduced hospital stays, shorter recovery times, greater compliance, improved patient satisfaction, and a better cost-benefit ratio, while avoiding the risks associated with anaesthesia.[3-5] Although See & Treat hysteroscopy is generally well-tolerated,[6] it can cause physical and emotional discomfort for some patients, leading to acute pain and anxiety; the anxiety and concern felt by women before and during the procedure can impact the perception of pain and the tolerability of the exam, potentially causing the procedure to fail.[7,8]

Common pain relief options during hysteroscopy include sedation, injectable local anaesthetics, and analgesics,[9-11] but the quality of evidence from studies supporting these methods is poor.[12] Therefore, there is a need to identify new pain control strategies that are alternative or complementary to pharmacological analgesia. One emerging strategy is the use of virtual reality (VR) technology, which has been increasingly studied and utilised in various medical fields for pain and anxiety management.[13-16]

VR technology provides a realistic, immersive virtual environment usually viewed through a headset, which can interactively produce a non-invasive analgesic condition that helps alleviate pain and anxiety.[16] Studies have shown promising results in several fields, including surgical training, patient education, rehabilitation, pain and anxiety management for a variety of scenarios, including burns treatment, medical and paediatric procedures, hysterosalpingography, dentistry, chronic pain, orthopaedic procedures, labour, episiotomy and phobias.[17-23]

To address the scarcity of scientific evidence on the use of VR technology, considering its potential as a supportive non-pharmacological anaesthetic technique during office gynaecological procedures and in the hysteroscopic field, this study aimed to evaluate the feasibility and effectiveness of using VR technology to improve pain and anxiety management during OPH compared to standard care, and to increase the acceptability of the 'See & Treat' philosophy.[24-30] Additionally, patient questionnaires and vital parameter recordings were used to obtain both subjective and objective criteria to ensure unbiased results.

Methods

An unblinded prospective randomised controlled trial was conducted at the Hysteroscopy Unit of University of Naples "Federico II", from May to July 2024. The study was approved by the Ethics Committee of the Campania Region (protocol N°: 112/2024, minutes N°: 7/24, dated: 14 May 2024).

Patients aged 18-70 years old, undergoing OPH for any indication, who provided informed consent to participate in the study and provided informed consent were included. The exclusion criteria included history of epilepsy, severe vertigo, neurodegenerative diseases (for example amyotrophic lateral sclerosis, multiple sclerosis), neuropathic pain (for example diabetic neuropathy), chronic pain (for example fibromyalgia), paralysis of the lower limbs, vulvodynia and vaginismus, significant visual or hearing impairment and predisposition to motion sickness, contraindications for hysteroscopic examination.

Eligible women were randomly assigned to the intervention VR or control group (1:1 ratio), using an online tool for randomisation.[15,16] Blinding of participants or researchers was not possible due to the nature of the intervention involving the use of a headset; however, randomisation and data analysis were performed by a separate member of the research team to minimise selection bias.

All procedures were carried out in an outpatient setting, using a vaginoscopic approach with a 5 mm Bettocchi continuous flow operating hysteroscope (Karl Storz, Germany), without analgesia or anaesthesia. Uterine cavity distension was achieved with a saline solution using the "Hamou Endomat®" pump (Karl Storz, Germany); the mean intrauterine pressure was constant at 30-40 mmHg, with a flow rate of 220-350 mL/min, an irrigation pressure of 75-100 mmHg and a suction pressure of 0.25 bars.

5 Fr mechanical instruments and bipolar electrodes, 15 Fr bipolar office resectoscope (Karl Storz, Germany) and Truclear™ Elite Mini tissue removal devices (Medtronic) were used to treat endouterine lesions. All procedures were performed by two experienced gynaecologists (A.D.S.S. and B.Z.).

In the control group, patients underwent OPH with our standard care, while in the VR group, patients received standard care along with VR therapy provided via a VR headset and headphones with hypno VR software [Deepsen VRx Device, Deepsen, DT Didier, Mont d'Or,

France (http://www.deepsen.io/)] (Figure 1). The headset transported women in a relaxing environment chosen according to the patient's preference from a range of options (mountain, hill, river). The headphones provided an audio-guided breathing exercise on a background of pleasant relaxing music.

This virtual scenario was developed with specialised psychologists to obtain an attentive shift, reducing procedure-related pain and anxiety. The headset was controlled by a researcher present in the ambulatory unit, and the operator could adjust the duration of the virtual projection to cover the expected length of the entire procedure. The patients could ask to stop the video or remove the headset at any point during the procedure.

Primary outcome measures were:

- Level of pain and anxiety reported by the patient, expressed on a 10-point numerical rating scale (NRS), from 0 indicating no pain or anxiety, to 10 corresponding to the worst pain or anxiety (subjective criteria), during diagnostic and operative procedures.

- Heart rate (HR) and respiratory rate (RR), collected by a dedicated nurse before and during diagnostic and operative procedure (objective criteria).

Figure 1. Virtual reality headset *(Deepsen VRx Device, Deepsen, DT Didier, Mont d'Or, France).*

Secondary outcome measures were:

- Procedure completion and suspension rate (defined as the proportion of suspended procedures for any reason),

- Time of procedure,

- Satisfaction rate (VR group: desire to use the headset again in the future/control group: desire to use the headset if they could),

- Reported side effects.

Participants completed pre- and post-procedure questionnaires, sharing data on pain and anxiety levels before and after the examination. In the pre-procedure questionnaire, patients were asked about the NRS scores for anticipated average pain and anxiety about the procedure. In the post-procedure questionnaire, instead, it was collected the NRS scores for average pain and anxiety felt during the procedure were collected. Data on women's age, body mass index, obstetric history, menopausal status, previous hysteroscopies, and indication for the exam were collected before the procedure.

Statistical Analysis

For categorical variables, data were presented as absolute values and incidence rates. For continuous variables, data were presented as mean and standard deviation (SD). Means and SDs were calculated for normally distributed data, and comparisons were made with the unpaired Student's t-test. A post-hoc analysis was performed using analysis of covariance (ANCOVA) to test the robustness of the finding after controlling for baseline pain and anxiety levels. Statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS) software (IBM Inc., Armonk, NY, USA), with significance set at $P \leq 0.05$.[31]

Results

During the recruitment period, 178 women undergoing a procedure at our hysteroscopy unit met the inclusion/exclusion criteria; 116 out of 178 (65.16%) agreed to participate in the study and were randomised (1:1) into one of the two study groups (Figure 2). The baseline characteristics of the patients are shown in Table 1. Fifty-eight patients were randomised to the VR group and fifty-eight to the control group. Neither local anaesthetic nor additional analgesic or anti-emetic drugs were administered during the procedure in either group.

The most common indication for the examination was incidental abnormal ultrasound findings (e.g., endometrial thickening, suspected polyps, or fibroids). Both diagnostic and operative procedures were performed; 40 out of 58 procedures (68.9%) were operative in the VR group and 34 out of 58 (58.6%) in the control group (*P*=0.68). Operative procedures were endometrial biopsy, polypectomy, myomectomy, adhesiolysis and metroplasty.

Thirty-five out of 58 (60.3%) women in the VR group and 38 out of 58 (65.5%) in the control group were undergoing hysteroscopic examination for the first time. Four patients (6.9%) in the VR group and only 2 patient (3.4%) in the control group had cervical stenosis; two patients asked to remove the visor before the end of the procedure in the VR group (suspension rate: 2/58); both suffered from panic attacks and did not enjoy the VR experience.

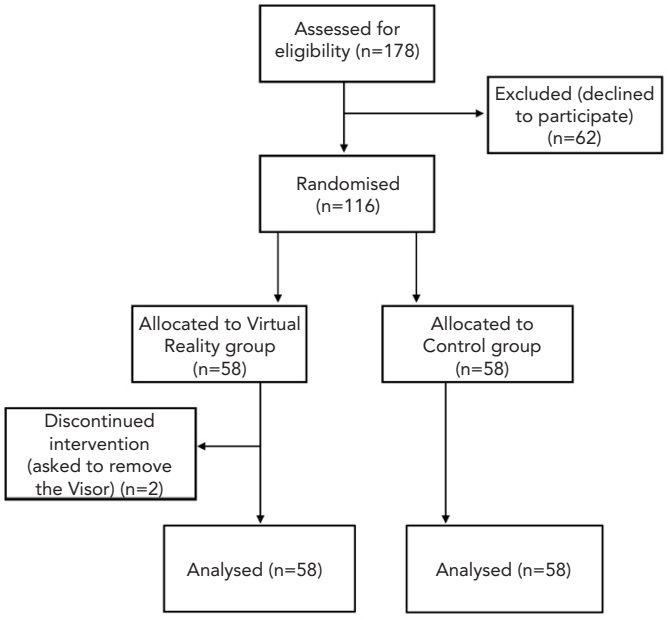

Figure 2. Consort flow diagram.

Levels of perceived pain and anxiety during the procedures were significantly lower in the VR group than in the control group; statistically significant differences in mean NRS scores for expected (pre-procedure) and perceived (post-procedure) pain and anxiety were found in the VR group compared with the control group (Table 2). When analysing NRS post-procedure scores and the mean difference in NRS scores for pre- and post-procedure pain separately for diagnostic and operative procedures, we found that perceived pain and anxiety were significantly lower in the control group compared to the VR group, but only for operative procedures. In contrast, for diagnostic procedures, these differences did not reach statistical significance (Supplementary Tables 1 and 2).

Differences between the 2 groups regarding objective parameters were not significant. After checking for normality, post-procedure anxiety and pain scores were found to be normally distributed, and the comparison of averages was performed with Student's independent t-test.

Regarding secondary outcomes, 100% of the procedures were completed in both study groups (Table 2). No serious side effects or procedure-related complications were reported in either group. However, the VR headset group, two patients reported mild nausea that did not require anti-emetics. In the control group, one patient reported a presumed vasovagal episode, which never occurred in the VR group, despite the use of the headset. Regarding satisfaction rate, 56/58 women (96.5%) would use the headset again in the future; 2/58 women (3.5%) instead asked to remove the visor before the end of the procedure. 58/58 (100%) women in the control group would like to use a source of distraction during the procedure if they could.

Table 1. Participant baseline characteristics.

Characteristics	Virtual reality group (n=58)	Control group (n=58)
Age (mean, SD)	45.00 (13.00)	43.24 (11.26)
BMI (mean, SD)	26.39 (5.11)	25.20 (5.64)
Previous CS (n, %)	14/58 (24.13%)	13/58 (22.41%)
Previous vaginal delivery (n, %)	20/58 (34.48%)	18/58 (31%)
Premenopausal (n, %)	41/58 (70.69%)	42/58 (72.41%)
Postmenopausal (n, %)	17/58 (29.31%)	16/58 (27.59%)
First hysteroscopy	35/58 (60.3%)	38/58 (65.5%)

SD: Standard deviation, BMI: Body mass index, CS: Caesarean section.

Table 2. Primary and secondary outcomes measures for both diagnostic and operative procedures.

Primary outcomes	**Virtual reality group (n=58)**	**Control group (n=58)**	**Difference of means (95% CI)**	***P*-value**
NRS score for post-procedure pain (mean, SD)	3.92 (2.70)	5.41 (2.98)	1.49; 95% CI 0.44 to 2.53	***P* 0.005**
Mean difference in NRS scores for pre- and post- procedure pain (mean, SD)	-2.48 (2.95)	-0.10 (3.06)	2.28, 95% CI 1.27 to 3.48	***P*<0.0001**
NRS score for post-procedure anxiety (mean, SD)	3.21 (2.13)	4.84 (2.79)	1.63; 95% CI 0.71 to 2.54	***P* 0.0006**
Mean difference in NRS scores for pre- and post- procedure anxiety (mean, SD)	-3.01 (2.55)	-1.00 (2.07)	2.1, 95% CI 1.24 to 2.95	***P*<0.0001**
HR during procedure (mean, SD)	85.35 (11.35)	88.68 (15.02)	3.30; 95 %CI -1.56 to 8.22	*P*=0.18
RR during procedure (mean, SD)	19.19 (4.60)	18.77 (3.69)	0.42; 95% CI -1.95 to 1.11	*P*=0.58
Secondary outcomes	VR group (n=58)	C group (n=58)	Difference of means (95% CI)	***P*-value**
Length of procedure, minutes	6.94 (4.49)	5.91 (3.32)	-1.03 95% CI -2.48 to 0.42	*P*=0.16
Satisfaction rate (VR group: would use the headset again in the future/C group: would like to use it if they could) (n, %)	56/58 (96.5%)	58/58 (100%)	-	-
Side effects (nausea, vasovagal episode) (n, %)	2/58 (3.45%)	1/58 (1.72%)	-	-
Incomplete procedures (n, %)	0/50	0/50	-	-

CI: Confidence interval, SD: Standard deviation, NRS: Numerical rating scale, HR: Heart rate, VR: Virtual reality.

Discussion

In the era of See & Treat procedures, in which nearly 90% of all hysteroscopic surgeries can be performed in outpatient setting, the major challenge is to minimise the physical and emotional discomfort of the patient; worry and anxiety increase the perception of pain and limit the tolerability of the exam, sometimes leading to the failure of the procedure itself. Therefore, reducing the patient's anxiety ensures a better result and a higher level of satisfaction.

Hence, there is a need to identify new alternatives for pain control strategies, ranging from emotional support provided by dedicated healthcare personnel ("vocal anaesthesia") to more recent visual and auditory sources of entertainment (such as music, videos), including VR.[12] To date, VR has been widely used in medicine, but there is still limited and conflicting data in the literature regarding its use in gynaecological and particularly hysteroscopic fields.

The mechanism through which VR acts is known as "distraction analgesia", where immersion in a virtual environment diverts the patient's attention from painful stimuli. This process is rooted in Melzack's[32] theory of "neuromatrix of pain", which states that pain is a multidimensional experience, generated in the brain by the particular and individual organisation of nervous stimuli, modified by sensory experience. Sensory distraction, therefore, leaves fewer resources for pain processing and shifting attention from unpleasant feelings to attractive or pleasant stimuli can help avoid negative mood states such as stress and anxiety.[32]

A meta-analysis revealed that VR may play a role in reducing pain scores in acutely painful procedures but was shown to be effective only in needles and burns physical therapy. However, it was limited by the clinical and statistical heterogeneity of the studies.[21]

Our findings suggest that the use of VR technology during OPH significantly reduces the subjective perception of pain and anxiety. In fact, Patients in the VR group experienced significantly less pain and anxiety during the procedure compared to the control group, with significant differences in expected pain and anxiety scores compared to perceived pain and anxiety scores. Subgroup analysis suggested this result was particularly

true for operative procedures. These results are highly relevant for the broader adoption of See & Treat procedures, allowing to perform most of the operative hysteroscopy in the outpatient setting without the need for an operating room, reducing the waiting list.

These data agree with the original work of Deo et al.[24], which reported a significant reduction in pain and anxiety while disagreeing with a recent study of Sewell et al.[27], which found no statistical difference in pain scores, only lower patient-reported anxiety during the procedure. Estadella Tarriel et al.[33] emphasised how VR can have a highly beneficial impact on pain and anxiety management associated with hysteroscopy. However, as a standard practice in their centre, all patients receive ibuprofen and diazepam 30 minutes before the procedure. In our study, we opted not to use any premedication to avoid influencing pain perception and to ensure the reliability of the collected data.[32] Notably a study by Pelazas-Hernández et al.[34] demonstrated a significantly positive impact of VR on both pain and anxiety, although they assessed only diagnostic hysteroscopies.

We also collected patients' vital parameters to obtain objective measures of pain and anxiety.[34]

The maximum HR recorded during the procedure was higher in the control group than in the VR group (although statistical significance was achieved only in the analysis of diagnostic procedures), suggesting that the distraction mechanism may, in certain categories of patients, help the patient in anxiety management.

In contrast, no difference was found in RR. These results are partially in disagreement with an earlier study by Fouks et al.[26] that reported an increase in HR of patients wearing headphones, but with no significant difference in patient-reported pain.

Our findings also indicate that VR technology is feasible without any significant increase in side effects or in procedure failure, or the length of the procedure.

Our study is among those with the largest sample size currently conducted on the use of VR in OPH; the baseline characteristics of the study population were well matched in terms of age, parity, and menopausal status, and they were randomly allocated to the two groups. Additional strengths include the fact that it was representative of the full range of procedures performed in our OPH department.

However, the lack of blinding could influence the patient-reported pain and anxiety scores and the heterogeneity of the procedures could influence the strength of conclusions, although the number of operative procedures was the same in the two groups. Another potential weakness is the lack of stratification of the groups based on the patients' anxiety status prior to the procedure. For instance, there could be more "anxious patients" in one group compared to the other. We hope that randomisation minimises the impact of any potential bias, but this aspect should be included as a possible limitation.

Conclusion

VR technology appears to be a feasible and effective technique as a distraction method in OPH for pain and anxiety management, particularly during operative rather than diagnostic procedures. This technological tool could facilitate the implementation and wider acceptance of the 'See & Treat' philosophy. Our data encourages further studies, which, by increasing the sample of patients undergoing outpatient operative hysteroscopies, could confirm the usefulness of VR technology and persuade doctors and patients to the increasing uptake of the outpatient approach, with all its associated advantages.

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Informed consent: Patients aged 18-70 years old, undergoing OPH for any indication, who agreed to participate in the study and provided informed consent were included.

Data sharing: The data that support the findings of this study are available from the corresponding author upon reasonable request. Restrictions apply to the availability of these data due to confidentiality agreements and the sensitive nature of patient information.

Transparency: The authors affirm that this manuscript is an honest, accurate, and transparent account of the cases reported. All relevant details have been included, and no important information has been omitted. The patients' identities have been protected in accordance with ethical standards.

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Supplementary Table 1. Primary and secondary outcome measures for diagnostic procedures.

Primary outcomes	**Virtual reality group (n=18)**	**Control group (n=24)**	**Difference of means (95% CI)**	***P*-value**
NRS score for post-diagnostic procedures pain (mean, SD)	4.21 (2.87)	4.66 (2.58)	-0.45; 95% CI -1.25 to 2.15	*P*=0.59
Mean difference in NRS scores for pre- and post-procedure pain (mean, SD)	-2.89 (3.12)	-1.25 (3.22)	-1.64 95% CI -3.64 to 0.36	*P*=0.10
NRS score for post-procedure anxiety (mean, SD)	3.21 (2.27)	4.75 (3.02)	-1.54 95% CI -3.2 to 0.17	*P*=0.07
Mean difference in NRS scores for pre- and post-procedure anxiety (mean, SD)	-2.36 (2.71)	-1.12 (1.4)	-1.24 95% CI -2.72 to 0.24	*P*=0.10
HR during procedure (mean, SD)	83.47 (9.29)	88.58 (14.02)	-5.11 95% CI -2.6 to 12.8	*P*=0.18
RR during procedure (mean, SD)	18.94 (4.41)	18.29 (3.73)	0.65 95% CI 3.19 to -1.89	*P*=0.60
Secondary outcomes	**VR group (n=18)**	**C group (n=24)**	**Difference of means (95% CI)**	***P*-value**
Length of procedure, minutes	3.84 (1.30)	4.75 (4.25)	0.91 (95% CI -1.18 to 3)	*P*=0.38
Satisfaction rate (VR group: would use the headset again in the future/C group: would like to use it if they could) (n, %)	18/18	24/24	-	-
Side effects (nausea, vasovagal episode) (n, %)	0/18	0/24	-	-
Incomplete procedures (n, %)	0/18	0/24	-	-

CI: Confidence interval, SD: Standard deviation, NRS: Numerical rating scale, HR: Heart rate, RR: Respiratory rate, VR: Virtual reality.

Supplementary Table 2. Primary and secondary outcome measures for operative procedures.

Primary outcomes	**Virtual reality group (n=40)**	**Control group (n=34)**	**Difference of means (95% CI)**	***P*-value**
NRS score for post-procedures pain (mean, SD)	3.78 (2.63)	5.32 (2.98)	-1.54 95% CI -2.84 to -0.23	*P*=0.02
Mean difference in NRS scores for pre- and post- procedure pain (mean, SD)	-2.27 (0.70)	-0.5 (2.75)	-1.77 95% CI -2.66 to -0.87	*P*=0.0002
NRS score for post-procedure anxiety (mean, SD)	3.21 (2.48)	4.91 (2.65)	-1.7 95% CI -2.89 to -0.5	*P*=0.005
Mean difference in NRS scores for pre- and post- procedure anxiety (mean, SD)	-3 (3)	-1.35 (2.41)	-1.65 95% CI -2.92 to- 0.37	*P*=0.01
HR during procedure (mean, SD)	86.32 (12.27)	88.52 (15.68)	2.2 95% CI -4.28 to 8.68	*P*=0.5
RR during procedure (mean, SD)	19.32 (4.76)	19.11 (3.68)	-0.21 95% CI -2.20 to 1.78	*P*=0.83
Secondary outcomes	**VR group (n=40)**	**C group (n=34)**	**Difference of means (95% CI)**	***P*-value**
Length of procedure, minutes	8.54 (4.72)	6.91 (2.42)	-1.63 (95% CI -3.41 to 0.15)	*P*=0.07
Endometrial biopsy, time	*(n=11)* *7.45 (±3.75)*	*(n=11)* *6.3 (±2.31)*	-1.15(95% CI -3.9201 to 1.6201)	*P*=0.39
Endometrial polypectomy, time	*(n=12)* *8 (±3.33)*	*(n=10)* *8.0 (±2.12)*	0 (95% CI 2.5453 to 2.5453)	*P*=1
Cervical polypectomy, time	*(n=8)* *5.42 (±0.78)*	*(n=7)* *5.85 (±2.41)*	0.43 (95% CI -1.5093 to 2.3693)	*P*=0.63
Myomectomy, time	*(n=2)* *13.5 (±9.19)*	*(n=2)* *11 (±1.41)*	2.5 (95% CI -30.7872 to 25.7872)	*P*=0.74
Metroplastic, time	*(n=3)* *11.66 (±4.04)*	*(n=4)* *6.5 (±1.29)*	-5.16 (95% CI -10.5465 to 0.2265)	*P*=0.0571
Synechiolysis, time	*(n=4)* *13.5 (±6.75)*	*(n=0)* -	-	-
Satisfaction rate (VR group: would use the headset again in the future/C group: would like to use it if they could) (n, %)	38/40 (95%)	34/34 (100%)	-	-
Side effects (nausea, vasovagal episode) (n, %)	2/40 (mild nausea) (5%)	1/34 (vasovagal episode) (2.94%)	2.06 % (95% CI -10.44% to 13.81%)	*P*=0.65
Incomplete procedures (n, %)	0/40	0/34	-	-

CI: Confidence interval, SD: Standard deviation, NRS: Numerical rating scale, HR: Heart rate, RR: Respiratory rate, VR: Virtual reality.

ORIGINAL ARTICLE

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The presacral-uterosacral hysteropexy - a novel native tissue repair for pelvic organ prolapse

Xiaojuan Wang, Jie Zhang, Keqin Hua, Yisong Chen

Department of Obstetrics and Gynaecology, Hospital of Fudan University, Shanghai, People's Republic of China

ABSTRACT

Background: Uterine-preserving procedures for pelvic organ prolapse (POP) are favoured and are becoming increasingly popular. Transvaginal natural orifice transluminal endoscopic surgery (vNOTES) presacral-uterosacral hysteropexy is a novel native tissue repair for POP.

Objectives: This study aimed to evaluate the safety of this uterine-preserving procedure and its midterm efficacy in treating POP.

Methods: Between December 2020 and December 2022, patients with symptomatic POP who underwent vNOTES presacral-uterosacral hysteropexy at a tertiary teaching hospital were retrospectively analysed. The patient characteristics, follow-up outcomes, and complications were recorded and analysed.

Main Outcomes Measures: We investigated anatomical success, subjective improvement, perioperative parameters, and operative complications.

Results: Fifty-eight patients (median age 41 years) completed a mean 24.4-month (± 6.8) follow-up. There were two women (3.4%) who experienced recurrence. There was a significant improvement in POP-Q scores in all compartments at the last follow-up compared to the baseline (P<0.001). 94.8% of patients were satisfied with their operations. The urinary and prolapse symptoms improved significantly (P<0.001), and sexual function was significantly improved (P<0.001). There were no intraoperative complications, and one patient experienced fever and delayed haemorrhage after surgery.

Conclusions: vNOTES presacral-uterosacral hysteropexy may be a safe and feasible technique for women with POP who desire to preserve their uterus. This procedure demonstrates promising medium-term anatomical and subjective outcomes in treating POP.

What is New? This is a new mesh-free surgical procedure that combines the benefits of laparoscopic sacrohysteropexy and vNOTES uterosacral ligament hysteropexy to treat women with POP who desire uterine preservation, aiming to gain long-term anatomical success and minor complications.

Keywords: Native tissue repair, transvaginal natural orifice transluminal endoscopic surgery, pelvic organ prolapse, presacral-uterosacral hysteropexy, uterine preservation

Introduction

Pelvic organ prolapse (POP) is a common and benign condition. It causes distressing symptoms such as vaginal bulging, pressure, voiding and defecatory dysfunction, or sexual dysfunction, which might adversely affect the quality of life (QoL) in women.[1] Even though surgical treatment for POP includes concomitant hysterectomy, traditionally, there is a

Corresponding Author: Keqin Hua, MD, Department of Obstetrics and Gynaecology, Hospital of Fudan University, Shanghai, People's Republic of China
E-mail: professorhuao9@163.com **ORCID ID:** orcid.org/0000-0001-5359-8841

Corresponding Author: Yisong Chen, MD, Department of Obstetrics and Gynaecology, Hospital of Fudan University, Shanghai, People's Republic of China
E-mail: cys373900207@163.com **ORCID ID:** orcid.org/0000-0002-2639-8753
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growing patient preference for uterine preservation.[2-5] The reasons why women with POP prefer to preserve their uterus include fewer surgical risks, a sense of femininity, sexual function, and maintenance of fertility.[4,6]

The uterine-preserving procedures are reported for apical prolapse, either through a vaginal or abdominal approach, with the use of mesh or not.[7-13] Despite efficacy, prosthetic surgery procedures have been proven to be accompanied by specific complications, including mesh exposure, dyspareunia, vaginal bleeding, and others, and the treatment for these complications can be challenging.[14,15] In pregnancy, it has been reported that there is higher risk of placenta previa, as well as the need for incision change during caesarean section, and incidence of pain syndromes in pregnant women after sacral mesh hysteropexy.[16,17] Therefore, there is an increasing interest in reconstructive native-tissue procedures for POP.

Even though both vaginal procedures have similar anatomical success and great patient satisfaction,[18] there was a higher rate of ureteric kinking in the uterosacral ligament hysteropexy (USHP) cohort than that in sacrospinous hysteropexy (SSHP) (P=0.023), and total cases of nerve injuries were in the SSHP cohort.[19] It's reported that dyspareunia was more frequently reported after vaginal SSHP compared to laparoscopic sacrohysteropexy (LSHP).[9] The weaknesses of USHP include the risk of ureteric injury and a higher apical failure rate compared to uterosacral suspension with hysterectomy.[20,21]

Transvaginal natural orifice transluminal endoscopic surgery (vNOTES) USHP could clarify the path of the ureter and reduce the risk of ureteric injury, which could also prevent abdominal wound infections, incisional pain, and provide a better cosmetic outcome.[22] There is a case report about vNOTES retroperitoneal promontory fixation in conjunction with the uterus-preserving Manchester procedure;[23] it is believed this procedure is feasible. Compared to the high cure rates (92%) of LSHP,[13] the failure incidence of USHP was as high as 25%.[24] Herein, we have developed a mesh-free surgical procedure that combines the benefits of LSHP and vNOTES USHP to perform vNOTES presacral-uterosacral hysteropexy for treating women with POP who desire uterine preservation. Our study aimed to evaluate the safety and midterm efficacy of this uterine-preserving procedure.

Methods

Patients

We reviewed the medical records of women with symptomatic POP who underwent vNOTES presacral-uterosacral hysteropexy with anterior/posterior colporrhaphy or without it between December 2020 and December 2022 at a tertiary teaching hospital. Patient information was recorded and updated during follow-up visits. This retrospective study was approved by the Ethics Committee of Obstetrics and Gynaecology Hospital of Fudan University (2019-32) on Mar 29th 2019. All patients provided written and oral informed consent for this surgical procedure and for using their data for research purposes.

Demographic information, perioperative parameters, and complications – including low urinary tract infection, pelvic pain, stitch exposure, vaginal bleeding, de novo urinary incontinence, were recorded. Physical examination with POP quantification (POP-Q) scores was conducted at baseline, six months, and annually after the procedure. The QoL questionnaires were used to assess patients' functional outcomes, including the Pelvic Floor Distress Inventory-20 (PFDI-20) questionnaire,[25] the validation of the Chinese version of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) questionnaire,[26] and the Patient Global Impression of Improvement (PGI-I) questionnaire[27] were used to assess patients' functional outcomes. Telephone interviews were used to gather information on patients' prolapse-related symptoms and questionnaire scores for those unable to come for a visit.

Surgical failure (defined as occurring within six months after the operation) or recurrence was considered present if any of the following criteria: POP-Q point C descended with the Valsalva manoeuvre more than one-third of the total vaginal length, or POP-Q points Aa, Ba, Ap, or Bp with the Valsalva manoeuvre were beyond the hymen.[28]

Surgical Procedure

All patients underwent vNOTES presacral-uterosacral hysteropexy performed by two surgeons (Y.C. and X.W.) under general anaesthesia. Patients were placed in the dorsal lithotomy position, and a catheter was inserted for continuous urinary drainage.

In the first vaginal step, after injecting a water cushion, a 2.5 cm posterior colpotomy was performed, and the posterior cul-de-sac was opened. The transvaginal single-port platform

was established, and a pneumoperitoneum was created.

In the second endoscopic step, after identifying the right ureter and promontory, the right pelvic peritoneum below the promontory was incised. The presacral space was dissected to expose the anterior longitudinal ligament (ALL) (Figure 1). A 0-0 non-absorbable stitch (Ethicon, Somerville, NJ) was secured to the ALL by a horoscope stitch. The end of the stitch was passed through to the right pelvic peritoneum at the ischial spine level, which was initially incised. Subsequently, three consecutive stitches were placed in the uterosacral ligament pedicles (Figure 2). The stitches were slightly pulled to confirm correct placement and ensure the right ureter was not being kinked. Next, the left ureter and uterosacral ligament were identified during single-port laparoscopy. Using three stitches, a 0-0 non-absorbable stitch was placed in the middle of the uterosacral ligament at the ischial spine level. Bilateral stitches were also slightly pulled to confirm correct placement and ensure that the ureters were not kinked. Before removing the single-port platform, adequate irrigation hydration of the pelvis is necessary to reduce the risk of adhesions forming.

In the third vaginal step, non-absorbable stitches were placed from medial to lateral along the cervical-uterine junction (Figure 3) and the uterosacral and cardinal ligament complexes. The stitches were secured with large bites into the junctional portion of the uterosacral ligament with the pubo-cervical ring (Figure 4). The bilateral stitches were locked in place to shorten the uterosacral ligaments further and reinforce their attachment to the uterus. After all the suspensory stitches were tied, these non-absorbable stitches would be buried retroperitoneally to avoid the risk of bowel adhesion and stitch exposure in the future.

In the final step, the colpotomy incision was closed using absorbable stitches. Cervical amputation was performed or not based on the length of the cervix. If point C-D measurements in the POP-Q examination exceeded 5 cm, cervical amputation was performed. Anterior-colporrhaphy and or posterior-colporrhaphy were performed based on the prolapse stage of the anterior/posterior vaginal wall. The surgical video is seen

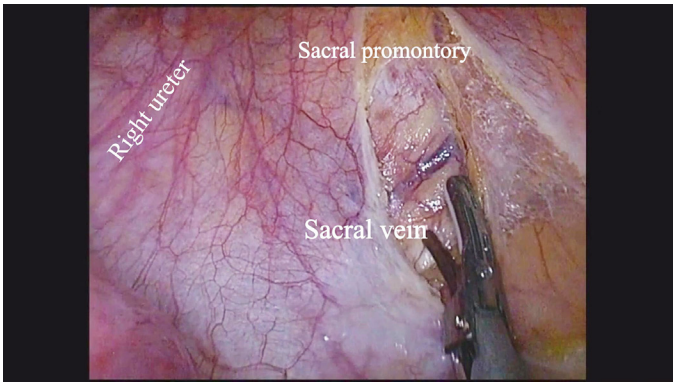

Figure 1. The presacral space was dissected to expose the anterior longitudinal ligament.

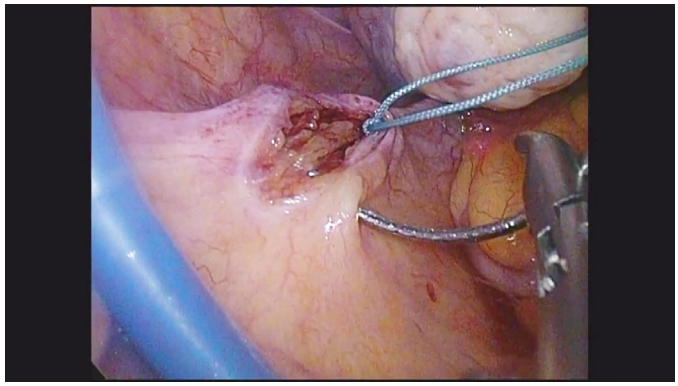

Figure 2. Three consecutive sutures were placed in the uterosacral ligament pedicles.

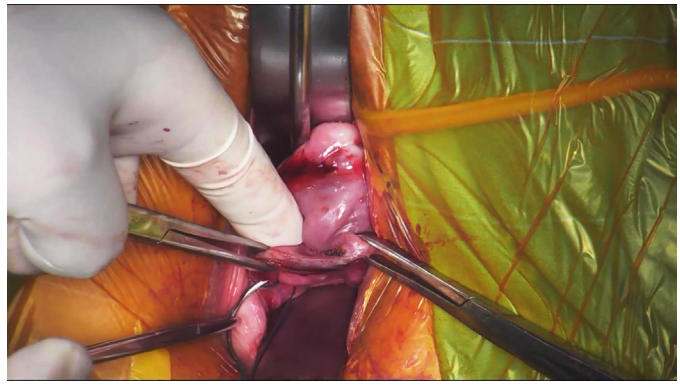

Figure 3. The non-absorbable suture was placed medially to laterally along the cervical-uterine junction.

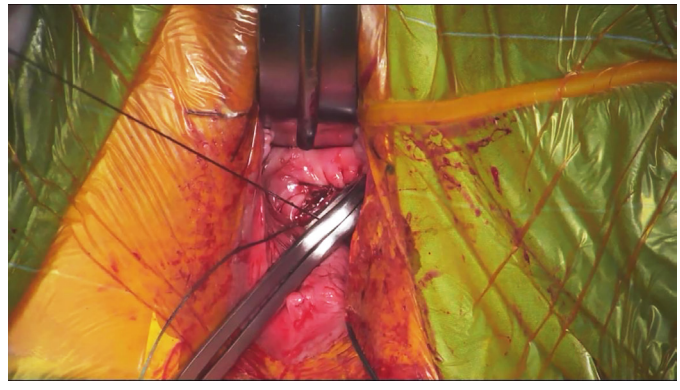

Figure 4. The suture was secured with large bites in the junctional portion of the uterosacral ligament and the pubocervical ring.

in Supplementary Video 1.

Statistical Analysis

Mean, standard deviation or median, interquartile range, and percentage were used to express descriptive statistics. Depending on normality, the Student's t-test or Wilcoxon rank test was used for continuous measures as appropriate, to compare preoperative POP-Q and QoL scores with those at the latest follow-up. A *P*-value of less than 0.05 was considered statistically significant. Statistical analyses were performed using SPSS software (Version 22.0; IBM Corp, Armonk, NY).

Results

vNOTES presacral-uterosacral hysteropexy was performed on 60 patients between December 2020 and December 2022. Two patients were lost to follow-up; fifty-eight patients were enrolled in this study, with a mean 24.4-month follow-up (± 6.8). Of these patients, most (86.4%, 51 of 58) came to the outpatient for follow-up, and seven were followed up by telephone. The patients' characteristics are shown in Table 1. Three patients (5.2%) converted to caesarean section from vaginal labour because foetal distress was confirmed. Eight patients (13.8 %) had a history of macrosomia, and eight patients (10.5%) had a history of dystocia. Nine patients (15.5%) had previous pelvic/abdominal surgeries. Twelve (20.7%) patients had stress urinary incontinence. Eighteen (31.0%) patients were diagnosed with stage 2, while 39 (67.2%) patients were diagnosed with stage 3.

Table 1. Baseline participant characteristics (n=58).

Characteristic	Value
Age, median (IQR), years	41 (25-63)
BMI, median (IQR), kg/m^2	23.2 (19.5-28.0)
Gravidity, median (IQR)	
Parity, median (IQR)	1 (0-3)
CS, no. (%)	3 (5.2%)
Foetal macrosomia, no. (%)	8 (13.8%)
Dystocia, no. (%)	7 (12.1%)
SUI, no. (%)	12 (20.7%)
Previous pelvic/abdominal surgery, no. (%) Comorbidities, no. (%)	9 (15.5%)
Diabetes mellitus	1 (1.7%)
Hypertension Connective tissue disease	2 (3.4%) 1 (1.7%)
Prolapse beyond the hymen, no. (%)	
Anterior (POP-Q Aa or Ba >0)	35 (60.3%)
Apical (POP-Q C >0)	51 (87.9%)
Posterior (POP-Q Ap or Bp >0)	11 (18.9%)
Overall POP-Q stage, no. (%)	
2	18 (31.0%)
3	39 (67.2%)
4	1 (1.7%)

IQR: Interquartile range, BMI: Body mass index, calculated as weight in kilograms divided by height in meters squared, CS: Caesarean section, SUI: Stress urinary incontinence; POP-Q stage 2: Most distal prolapse is between 1 cm above and 1 cm beyond hymen, Stage 3: Most distal prolapse is prolapsed >1 cm beyond hymen but ≤2 cm lewss than total vaginal length, Stage 4: Total prolapse.

The majority of patients i.e. 94.8% (55 out of 58 patients) were satisfied with this surgical procedure, based on the PGI-I scores (1 ranging from 2). Comparisons of POP-Q and QoL scores in the latest follow-up (at least 15 months after surgery) with baseline are shown in Table 2. There was a significant improvement in POP-Q scores in all compartments in the last follow-up compared to the baseline (P<0.001). Significant improvements were found in the following symptom scores at the last follow-up compared to the baseline: PFDI-20 (43.4 ± 5.3 vs. 36.8 ± 5.5, P<0.001), POP distress inventory (9.8 ± 4.1 vs. 7.2 ± 2.9, P=0.004), Urinary Distress Inventory (6.7 ± 2.3 vs. 4.7 ± 3.9, P<0.001), colorectal anal distress inventory (3.1 ± 1.7 vs. 2.3 ± 1.7, P<0.001), urinary distress inventory (3.1 ± 1.7 vs. 2.3 ± 1.7, P<0.001), and PISQ-12 (30.5 ± 3.3 vs. 27.3 ± 4.3, P<0.001).

We also conducted further subgroup analysis between women with cervical amputation and those who kept their cervix. Except for point D (-1.9 ±1.1 vs. -3.0 ± 1.4, P=0.0018) in preoperative evaluation, there were no significant differences in POP-Q measures between women with a preserved cervix and those with cervical amputation. During the last follow-up, these two subgroups had no significant differences in POP-Q measures. All values are shown in Table 3.

Surgery-related characteristics are seen in Table 4. Concomitantly, 12 patients (20.7%) received anti-incontinence procedures with mid-urethral slings, two patients (3.4%) underwent cystoscopy, and 27 patients (46.6%) underwent cervical amputation. Twenty-three patients (39.7%) underwent anterior colporrhaphy, and 16 (27.6%) underwent posterior colporrhaphy. No patient experienced intraoperative complications. There was one patient who experienced fever with a temperature >38 °C measured twice in 12 hours and combined with delayed haemorrhage.

Table 2. Preoperative and latest follow-up (at least 15 months) POP-Q and QoL scores change.

Variable	Preoperative (n=58)	The latest follow-up (n=58)	Difference (95% CI) (n=58)	*P*-value
POP-Q				
Aa	0.4 ± 1.0	-2.4 ± 0.8	-2.8 (-3.1 to -2.6)	<0.001
Ba	0.9 ± 1.4	-2.4 ± 0.8	-3.3 (-3.6 to -2.9)	<0.001
C	1.7 ± 1.4	-6.4 ± 1.2	-8.1 (-8.5 to -7.8)	<0.001
D	-2.4 ±1.4	-6.5 ± 0.9	-4.0 (-4.4 to -3.6)	<0.001
Ap	-0.9 ± 1.0	-2.6 ± 0.7	-1.7 (-1.9 to -1.4)	<0.001
Bp	-0.8 ± 1.2	-2.6 ±0.7	-1.8 (-2.1 to -1.6)	<0.001
TVL	7.3 ± 0.6	7.4 ± 0.6	0.1 (0 to 0.1)	0.083
QoL				
PFDI-20	43.4 ± 5.3	36.8 ± 5.5	-6.6 (-8.1 to -5.1)	<0.001
POPDI-6	9.8 ± 4.1	7.2 ± 2.9	-2.6 (-3.9 to -1.2)	0.004
UDI-6	6.8 ± 2.3	4.7 ± 3.9	-2.3 (-3.1 to -1.6)	<0.001
CRADI-8	3.1 ± 1.7	2.3 ± 1.7	-0.9 (-1.2 to -0.6)	<0.001
PISQ-12	30.5 ± 3.3	27.3 ± 4.3	-3.2 (-4.1 to -2.3)	<0.001

P-values representing the difference in score (difference in data pre-operative versus the latest follow-up data after surgeries) are statistically significant (Student's t-test). POP-Q: Pelvic organ prolapse quantification, QoL: Quality of life, TVL: Total vaginal length, PFDI-20: Pelvic Floor Distress Inventory-20, higher scores indicate more symptom distress, POPDI-6: Pelvic Organ Prolapse Distress Inventory-6, UDI-6: Urinary Distress Inventory-6, CRADI-8: Colorectal Anal Distress Inventory-8; PISQ: Pelvic Organ Prolapse Sexual Questionnaire, Mean (standard deviation), Difference score is based on measurements taken pre-operatively and at the latest follow-up (at least 15 months), CI: Confidence interval.

Table 3. Subgroup analysis of POP-Q values in patients with cervical amputation and those with a preserved cervix.

Variable	Non-amputation (n=31)	Cervical amputation (n=27)	*P*-value
POP-Q			
Aa (pre-operation)	0.4 ± 1.0	-0.4± 1.1	0.8142
Aa (Post-operation)	-2.5 ± 0.6	-2.3 ± 1.1	0.5179
C (pre-operation)	1.5 ± 1.3	1.9 ± 1.4	0.2641
C (post-operation)	-6.6 ± 0.8	-6.1 ± 1.5	0.1388
D (pre-operation)	-1.9 ± 1.1	-3.0 ± 1.4	0.0018
D (post-operation)	-6.6 ± 0.8	-6.3 ± 1.0	0.1193

Mean (standard deviation), Difference score is based on measurements taken preoperatively and at the latest follow-up (at least 15 months); *P*-values representing the difference in score (difference in data preoperative versus the latest follow-up data after surgeries) are statistically significant (Student's t-test). POP-Q: Pelvic organ prolapse quantification.

The mean follow-up duration was 24.4 months (± 6.8), and two cases (3.4%) experienced recurrence. One of them had prolapse at 12 months after surgery and was diagnosed with concomitant anterior vaginal wall and apical prolapse; this patient underwent a hysterectomy and vNOTES sacrocolpopexy later. The other patient was diagnosed with anterior vaginal wall prolapse 18 months after the surgery, and she was placed under observation and received Kegel exercises and pelvic floor muscle training.

Discussion

Main Findings

Due to the risk of complications associated with mesh, native tissue surgery is increasingly playing a significant role in pelvic reconstructive surgery.[20] Herein, we report our experience of performing vNOTES presacral-uterosacral hysteropexy for women with POP who desire to preserve their uterus and present its promising medium-term surgical success and subjective outcomes.

In order to achieve long-term anatomical and functional success without mesh, the permanent stitches were placed in ALL of the presacral and uterosacral ligaments. The remaining stitches were buried retroperitoneally to prevent future erosion or exposure. Until the last follow-up, there was no stitch erosion or exposure.

In our study, not all patients underwent cervical amputation, and whether performing cervical amputation was based on the cervix length. Even though cervical elongation is often presented as cervical bulging beyond

Table 4. Surgery-related parameters of the patients (n=58).

Characteristic	Value
Operation time, median (IQR), minutes	95 (55-170)
Estimated blood loss, median (IQR), millilitres	80 (20-200)
Concomitant surgeries, no. (%)	
Mid-urethral sling	12 (20.7%)
Cystoscopy	2 (3.4%)
vNOTES ovarian cystectomy	5 (8.6%)
vNOTES myomectomy	2 (3.4%)
Cervical amputation	27 (46.5%)
Anterior colporrhaphy	23 (39.7%)
Posterior colporrhaphy	16 (27.6%)
Perineal body repair	2 (3.4%)
Intraoperative complications, no. (%)	0
VAS score after operation: median (IQR)	1 (1-3)
Length of hospital stay: median (IQR)	2.5 (1-4)
Postoperative complications, no. (%)	
Temperature >38 °C measured twice in 12 hours	1 (1.7%)
Delayed haemorrhage	1 (1.7%)

[a]Delayed haemorrhage is defined as that which occurred after leaving the operating room, IQR: Interquartile range, vNOTES: Transvaginal natural orifice transluminal endoscopic surgery, VAS: Visual analogue scale.

the hymen, cervical elongation should be evaluated from various perspectives. It is reported that approximately 40% of women with prolapse have cervical elongation.[29] FIGO working group recommendation published in 2017 showed that the Manchester procedure was mainly obsolete due to post-Manchester cervical incompetence resulting in preterm deliveries and cervical stenosis, and there were better alternatives for women who desire preservation of their fertility.[30] Based on our experience, if point C-D measurements in preoperative POP-Q examination exceeded 5 cm, cervical amputation was performed. Together, this surgical procedure aimed to gain long-term anatomical success and a successful pregnancy and delivery in the future.

It is reported that the pregnancy rate was found to be 17.3% (8 of 46 patients) after abdominal sacrocervicopexy, with pregnancies occurring 23.2 months (18-30) after the operation.[31] However, the average age of their patients was 37.8 year-old, which was younger than our study's (mean age 41 years). In our study, two patients became pregnant 12 months after surgeries, and one of them had a vaginal delivery without any issues or complications. Regarding the delivery mode, we have little experience to recommend, and we should consider prior mode of delivery and the obstetricians' advice. Regarding the pregnancy rate, we will need long-term follow-up. Besides, we should exclude women who have undergone bilateral tubal ligation or are postmenopausal in future cases.

The LAVA trial reported that LSHP was non-inferior for surgical failure and QoL compared with SSHP at 12 months follow-up.[7] However, stitch placement, even in the correct position as described, does not guarantee safety during SSHP due to variable vascular anatomy.[20] It is reported that the risk of recurrent prolapse of the anterior vaginal wall after SSHP is considered to be related to the change in vaginal axis to a more posterior and horizontal position.[32] Our mesh-free surgical procedure combines the advantages of sacrocolpopexy and uterosacral ligament suspension, hoping to gain the highest surgical success rate and the fewest complications. During our medium-term follow-up (mean 24.4 months, range 15-36 months), only two patients (3.4%) experienced a recurrence. One of these patients was diagnosed with stage 4 before surgery and insisted on preserving the uterus. It is well-known that advanced prolapse poses a risk for recurrence.

Compared to SSHP, USHP could have potential advantages. First, uterosacral ligament identification is more straightforward, decreasing dissection compared to sacrospinous ligament preparation. Besides, one LAVA trial reported that dyspareunia occurred almost three times as often after SSHP than after LSHP,[9] which might be due to vaginal narrowing and scarring as well as damage of the vascularization and innervation of the vaginal wall.[33] However, USHP associated with ureteric kinking should not be ignored. During laparoscopy, the bilateral ureters are easy to discern, allowing for the avoidance of ureteric injury or kinking. Our study had no perioperative complications. One patient experienced fever and delayed vaginal haemorrhage one week after the operation, and later coronavirus disease-2019 testing was positive; there was no active bleeding in vaginal trauma, and the estimated blood loss was 100 mL; after sterilising, a gelatine sponge covered the vaginal wound, anti-inflammatory and tranexamic acid haemostatic treatment was given.

The vNOTES approach has made groundbreaking advances in urogynaecology surgeries in recent years. It's reported that vNOTES can provide a better perspective

on the presacral anatomy in front of the S1 and avoid ureteric injury and abdominal incisions,[34,] which also has a fast recovery and aesthetic advantage. The surgeons can directly visualise the uterosacral ligament without requiring additional retractors or a change in position if they follow the vNOTES approach, which could offer improved ergonomics for more successful and safer suspension procedures.[35] Even though vNOTES might influence adhesion formation in Douglas's pouch, several factors are considered to avoid adhesion. Besides meticulous surgical technique, minimized tissue trauma, reducing infection risk, adequate hydration, and sterile technique are helpful to decrease adhesion formation in the pouch of Douglas.

Strengths and Limitations

Compared to other similar studies published, this study has the following strengths. First, the participants in our study were followed for medium-term follow-up (mean 24.4 months) after their procedures, and this period exceeds the follow up duration of most previous studies on vNOTES hysteropexy. Additionally, our study's sample size was larger than that of other similar studies. Second, validated questionnaires were used for preoperative and postoperative evaluation of each patient. The main shortcomings of our study are the inherent limitations of retrospective studies and the lack of a control group.

Future Directions

A reconstructive native-tissue procedure for uterine preservation is regarded as the safest option in women desiring pregnancy. both USHP and SSHP were considered as first-line options due to the higher level of evidence and lower incidence of adverse obstetrical outcomes.[20] Therefore, a prospective randomised controlled trial should be implemented to further investigate this novel surgical procedure vNOTES presacral-uterosacral hysteropexy without mesh for women with POP who desire to preserve their uterus.

Conclusion

Our pilot experiences suggest that presacral-uterosacral hysteropexy might be a feasible and safe technique for women with POP who desire to preserve their uterus, with promising medium-term anatomical and subjective outcomes.

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Contributors: Surgical and Medical Practices: X.W., C.Y., Concept: C.Y., K.H., Design: C.Y., K.H., Data collection or Processing: X.W., J.Z., Analysis or Interpretation: X.W., J.Z., Literature Search: X.W., J.Z., Writing: X.W.

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Competing interests: The authors declare that they have no competing interests.

Ethical approval: Ethics Committee of Obstetrics and Gynaecology Hospital of Fudan University (2019-32) on Mar 29th 2019.

Informed consent: All patients enrolled in this study provided written and oral informed consent for this surgical procedure and for using their data for research purposes.

Data sharing: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Transparency: We affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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Supplementary Video 1. https://youtu.be/upzKiHu8uvg

SHORT COMMUNICATION

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Uptake of virtual reality in outpatient hysteroscopy: a prospective observational study

Bibi Zeyah Fatemah Sairally[1,2], Lucy Davies[2], Paul P. Smith[1], Siobhan O'Connor[1], Charlotte Yates[1], T. Justin Clark[1,2]

[1]Birmingham Women's Hospital, Birmingham Women's and Children's NHS Foundation Trust, Birmingham, UK
[2]College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK

ABSTRACT

This prospective cohort study evaluated virtual reality (VR) use during outpatient hysteroscopy in a UK tertiary hospital (Nov 2022-Apr 2023). Of 105 eligible women, 38 (36.2%) used VR; most who declined preferred to remain undistracted. Mean pain score was 5.5, slightly lower than the expected 5.7. Mild side effects included dizziness and claustrophobia. Nearly all users (94.7%) would recommend VR, and all rated it "acceptable" or "very acceptable." While VR may improve patient experience, limited uptake highlights the importance of tailoring pain management to individual preferences.

Keywords: Outpatient hysteroscopy, virtual reality, pain, anxiety, patient experience, non-pharmacological analgesia

Introduction

Hysteroscopy is a key intervention used within gynaecology[1,2], which can be completed in an outpatient setting[3] without needing general anaesthesia or an operating theatre. This provides several benefits to both patient and healthcare system: shorter recovery time, lower complication rates, reduced costs, increased convenience, and the potential for a "see-and-treat" approach.[4-8] However, pain has been cited as the most common reason for a failed outpatient hysteroscopy (OPH) procedure, and it is known that up to a third of patients will experience "severe" pain during such procedures.[6,8]

The increasing use of technology within healthcare has propelled virtual reality (VR) forward as a potential distraction technique to reduce pain perception.[9] There has been an interest in the use of VR as a non-pharmacological pain relief option in OPH to improve patient experience. Indeed, there have been a few randomised controlled trials (RCTs) assessing the use of VR during OPH for pain management.[10-15] A meta-analysis in 2023 concluded that VR does not decrease pain during office-based hysteroscopy, but it may reduce anxiety.[16] However, the meta-analysis highlighted several limitations, including the relatively small number of patients evaluated thus far using VR during OPH.

We conducted a prospective observational study to evaluate the uptake, acceptability and effectiveness of VR for pain control in routine OPH clinics for both diagnostic and operative procedures.

Corresponding Author: Bibi Zeyah F. Sairally, MD, Birmingham Women's Hospital, Birmingham Women's and Children's NHS Foundation Trust; College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK
E-mail: zeyah.sairally@nhs.net **ORCID ID:** orcid.org/0000-0001-5704-6489
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Methods

Study Design

An uncontrolled, prospective observational cohort study in a single tertiary specialist National Health Service Hospital in Birmingham, UK was conducted between November 2022 and April 2023 to evaluate the acceptability of VR headsets during OPH and other intrauterine procedures and their efficacy for controlling pain. Local Institutional Review Board approval was gained for a quality improvement project (CARMS-31988). VR headsets were provided by SyncVR Medical (https://www.syncvrmedical.com/) and controlled by a healthcare assistant supporting the patient. The patient could choose between a variety of relaxing virtual environments or a guided breathing/relaxation session. The sound from the simulated environment was played aloud in the room or on headphones, depending on the patient's preference of having a fully immersive experience. The headset and headphones were sanitised (in accordance with infection control policies) between patients using disposable alcohol wipes. 3.1 mm diameter hysteroscopes (Karl Storz, Germany) were used for most procedures, apart from hysteroscopic polypectomies, which were performed using 5.0 mm hysteroscopes (TruClear™ 5C Hysteroscope Set, Medtronic, US).

Participants

A poster advertised VR use in the clinic waiting area (Supplementary Questionnaire 1). Women aged 18 and over attending for elective intrauterine procedures were eligible; those with limited English comprehension were excluded.

Consenting women completed a pre-procedure questionnaire including demographic data (Supplementary Questionnaire 2). A clinician questionnaire captured VR uptake and reasons for refusal (Supplementary Questionnaire 3).

Outcomes

The primary outcome was pain experienced during the procedure on a 10 cm visual analogue scale (VAS) ranging from 0 (no pain) to 10 (worst pain imaginable) (Supplementary Questionnaire 4). This was completed in the immediate post-operative period when the patient was reviewed. Women were asked to complete the VAS and indicate the amount of pain they expected to experience as well as their current level of anxiety, ranging from 0 (no anxiety) to 10 (worst imaginable anxiety), before the procedure (Supplementary Questionnaire 2). Secondary patient-centred outcomes were collected in the post-procedure questionnaire (Supplementary Questionnaire 4). This included the overall experience using a 5-point Likert scale ("very acceptable"; "acceptable", "neither acceptable nor unacceptable"; "unacceptable" and "very unacceptable"), whether patients would recommend undergoing this procedure using VR, whether the use of VR headset was partial or throughout the procedure and any side effects experienced. Patients also had an opportunity to provide additional feedback through free-text comments.

The use of any pre-procedural analgesia was documented along with its timing, and any additional analgesia provided was recorded by the clinician (Supplementary Questionnaires 2 and 3).

Statistical Analysis

Descriptive statistics were used. Dichotomous outcomes were reported as counts and percentages; continuous outcomes as means with 95% confidence intervals (CI). For pain analysis, combined procedures were ranked hierarchically by typical pain intensity: endometrial polypectomy > coil insertion/change > blind Pipelle® endometrial biopsy > directed Pipelle® biopsy > diagnostic OPH > cervical polypectomy, based upon published procedural pain data.[8,17] All statistical analysis was performed using SPSS software version 29 (IBM, Armonk, USA).

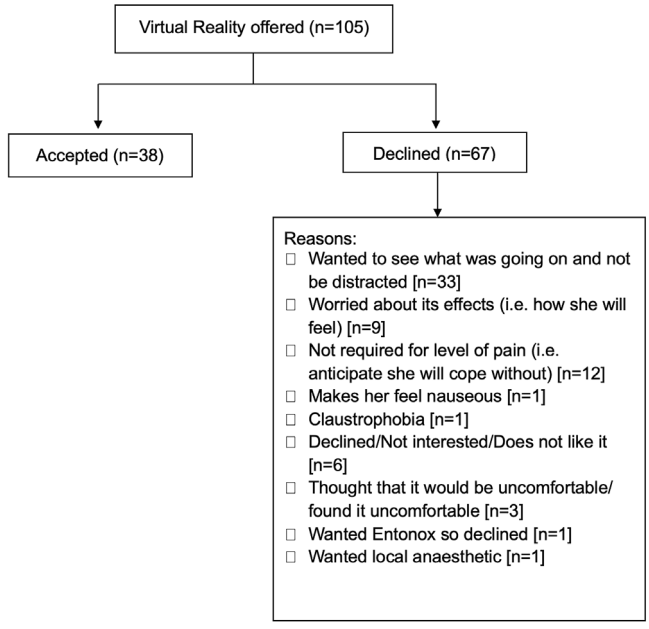

Figure 1. Flow chart of virtual reality (VR) uptake and reasons for declining use during outpatient hysteroscopy (OPH) and other intrauterine procedures.

Table 1. Pain during 38 procedures using virtual reality (VR).

Intrauterine procedure	Number (%)	Mean intraprocedural pain	95% confidence interval	
			Lower limit	Upper limit
All procedures	38 (100%)	5.5	4.6	6.3
Hysteroscopic polypectomy	4 (10.5%)	4.7	2.0	7.3
Coil insertion/change	7 (18.4%)	7.0	5.7	8.4
Endometrial Pipelle® biopsy	15 (39.5%)	5.4	4.1	6.6
Directed hysteroscopic biopsy	2 (5.3%)	7.8	4.8	10.8
Hysteroscopy alone	9 (23.7%)	4.7	2.8	6.6
Cervical polypectomy	1 (2.6%)	0.9	*NA	*NA

*NA: Not available.

Results

Out of 105 eligible women approached during the study, 38 (36.2%) women agreed to participate and use VR headsets during their procedures. Figure 1 shows a list of reasons for declining the use of VR headsets.

The mean age of the participants was 48.6 years (range: 29-75 years old). The ethnicity spread was representative of the local population [ethnicity: White 55.3% (48.6%); Asian 31.6% (31.0%), and Black 13.2% (10.9%)].[18] 36.8% (n=14) of the participating women were post-menopausal and 57.9% (n=22) had a history of vaginal delivery. Participants underwent a variety of procedures, ranging from OPH (n=36, 94.7%), Pipelle® (Cooper Surgical, CA, USA) endometrial biopsy (n=18, 47.4%), polypectomy using a hysteroscopic tissue removal system (Truclear® Office 5C, Medtronic, MI, USA) (n=4, 10.5%), coil insertion/change (n=7, 18.4%), directed hysteroscopic biopsy (n=2, 5.3%) and cervical polypectomy (n=1, 2.6%).

Eighteen participants had some form of analgesia before or during the procedure (47.4%), with a median time of 60 minutes pre-procedure (range: 0-360 minutes). This included paracetamol, non-steroidal anti-inflammatory drugs, co-codamol, codeine phosphate and tramadol. Two women (5.3%) had an intracervical local anaesthetic block during their procedure, and one woman (2.6%) required inhalational analgesia in the form of Entonox®.

The overall mean pain score experienced was 5.5 (95% CI: 4.5–6.1) [standard deviation (SD): 2.8] which was lower than the mean expected pain score of 5.7 (95% CI: 5.0–6.5) (SD: 2.2). The mean level of anxiety before the procedure was 5.3 (95% CI: 4.5–6.1) (SD: 2.4). The most painful procedure in this cohort was a directed hysteroscopic biopsy and the least painful procedure was a cervical polypectomy (Table 1).

Mild side effects were reported by three women (7.9%); two reported claustrophobia, and one reported dizziness. Six women (15.8%) used a VR headset during part of their procedure only, with three wanting to see what was going on and not be distracted. Other reasons for stopping included anxiety (n=2) and the use of Entonox® (n=1). The majority of participants would recommend undergoing their procedure using VR (n=36, 94.7%), and all women rated their procedure as either "acceptable" or "very acceptable" (n=38, 100%).

Discussion

Principal Findings

All the patients who used VR headsets found them acceptable during OPH and other intrauterine procedures, with less than one in ten reporting some mild side effects. However, only a third of women were willing to use VR during their procedure. Of those that did, almost one in five discontinued their use. Half of those declining VR stated that they wanted to see what was going on and not be distracted, and this was also the main reason for discontinuation. The average pain experienced was marginally less than the pain patients expected and in keeping with published data.[8] The vast majority of women who used VR recommended its use for undergoing common OPH or intrauterine procedures.

Strengths and Limitations

In this study, we assessed pain using an assessment scale which is validated to assess acute pain.[19,20] We also explored the utility and side effects of using VR in an outpatient gynaecology setting with no missing outcome data. This was not a randomised study, and the absence of a control group limits the strength of the conclusions.

The small number of participants who used VR further limits the reliability of the findings. Due to this small study size and the lack of a control group, reliable comparative analysis between procedures was not possible, nor was the ability to make strong inferences for clinical practice. However, we believe that our data collected from a routine clinical setting is generalisable and adds to the overall data accumulating from observational and experimental studies evaluating the use of VR for gynaecological procedures like hysteroscopy.

Comparison with Existing Literature

A review of the existing literature identified six RCTs involving the use of VR in OPH. One of those trials was a conference abstract reporting an analysis of the preliminary results and included only a quarter of the intended sample size.[11] The five other RCTs looking at the use of VR for pain scores during hysteroscopy reported variable and conflicting findings.[10,12-15] Three also looked at the associated anxiety levels of the patient.[10,13,15]

A systematic review and meta-analysis by Cohen et al.[16] in 2024 included four of these six RCTs[10,12,14,15] and showed that intraprocedural pain score was not improved by the use of VR, but there was a reduction in anxiety levels during OPH. A more recent systematic review with meta-analysis included two additional RCTs involving a total of 457 patients. In contrast, they found that VR was associated with a significant reduction in pain score during the procedure compared to the control group [mean difference (MD): -1.43, 95% CI, $P<0.001$).[21] There was also a significant decrease in anxiety ($P=0.01$) and the pain score post-procedure (MD: -1.52, 95% CI, $P<0.001$) in the VR group.[21]

Inferences from these meta-analyses are limited by relatively small samples, differences in the VR equipment used, VR environment video, types of hysteroscopes, other analgesia provided, as well as different pain measurement scoring systems. Future research should look at the type of VR technology used, the context where it is deployed and for what kind of procedure.

Implications for Clinical Practice

While most users found VR acceptable and would recommend it for hysteroscopy and intrauterine procedures, its utility for short procedures appears limited. In our study, two-thirds of women declined its use to aid pain control. This proportion is higher than the first RCT evaluating VR for OPH, where only 6/53 (11%) declined to use VR.[10] The observation from our study, performed in a routine, day-to-day clinical setting, gives an insight into the willingness of the typical woman attending the ambulatory gynaecology setting to use VR. The low uptake is likely to impact the cost-effectiveness of utilising VR technology in this setting. The target procedures in our study were short but intimate examinations by nature, necessitating continuous two-way communication between the clinician and conscious patient for reassurance and information-giving. This communication is disrupted by the use of VR headsets, and the desire to no longer be distracted was the main reason for discontinuation in those initially using VR. Cheaper, more individualised alternatives such as listening to music or looking at a relaxing landscape on the ceiling, while not fully immersive, may be simpler and more cost-effective distraction techniques for short, common intimate procedures.

Conclusion

The provision of adequate analgesia in the outpatient setting for hysteroscopy and other intrauterine procedures remains a challenge, and it is often a case of taking a tailored approach to each patient. While VR is an emerging medical tool, its place and usefulness in ambulatory gynaecology are yet to be determined.

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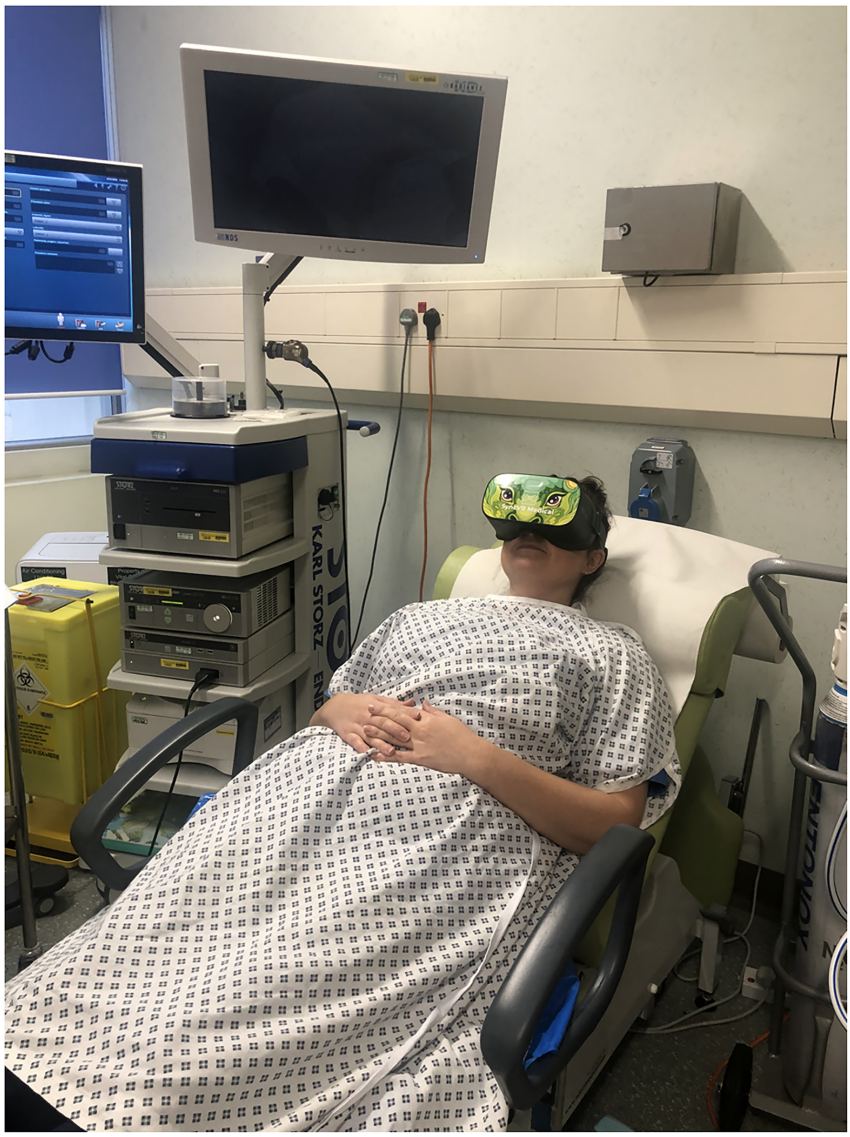

Supplementary Figure 1. Virtual reality in outpatient hysteroscopy. We are currently trialling virtual reality headsets in outpatient hysteroscopy to see if it improves your experience. Please speak to your doctor/nurse if you want more information or if you would like to try them during your appointment.

Supplementary Questionnaire 2.

Virtual Reality Headset PATIENT Pre-procedure Questionnaire

Please complete this short questionnaire about yourself.

1. Today's date: ___ /___ /___

2. Age: _____ What is your month & year of birth? ___ /___

3. Which of these options best describes your ethnicity?
   - ☐ White Caucasian
   - ☐ Asian
   - ☐ Afro-Caribbean or African
   - ☐ Other (*specify*): _____

4. Have you been through the menopause?
   - ☐ Yes
   - ☐ Currently going through it (menopausal symptoms but still having periods)
   - ☐ No

5. Have you had children?
   - ☐ Yes
   - ☐ No

6. Did you have a vaginal delivery?
   - ☐ Yes
   - ☐ No
   - ☐ Not applicable

7. Did you take any pain relief before the procedure?
   - ☐ Yes
   - ☐ No

8. Which medication(s) did you take? (*Please tick all that apply*)
   - ☐ None
   - ☐ Paracetamol
   - ☐ NSAIDs (e.g. Ibuprofen, naproxen, diclofenac, mefenamic acid, etc)
   - ☐ Codeine phosphate
   - ☐ Co-codamol
   - ☐ Other (*specify*): _____

9. Roughly how long before the procedure did you take the medication? _____ mins

Supplementary Questionnaire 2.

10. Please place a mark (**X**) on the scale indicating the amount of pain you **expect** during the procedure?

0	5	10
No pain at all	Moderate pain	Worst pain imaginable
		

11. Please place a mark (**X**) on the scale indicating your **current** level of anxiety regarding the procedure?

0	5	10
No anxiety at all	Moderate anxiety	Worst anxiety imaginable
		

Supplementary Questionnaire 3.

Virtual Reality Headset CLINICIAN Questionnaire

*Please complete this questionnaire **even if the patient had been offered the VR headset as analgesia but declined**. Thank you.*

Date: ___ /___ /___ Clinician Initials: _____ Patient DOB (MM/YY ONLY): ___ /___

1. Name of procedure (*please tick all that apply*):
   - ☐ Diagnostic OPH
   - ☐ OPH + pipelle biopsy
   - ☐ OPH + directed biopsy
   - ☐ OPH + polypectomy
   - ☐ MVA
   - ☐ Mirena Coil insertion/change
   - ☐ Bartholin's abscess drainage/insertion of word catheter
   - ☐ Other (*specify*): _____

2. Did the patient have a friend, carer or relative with them during the procedure?
   - ☐ Yes
   - ☐ No

3. Analgesia given before or during the procedure (*please tick all that apply*):
   - ☐ None
   - ☐ Paracetamol
   - ☐ NSAIDs
   - ☐ Codeine phosphate
   - ☐ Co-codamol
   - ☐ Tramadol
   - ☐ Pethidine
   - ☐ Morphine
   - ☐ Entonox
   - ☐ Intracervical block
   - ☐ Diclofenac
   - ☐ Other (*specify*): _____

4. If the VR headset was offered and declined, what was the main reasons she provided? (*please tick all that apply*)
   - ☐ Thought that it would be uncomfortable
   - ☐ Wanted to see what was going on and not be distracted
   - ☐ Worried about its effects (i.e. how she will feel)
   - ☐ Claustrophobia
   - ☐ Worried about potential side effects

Supplementary Questionnaire 4.

Virtual Reality Headset PATIENT Post-procedure Questionnaire

Please complete this short questionnaire about yourself and your experience of using of the Virtual Reality headset for pain control.

1. Today's date: ___ /___ /___

2. Age: _____ What is your month & year of birth? ___ /___

3. Please place a mark (**X**) on the scale indicating the amount of pain you **experienced** *during* the procedure?

0	5	10
No pain at all	Moderate pain	Worst pain imaginable

4. How would you describe your overall experience today?
   - ☐ 1 - Very acceptable
   - ☐ 2 - Acceptable
   - ☐ 3 - Neither acceptable nor unacceptable
   - ☐ 4 - Unacceptable
   - ☐ 5 - Very unacceptable

5. Would you recommend this procedure?
   - ☐ Yes
   - ☐ No

6. Did you use the Virtual Reality headset during the procedure?
   - ☐ Yes throughout
   - ☐ Yes, for part of it (*if you tick this box, please answer question 6a*)

6a. If you stopped using the Virtual Reality headset during the procedure, can you tell us why? (*Please tick all that apply*):
   - ☐ Headset uncomfortable
   - ☐ Anxiety
   - ☐ Wanted to see what was going on (i.e. not be distracted)
   - ☐ Claustrophobia
   - ☐ Other (*specify*): _____

Supplementary Questionnaire 4.

7. Which side effects did you experience from the Virtual Reality headset? (*Please tick all that apply*)

   - ☐ None
   - ☐ Nausea
   - ☐ Vomiting
   - ☐ Dizziness
   - ☐ Discomfort
   - ☐ Claustrophobia
   - ☐ Other (*specify*): _____

8. Please provide any comments about your experience?

   _____
   _____
   _____
   _____

SYSTEMATIC REVIEW

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Facts Views Vis Obgyn 2025;17(2):149-156

Pre-conceptional laparoscopic cerclage for prevention of preterm birth: a systematic review

Dimitrios Rafail Kalaitzopoulos[1], Ioannis Maris[1], Konstantinos Chatzistergiou[2], Georgios Schoretsanitis[3], Grigoris Grimbizis[4], Angelos Daniilidis[4]

[1]Department of Gynecology and Obstetrics, Cantonal Hospital of Schaffhausen, Schaffhausen, Switzerland
[2]Department of Gynecology and Obstetrics, Montreuil Hospital, Montreuil, France
[3]Department of Psychiatry, Psychotherapy and Psychosomatics, Hospital of Psychiatry, University of Zurich, Zurich, Switzerland
[4]1st Department of Obstetrics and Gynecology, Aristotle University of Thessaloniki, Thessaloniki, Greece

ABSTRACT

Background: Cervical cerclage is used to prevent preterm delivery caused by cervical insufficiency, thereby reducing neonatal morbidity and mortality rates. Transabdominal cerclage is usually performed in women who previously underwent transvaginal cerclage that failed to prevent pregnancy loss, or in those with a short cervix where transvaginal cerclage was not feasible.

Objectives: To estimate the efficacy of pre-conceptional laparoscopic cerclage in facilitating term delivery and live birth.

Methods: A systematic review was conducted according to the PRISMA 2020 guidelines. This study was registered in PROSPERO (CRD42024545316). A search was conducted up to the 15th of April 2024, in the PubMed and Cochrane databases, using a combination of terms "laparoscopy", "transabdominal" and "cerclage". Original studies investigating the role of pre-conceptional laparoscopic cerclage on pregnancy outcomes after follow-up were eligible for inclusion in this review.

Main Outcomes Measures: Prevalence of deliveries after 37 weeks of gestation and live birth rates.

Results: Ten studies involving 1060 patients were included. The pooled prevalence of deliveries after 37 weeks of pregnancy was 70% [95% confidence interval (CI) 60%-79%, 7 studies, 515 pregnancies, I^2: 85%] and the pooled prevalence of live birth was 92% (95% CI 86%-95%, 10 studies, 713 pregnancies, I^2: 69%). Significantly higher rates of delivery after 37 weeks of pregnancy were associated with the use of mersilene tape compared to conventional sutures [odds ratio (OR): 2.98, 95% 1.95-4.56] and the use of an anterior knot compared to a posterior knot (OR: 2.26, 95% CI: 1.50-3.40).

Conclusions: Pre-conceptional laparoscopic cerclage achieved high rates of live birth after 37 weeks in women considered at high risk of preterm delivery. Comparative research is needed to better understand the efficacy of pre-conceptional laparoscopic cerclage as well as refine the indications for this procedure, optimise surgical techniques, and determine the best timing for cerclage placement.

What is New? Pre-conceptional laparoscopic cerclage may prevent future preterm births and second-trimester pregnancy losses.

Keywords: Cervical cerclage, laparoscopy, preterm birth, miscarriage, live birth

Corresponding Author: Dimitrios Rafail Kalaitzopoulos, Department of Gynecology and Obstetrics, Cantonal Hospital of Schaffhausen, Schaffhausen, Switzerland
E-mail: dimkal1991@windowslive.com **ORCID ID:** orcid.org/0000-0002-8053-1308
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Introduction

Cervical cerclage is used to prevent preterm delivery due to cervical insufficiency, thereby reducing neonatal morbidity and mortality rates.[1] There are three major indications for the cervical cerclage: (1) women with risk factors for a preterm birth, (2) cervical shortening on ultrasound and (3) where the cervix is already open and the foetal membranes are exposed (rescue cerclage).[1]

A synthetic suture or tape is used to mechanically maintain the structural integrity of the cervix, thereby prolonging gestation.[2] Four different surgical approaches have been used to date: the transvaginal, transabdominal with laparotomy, laparoscopic and robotic transabdominal cerclage.[1,3] The two most common transvaginal techniques for cerclage were described by McDonald and Shirodkar. The Shirodkar cerclage is placed as close as possible to the internal os, while the McDonald technique is applied closer to the external os.[4]

Most guidelines suggest that prophylactic cerclage can be placed before or after conception in women with a history of three or more previous preterm deliveries and/or second-trimester pregnancy losses.[5] To reduce perioperative risk during pregnancy, pre-conceptional transabdominal cerclage was first proposed in 1998 and has been increasingly utilised since.[6,7] Transabdominal cerclage is usually performed in women who have had a previous transvaginal cerclage that failed to prevent pregnancy loss, or in women with a short cervix, where transvaginal cerclage is not possible.[8] Laparoscopic approaches to transabdominal pre-conceptual cervical cerclage are now commonly used.[9]

We conducted a systematic review to determine the efficacy of pre-conceptional laparoscopic cerclage by calculating the pooled prevalences of delivery after 37 weeks of pregnancy and live birth following this procedure.

Methods

A systematic review was conducted following the PRISMA 2020 guidelines. This study was registered in PROSPERO (CRD42024545316). A search was carried out up to April 15, 2024, in the Medline and Cochrane databases. The search strategy included a combination of terms "laparoscopy", "cerclage", "transabdominal" ((cerclage) AND ((transabdominal) OR (laparoscopy [MeSH Terms]))). Citation tracking was also performed. Studies published in English, German or French were assessed for eligibility. Original studies investigating the role of pre-conceptional laparoscopic cerclage on pregnancy outcomes were eligible for inclusion. The primary outcome of this review was the rate of delivery after 37 weeks of gestation, and the live birth rate was a secondary outcome. Studies were excluded if the groups were mixed with pre- and post-conceptional laparoscopic cerclage or pre-conceptional laparoscopic and pre-conceptional cerclage placed via laparotomy, in order to reduce heterogeneity between studies caused by different procedures. Conference papers were omitted from the review due to their restricted data availability, lack of peer review and potential for duplicating published research.

The search was conducted by two investigators (D.R.K., I.M.), with any discrepancies resolved through consultation with a third investigator (K.C.), who was not part of the initial process. Data extraction from each study was conducted independently by two reviewers using a standardised data extraction form in Excel. This included study characteristics (author, year of publication, country, study design, number of patients, follow-up time), clinical characteristics of the patients (age, body mass index, indication), information about surgical techniques of cerclage in every study (type of tape used, type of knot, manipulator used and number of surgeons conducted the procedure, hysteroscopy conducted after the placement of the cerclage) and requested outcomes (rate of delivery after 37 weeks of gestation, live birth rate and complications). In cases of missing data, the corresponding authors were contacted.

Each study underwent a quality assessment using a modified Newcastle-Ottawa quality assessment scale, evaluating the domains representativeness of the sample, sample size, non-respondents, ascertainment of exposure, assessment of outcome and statistical test with a maximum possible score of 8. Studies were classified according to the score in poor (0-2), fair (3-5) and good quality (6-8).[10]

The pooled prevalence and 95% confidence interval (CI) were estimated using a random-effects model via the Metaprop command in STATA (Stata Statistical Software: Release 16. StataCorp LLC, College Station, TX). Odds ratios (OR) with 95% CI and chi-square tests for the analysis of delivery rates after 37 weeks and live birth rates between the subgroups were calculated. Statistical significance was set at *P*-values <0.05 and 95% CI that did not include 1, were considered statistically significant. OR with 95% CI and chi-square tests were calculated using SPSS version 10.

Results

Ten studies involving 1060 patients were included in this systematic review (PRISMA Flowchart, Figure 1). All studies were cohort studies with follow-up; five of them were retrospective,[9,11-14], and the remaining five were prospective.[15-19] The studies were conducted across nine different countries, with three of them conducted in China. The number of participants with pre-conceptional laparoscopic cerclage in the included studies ranged from 18 to 250. The duration of follow-up was not clearly reported in the majority of the studies. The indications across most studies were failed or impossible vaginal cerclage, typically after history of cervical surgery and previous adverse obstetrical outcomes. Delivery rates after 37 weeks of pregnancy were reported in 7 out of 10 studies, while live birth rates were reported in all of the included studies. The characteristics of the included studies are summarised in Table 1.

The methodological quality of studies is presented in Table 2. All studies had a high risk of selection bias due to the absence of random sampling and control groups. A sensitivity analysis based on study quality was not performed as all the included studies were classified as fair and good.

The rates of delivery after 37 weeks of pregnancy varied across the studies from 52% to 82%. Four of the included studies reported a delivery rate after 37 weeks of pregnancy of more than 75%,[13,16,18,19] while three studies reported a prevalence between 52% and 61%.[9,12,17] A multicentre study reported that 90% (94/104) of deliveries were after 34 weeks of pregnancy,[14] while another study found 73.3% (33/45) delivery rates after 36 weeks of pregnancy.[15]

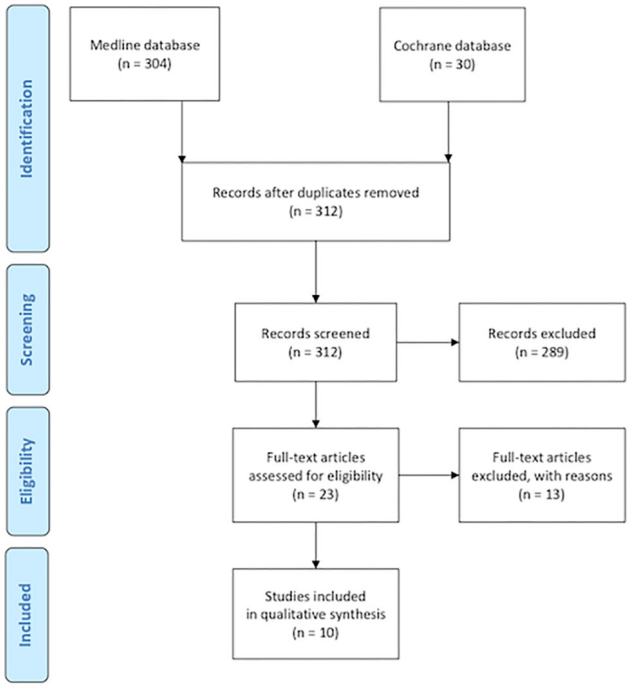

Figure 1. Flowchart diagram.

The pooled prevalence of deliveries after 37 weeks of pregnancy was 70% (95% CI: 60-79%, 7 studies, 515 pregnancies, I^2: 85%) (Figure 2). A subgroup analysis based on knot localisation showed that the anterior knot was associated with significantly higher delivery rate after 37 weeks in comparison to the posterior knot (OR: 2.26, 95% CI: 1.50-3.40, P<0.05). Comparison of suture types showed that women who underwent pre-conceptional laparoscopic cerclage with Mersilene tape had a higher delivery rate after 37 weeks than those with conventional suture (OR: 2.98, 95% 1.95-4.56, P<0.05). Additionally, women who did not undergo hysteroscopy after cerclage placement had a significantly higher delivery rate after 37 weeks of pregnancy (OR: 1.61, 95% CI: 1.02-2.56, P=0.04).

Live birth rates were high across the included cohort studies, ranging from 78 to 100%. The majority of the studies reported live birth rates exceeding 90%.[11,16-19] Demirel et al.[12] found that 84% of pregnancies reached the stage of viability, with 5 out of 25 women over 29 weeks pregnant at the time of publication. Another study reported live birth rates below 80%.[9] The pooled prevalence of live birth was 92% (95% CI: 86-95%, 10 studies, 713 pregnancies, I^2: 69%) (Figure 3). The comparison between the subgroups according to the knot localisation showed that the posterior knot was associated with higher live birth rates (OR: 2.26, 95% CI: 1.50-3.40, P=0.01). The conventional suture was also associated with higher live birth rates in comparison to Mersilene tape (OR: 2.98, 95% 1.95-4.56, P<0.05). Subgroup analysis also indicated that patients who did not undergo hysteroscopy after cerclage placement had significantly higher live birth rates (OR: 5.03, 2.65-9.54, P<0.05). Additionally, cohorts with a single surgeon for the laparoscopic cerclage had significantly higher pooled live birth rate in comparison to cohorts with more than one surgeon (OR: 2.70, 95% CI: 1.27-5.74, P<0.05).

Discussion

Main Findings

The pooled prevalence of delivery after 37 weeks of pregnancy in this systematic review was 70% among women who underwent preconception laparoscopic cerclage, with an even higher live birth rate of 92%. These findings demonstrate the efficacy of this intervention in a high-risk population for second-trimester pregnancy loss or preterm birth.

Table 1. Characteristics of studies included in systematic review.

Studies included					**Clinical characteristics**			**Surgical technique**				
Study	Country	Design	Year	n	Age	BMI	Indication	Number of surgeons	Manipulator	Tape	Knot	Hysteroscop
Riiskjaer et al.[15], 2012	Denmark	Prospective cohort study	2004-2011	52	n/a	n/a	Obstetrical and surgical indications	Unclear	Manipulator used unclear	Mersilene tape	Anterior	No
Luo et al.[16], 2014	China	Prospective cohort study	2008-2013	19	31 (27-35)*	n/a	Failed previous or impossible vaginal cerclage	1	Manipulator used unclear	Mersilene tape	Posterior	Yes
Bolla et al.[10], 2015	Switzerland	Retrospective cohort study	2008-2014	18	33 (4)	n/a	Failed previous or impossible vaginal cerclage	Unclear	Rumi or Hegar	Mersilene tape	Anterior	No
Huang et al.[9], 2016	China	Retrospective cohort study	2010-2015	100	31.2 (3.9)	n/a	Failed previous vaginal cerclage	Unclear	Cervical cup	Mersilene tape	Anterior	Yes
Ades et al.[17], 2018	Australia	Prospective cohort study	2007-2017	225	33.9 (4.39)	n/a	Obstetrical and surgical indications, failed previous vaginal cerclage	1	Manipulator used unclear	Prolene suture	Posterior	No
Saridogan et al.[18], 2019	England	Prospective case series	2004-2017	54	36 (23-44)*	n/a	Obstetrical and surgical indications	1	Spackman cannula	Mersilene tape	Posterior	No
Li et al.[13], 2021	China	Retrospective cohort study	2015-2017	247	n/a	n/a	Obstetrical and surgical indications	Unclear	Cervical cup	Mersilene tape	Anterior	No
Demirel et al.[12], 2021	Turkey	Retrospective cohort study	2012-2020	40	Range 21-42	n/a	Obstetrical indications	1	Manipulator used unclear	Mersilene tape	Anterior	Yes
Yanamandra and Pooskuru, 2023	India	Prospective case series	2017-2021	55	34 (28-42)*	29.64 (21-42)	Failed previous vaginal cerclage	1	Hegar 6	Mersilene tape	Mixed	No
Abdulrahman et al.[14], 2024	Holland/ USA	Retrospective cohort study	1997-2021	250	34.4 (4.4)	n/a	Failed previous or impossible vaginal cerclage	2	Type of manipulator used unclear	Mersilene/ polyeste	Mixed	Some

All values are presented as mean (standard deviation) unless otherwise indicated. Values marked with * are presented as median (interquartile range). BMI: Body mass index, n/a: Not applicable.

Table 2. Quality assessment of included studies using modified Newcastle-Ottawa quality assessment scale.

Study	Representativeness of the sample	Sample size	Non-respondents	Ascertainment of the exposure	Assessment of outcome	Statistical test	Total score (max 8)	Quality rank
Riiskjaer et al.[15], 2012	*	0	*	*	*	*	5	Fair
Luo et al.[16], 2014	*	0	0	*	**	*	5	Fair
Bolla et al.[11], 2015	*	0	0	*	*	*	4	Fair
Huang et al.[9], 2016	*	0	*	*	*	*	5	Fair
Ades et al.[17], 2018	*	0	*	**	**	*	7	Good
Saridogan et al.[18], 2019	*	0	0	*	*	*	4	Fair
Li et al.[13], 2021	*	0	0	*	*	*	4	Fair
Demirel et al.[12], 2021	*	0	0	*	*	*	4	Fair
Yanamandra and Pooskuru, 2023	*	0	*	**	**	*	7	Good
Abdulrahman et al.[14], 2024	*	0	0	*	*	*	4	Fair

max: Maximum.

Strengths and Limitations

To the best of our knowledge, this is the first systematic review examining the effect of preconception laparoscopic cerclage. The strengths of this study are the large sample size of the included studies with only preconception laparoscopic cerclage and similar outcomes. However, several limitations need to be acknowledged. All the included studies were observational, uncontrolled cohort studies, with the majority being retrospective, carrying a high risk of selection bias due to the inclusion of patients, which is based on pre-existing conditions, the presence of various confounders, and missing data. The cohorts studied were heterogeneous, with variations in maternal age, previous obstetric history, and indications for cerclage. Additionally, the follow-up periods varied across studies, and many did not report follow-up duration. Although subgroup analyses were performed, when possible, to address discrepancies, these limitations may affect the generalisability of the findings.

Strengths and Limitations Compared to Other Studies

The incidence of pregnancy loss between 12 and 24 weeks of gestation ranges from 2% to 3%,[20] while the incidence of preterm birth, defined as delivery before 37 weeks of gestation, varies between 5% and 18% according to the World Health Organization (WHO).[21] The causes for both second trimester pregnancy loss and preterm birth are multifactorial, with cervical insufficiency, infection, congenital anomalies and previous cervical dilatation or cervical lacerations due to traumatic deliveries proposed as the main causes.[22,23]

A poor obstetric history with previous failed transvaginal cerclage and a history of cervical surgery resulting in no visible ectocervix or a short cervix, where transvaginal cerclage was not feasible, were the two most common indications for preconception laparoscopic cerclage in the studies included in this systematic review. Subgroup analysis based on the indication for cerclage was not possible in this review, as most of the included studies did not report outcomes according to the indication. Saridogan et al.[18], found comparable deliveries after 37

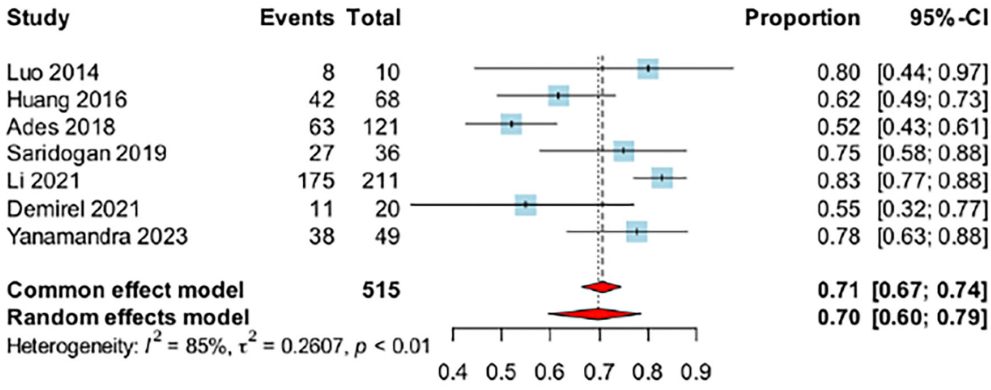

Figure 2. Pooled prevalence of delivery after 37 weeks of pregnancy.

CI: Confidence interval.

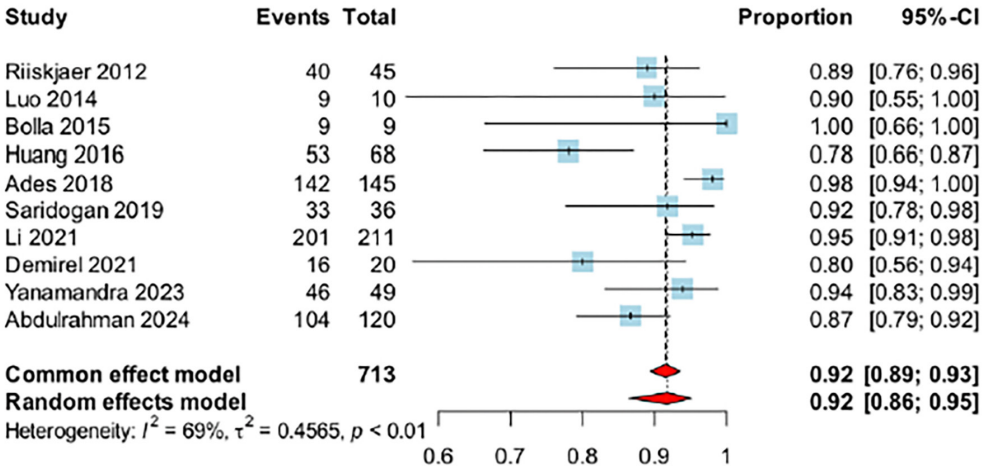

Figure 3. Pooled live birth rate.

CI: Confidence interval.

weeks, live birth rates and neonatal survival rates between the different subgroups according to indication. The authors suggested that cerclage may act as a protective mechanism by preserving cervical mucus, preventing ascending infection and offering mechanical support for the cervix, thereby reducing the risk of preterm birth and second-trimester pregnancy loss.

Regarding different surgical approaches, a multicentre randomised controlled trial (MAVRIC) included women with a history of failed cerclage who underwent both pre- and postconceptional cerclage and showed that transabdominal cerclage was superior to both high and low vaginal cerclage in reducing early preterm birth and foetal loss.[22] In another study, Moawad et al.[24], compared both pre- and postconceptional cerclage performed via laparoscopy versus laparotomy, finding significantly better neonatal survival rates and higher rates of delivery after 34 weeks of gestation for laparoscopy group. Similarly, Tulandi et al.[8], found higher third-trimester delivery and live birth rates with laparoscopic cerclage compared to laparotomy, concluding that laparoscopic cerclage should be considered as the first option, preferably during the pre-conceptional period. Robotic-assisted cerclage, a technique gaining popularity due to enhanced visualisation, precise dissection, and knot-tying capabilities, has also shown promising results.[3] Recent studies have found comparable favourable obstetric outcomes for both pre-conceptional and post-conceptional robotic-assisted cerclage compared to transabdominal cerclage via laparotomy.[3,25]

Pregnancy rates after a pre-conceptional cerclage in the publications included varied from 56%,[17] to 97.2%,[13] with an overall pregnancy rate of 76.3%, however, these studies are heterogeneous in terms of follow-up periods, which ranged from 2 months[11] to more than 18 months[9] and the pregnancies were achieved both spontaneously and through assisted reproductive techniques. As far as the optimal timing for laparoscopic pre-conceptional cerclage,

there is no current evidence indicating the best time before pregnancy to achieve better outcomes. Tulandi et al.[8] found comparable live birth rates between pre-conceptional and post conceptional laparoscopic cerclage.

Most of the included studies used a Mersilene tape. The subgroup analysis revealed significantly higher chances of delivery after 37 weeks of pregnancy in women who had a Mersilene tape compared to those with conventional sutures. However, the live birth rate was significantly higher in the conventional suture group. This discrepancy could be attributed to the small sample size of the conventional suture group, as only Ades et al.[17] used conventional sutures for pre-conceptional laparoscopic cerclage.

A previous systematic review, which included five studies comparing Mersilene tape with conventional sutures in transvaginal cerclage, found a lower incidence of preterm birth before 34 weeks with Mersilene. However, the risk of preterm birth between 34 and 37 weeks was higher with Mersilene compared to conventional sutures, with comparable adverse events such as chorioamnionitis and neonatal death.[26] The authors concluded that the existing evidence is limited and insufficient to definitively support the superiority of Mersilene tape in transvaginal cerclage. A large multicentre randomised controlled trial (C-STICH), which compared two different sutures (monofilament versus braided sutures) in vaginal cerclage, found comparable pregnancy outcomes.[27] However, findings from transvaginal cerclage may not be directly applicable to transabdominal cerclage, as the exposure of the tape and sutures, which could potentially cause infection and pre-term delivery, differs.

According to the studies included in our systematic review, the anterior knot had higher rates of delivery after 37 weeks of pregnancy in comparison to the posterior knot. However, the subgroup with the posterior knot had a significantly higher live birth rate. The anterior knot was used in most of the included studies; thus maybe the above discrepancy could be explained by the small group of women with a posterior knot. In addition, another explanation could be that the anterior wall of the uterus is more accessible for the surgeon, allowing the knots to have better stability and leading to more deliveries after 37 weeks of pregnancy. Anterior knots can be also easily removed via laparoscopy without accessing the posterior cul de sac, while posterior knots have the advantage of potential vaginal removal. A third type of knot, the intravaginal knot, is also proposed by some authors, with the advantage of simplified knot removal.[28]

Hysteroscopy after the placement of cerclage was conducted in three of the included studies.[9,12,16] The subgroup analysis showed significantly fewer deliveries beyond 37 weeks of pregnancy and a lower live birth rate. Limited information was provided about the procedure or the size of the hysteroscope. Luo et al.[16] reported the use of a Hegar 6 dilatator before hysteroscopy, while Demirel et al.[12] reported that patients underwent office hysteroscopy, but did not specify the hysteroscope's diameter. Huang et al.[9], did not detail the method of hysteroscopy. The adverse effects of hysteroscopy on pregnancy outcomes could be attributed to cervical dilation performed before hysteroscopy in some of these studies, following cerclage placement. A hysteroscope less than 5 mm in diameter could potentially allow passage through the cervix after cerclage placement without requiring cervical dilation.[29]

Clinical and Policy Implications

Preconception laparoscopic cerclage seems to be safe because few complications, such as uterine perforation, were reported. Our study found that single-surgeon cohorts had significantly higher live birth rates. Women with poor obstetric histories, including failed transvaginal cerclage, cervical surgery with no visible ectocervix, or a short cervix, should be counselled about the option of pre-conceptional cerclage. This procedure has been shown to be effective, especially when performed by an experienced surgeon, leading to high rates of delivery after 37 weeks.

Unanswered Questions and Future Research

Our review suggests that pre-conceptional laparoscopic cerclage is an effective intervention for women at high risk of preterm delivery, achieving high rates of delivery after 37 weeks and live birth. Comparative research is needed to better understand the efficacy of pre-conceptional laparoscopic cerclage as well as refine the indications for this procedure, optimise surgical techniques, and determine the best timing for cerclage placement before pregnancy.

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Euro-Chinese consensus on accessory cavitated uterine malformation*,†

Lan Zhu[1#], Zichen Zhao[1#], Attilio Di Spiezio Sardo[2#], Maribel Acién[3#], Joel Naftalin[4#], Thierry Van den Bosch[5#], Charleen Sze-yan Cheung[6#], Dabao Xu[7#], Xiaowu Huang[8#], Grigoris Grimbizis[9#]

[1]Department of Obstetrics and Gynecology, National Clinical Research Center for Obstetric and Gynecological Diseases, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China
[2]Department of Obstetrics and Gynecology, Università degli Studi di Napoli "Federico II", Naples, Italy
[3]Department of Gynecology, Miguel Hernandez University of Elche, San Juan Campus, Alicante, Spain
[4]University College Hospital, University College London Hospitals NHS Foundation Trust, London, United Kingdom
[5]Department of Obstetrics and Gynecology, University Hospitals Leuven, Leuven, Belgium
[6]Department of Obstetrics and Gynecology, Queen Mary Hospital, The University of Hong Kong, Hong Kong, China
[7]Department of Gynecology, The Third Xiangya Hospital, Central South University, Changsha, Hunan, China
[8]Department of Hysteroscopic Centre, Fuxing Hospital, Capital Medical University, Beijing, China
[9]1st Department of Obstetrics and Gynecology, "Papageorgiou" Hospital, Aristotle University of Thessaloniki, Thessaloniki, Greece

#These authors contributed equally to the work.

ABSTRACT

Background: Accessory cavitated uterine malformations (ACUMs) are a rare obstructive uterine anomaly that remains poorly understood, posing challenges for clinical management. The aetiopathogenesis is hypothesised to involve the duplication and persistence of ductal Müllerian tissue usually near the round ligament attachment, potentially related to gubernaculum dysfunction. ACUM is specifically classified by Acién's system, though rare variants necessitate continued international research to refine classification frameworks.

Objectives: This consensus aims to develop good clinical practice recommendations for the pathophysiology, terminology, clinical presentation, diagnosis, and treatment of ACUM.

Methods: A working group consisted of Chinese and European experts, after approval from the European Society for Gynaecological Endoscopy, developed recommendations based on the best available evidence and experts' opinion.

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Corresponding Author: Grigoris Grimbizis, Prof., 1st Department of Obstetrics and Gynecology, "Papageorgiou" Hospital, Aristotle University of Thessaloniki, Thessaloniki, Greece
E-mail: grigoris.grimbizis@gmail.com **ORCID ID:** orcid.org/0000-0002-6230-4638
Corresponding Author: Lan Zhu, MD, Department of Obstetrics and Gynecology, National Clinical Research Center for Obstetric and Gynecological Diseases, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China
E-mail: zhu_julie@vip.sina.com **ORCID ID:** orcid.org/0000-0001-5753-5426
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ABSTRACT

Results: Patients with ACUM present with typical symptoms such as dysmenorrhea and dyspareunia, and atypical symptoms, including gastrointestinal and generalised pelvic pain. Diagnostic criteria include isolated cavitated lesions in the anterolateral myometrium near the round ligament, lined by endometrial tissue and filled with haemorrhagic fluid, surrounded by a myometrial mantle with concentric orientation of myometrial fibres, and typically associated with a normal uterine cavity. Diagnosis is most accurately made through ultrasound and magnetic resonance imaging. Surgical excision of the ACUM is considered the definitive treatment offering near-complete symptom resolution, and minimally invasive approach should be preferred when possible. The timing of surgery and the interval before attempting pregnancy remain unclear. The mode of delivery post-surgery is individualised based on the degree of myometrial involvement.

Conclusions: The current consensus summarises the existing evidence on ACUM providing good clinical practice recommendations for their management. Existing gaps in the understanding and management of ACUMs, highlight the need for further research to guide clinical decision-making.

What is New? Good clinical practice recommendations for ACUM aiming to understand and optimise their management.

Keywords: Accessory cavitated uterine malformation, Müllerian anomalies, obstructive anomalies, adenomyotic cyst, cyclic pelvic pain, dysmenorrhea

Part I: Background

Embryology of the Internal Genitalia

The formation of the gonads begins as swellings located on either side of the dorsal mesentery, at the ventromedial surface of the mesonephros or Wolff's body. These protrusions form the gonadal or genital ridge as part of the primitive urogenital ridge.

During the sixth week, within the thickness of the urogenital ridge, the mesonephric excretory tubules converge in a mesonephric or Wolffian duct that descends to the cloacae, opening in the urogenital sinus. Meanwhile a longitudinal invagination of the coelomic epithelium is formed on the outer side of the urogenital ridge that originates the paramesonephric or Müllerian duct.[1]

This duct, at the top, opens into the coelomic cavity and descends in parallel and externally to the mesonephric duct. Then, both Müllerian ducts cross ventrally the mesonephric ducts, and grow in the caudomedial direction until fusing together and forming in the midline line a Y-shaped structure that is the uterine primordium, but without reaching the urogenital sinus (Figure 1).

Three portions can now be distinguished in the Müllerian ducts: a superior converging, a middle fused and an inferior diverging portion. The tubes come from the uppermost part of the Müllerian ducts, the converging portion, which remain separated and open into the coelomic cavity. The middle-fused parts of the paramesonephric ducts form the uterus, and the diverging portion forms the cervix up to the external cervical os.[2] And it's interesting to note that these different areas have also been related to different gene expressions of the HOXA family.[3]

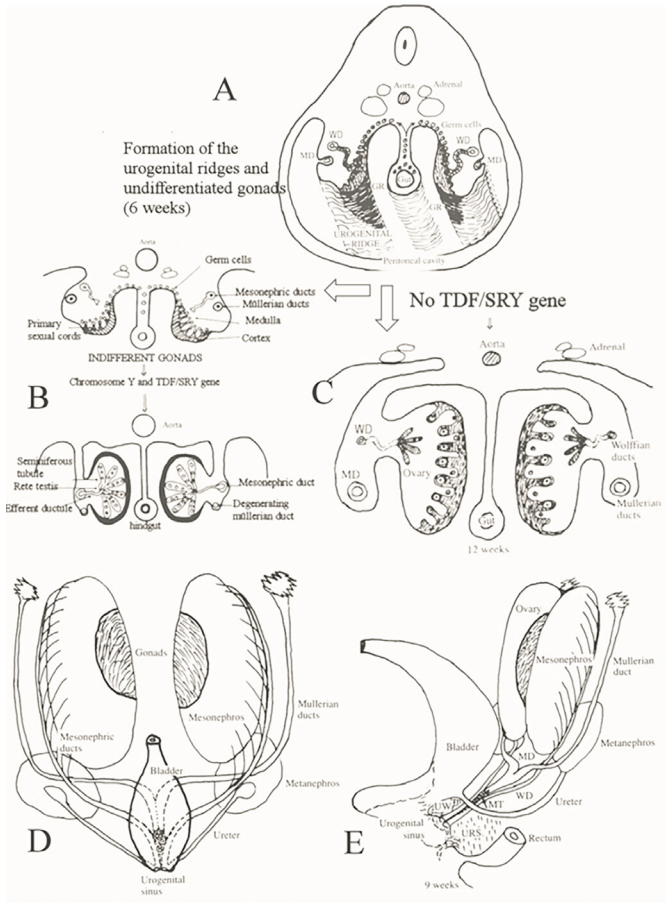

Figure 1. A) Urogenital ridge and undifferentiated gonads. B) Development of the gonads and Wolffian ducts in the male, and the Müllerian ducts in the female in (C). D) Development of the genital ducts in the female. The formation of the uterine primordia and opening of the mesonephric ducts to the urogenital sinus is shown. E) Lateral view showing the urorectal septum and the urogenital wedge (taken from Acién et al.[49] with permission).

When the ovary is being formed, and therefore testosterone and anti-Müllerian hormone (AMH or Müllerian inhibitor factor) are absent, the Wolffian ducts become atretic and regress cranially, and the Müllerian ducts develop. However, the adequate development and fusion of the paramesonephric ducts, the reabsorption of the middle septum and the correct formation of the normal uterus are induced by the laterally located mesonephric ducts. These fusion and reabsorption processes begin at the uterine isthmus (which is the most proximate part between both Müller ducts, right above the internal cervical os) and progress simultaneously, but independently, in both cranial and caudal directions, acting the mesonephric ducts as guide elements.[4,5]

The gubernaculum forms from the caudal fold that provokes the mesonephros, elevating the covering peritoneum (Figure 2). It begins as a muscular cord-like structure that extends from the abdominal wall

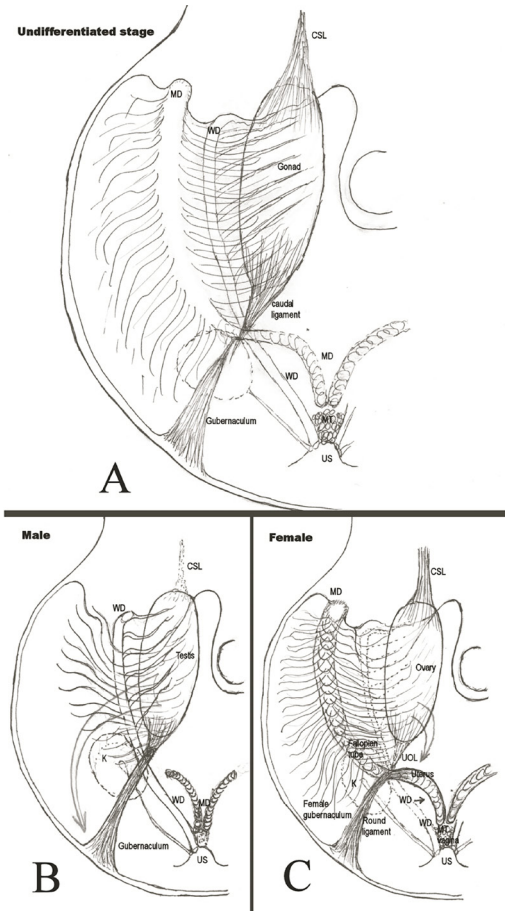

Figure 2. Schematic illustration of the possible development of the gubernaculum. A. At an Undifferentiated Stage. B. In Males. C. In Females. CSL, cranial suspensory ligament. WD, Wolffian duct. MD, Müllerian duct. MT, Müllerian tubercle. US, urogenital sinus. K, kidney. UOL, uteroovarian ligament (caudal ligament of the gonad) (taken from Acién et al.[7] with permission).

to the gonadal ridge. But the development of the paramesonephric or Müllerian duct interferes with the connection of this tissular column that has arisen between the inguinal cone and the caudal ligament of the gonad. Therefore, the gubernaculum then grows over the paramesonephric ducts, and its muscular fibres incorporate into the wall of the Müllerian ducts, becoming the round ligament. Behind and above, only atretic remnants of the mesonephric duct remain; and, the caudal ligament, uniting the gonad's inferior pole to the posterior wall of the Müllerian ducts, constitutes the utero-ovarian ligament.[6,7]

The female gubernaculum is likely formed by muscle fibres that are not of a mesonephric or paramesonephric origin, and their attachment to the Müllerian ducts allows the adequate development of the uterus. But the gubernaculum might also be responsible for many other specific human characteristics, including the uterus simplex, the anteflexion and low-intra-abdominal position of the uterus, and the disposition of uterine muscular fibres.[6,7]

Key question: What are the current theories on the aetiopathogenesis of accessory cavitated uterine malformation?

The pathogenesis of this entity is controversial. It is possible that the accessory cavitated uterine malformations (ACUMs) associated with an otherwise normal uterus should be considered Müllerian choristomas[8] as by definition the term refers to the growth of normal tissue at an ectopic location, thus suggesting developmentally misplaced Müllerian tissue. But where does this ectopic tissue come from and why?

During the eighth week of male embryo development, the production of testosterone and AMH begins. The consequence of this is that the mesonephric or Wolffian ducts develop while the paramesonephric or Müllerian ducts become atretic. Androgens, together with AMH and INSL-3 (insulin-like hormone), stimulate the growth of the tissular column which from the inguinal cone crosses the mesonephric or Wolffian duct to reach the caudal ligament at the inferior pole of the gonad. Thus, this third element in the crossing area, the gubernaculum, does not attach to the Müller duct and becomes the scrotal ligament, responsible for pulling down the gonad to the scrotum. Current thinking is that this process may be influenced by the cranial gonadal suspensory ligaments, hormones, genes as well as other factors[9] and its failure leads to cryptorchidism.

ACUM could be caused by the duplication and persistence of ductal Müllerian tissue in the critical area at the attachment level of the round ligament, possibly related to a gubernaculum dysfunction or abnormal traction and, as such, of congenital origin.[10] Alternatively, increased tension or traction of the gubernaculum could prevent fusion of the Müllerian ducts or traction of a hemi-uterus or rudimentary horn towards the inguinal duct and its herniation.[6,7] The observation of a tubal rudiment adjacent to the ACUM would speak in favour of detached Müllerian choristoma arising from abnormal gubernaculum traction in a female embryo.[11]

Key point

- *ACUMs could be caused by the duplication and persistence of ductal Müllerian tissue in the critical area at the attachment level of the round ligament, possibly related to a gubernaculum dysfunction or abnormal traction.*

Key question: What is the most appropriate terminology for accessory cavitated uterine malformation?

Various terms have been used for ACUM, including adenomyotic cyst, juvenile cystic adenomyosis, myometrial cyst, and uterine-like mass.

It has often been published under the term "Juvenile cystic adenomyoma", but it actually refers to the same pathology as the ACUM.

The Pros and Cons of using the words "malformation" and "mass" are shown in the Table 1.

We recommend using the word "malformation" rather than "mass". Not only is it a more accurate reflection of what ACUMs are, but the word "mass" implies uncertainty of the nature of a lesion which can lead to unnecessary concern over possible malignancy.

Key point

- *ACUM is the preferred terminology.*

Key question: How is accessory cavitated uterine malformation classified according to the existing classification systems?

Over the last two centuries, we have gained better knowledge on the embryology and pathogenesis of congenital malformations of the female genital tract. There have been different attempts to classify female reproductive tract anomalies.[6,7,12-20]

Despite many classification systems of female genital tract anomalies being available, Acién's proposal was the first and only one to include ACUM as a gubernaculum anomaly.

The classification system is based on the embryological development and the clinical presentation of the anomaly.

Key point

- *Acién's classification is the only system which specifically refers to the ACUM.*
- *Clinicians who care for patients with Müllerian anomalies should be mindful of the existence of other rare, unique and potentially very complex variants.*
- *Continued international efforts are needed to conduct high-quality studies that offer evidence-based data to improve the classification systems and their applicability in clinical practice.*

Part II: Clinical Presentation, Diagnosis and Differential Diagnosis

Key question: What are the typical and atypical symptoms in patients with accessory cavitated uterine malformation?

ACUMs were associated with substantial pelvic pain symptoms in all published cases. The most frequently reported symptoms are severe menstrual pain that can be central or ipsilateral to the side of the ACUM, and chronic pelvic pain. Other symptoms reported in the

Table 1. Pros and Cons of using the words "malformation" and "mass".

	Accessory cavitated uterine mass	Accessory cavitated uterine malformation
Pros	It highlights the fact that the anomaly looks like a tumour, plus it is often present in a uterus which is otherwise completely normal, making it different from other uterine malformations like rudimentary horns or the Robert's uterus	It highlights the fact that the anomaly is a malformation
Cons	A mass, can be benign or malignant	The term anomaly is preferred nowadays to refer to malformations plus, fewer papers are retrieved in PubMed using the term "mass"

literature include dyspareunia and hypogastric pain. The pelvic pain is thought to be caused by the accumulation of an increasing volume of menstrual fluid from the functioning endometrium lining the ACUM, within a cavity that has no outflow. The presumed mechanism for this causing pain is that it leads to increased pressure within the ACUM and subsequent stretching of the cavity.

Like other obstructive uterine anomalies, it tends to present in young women and girls. Nevertheless, while there are case reports describing diagnosis at as young an age as 13 years old,[21] the mean age at diagnosis in the larger case series' varies from 21 years old to 29 years old.[10,22-29] This most likely reflects the commonly experienced delays in reaching a diagnosis of ACUM, rather than being an accurate description of the onset of symptoms, which is classically described as starting with menarche or soon afterwards.

Key points

- *Typical symptoms: dysmenorrhea, dyspareunia and recurrent pelvic pain.*
- *Atypical symptoms: gastrointestinal pain and generalised pelvic pain, as can be seen in any chronic/ recurrent pain problem.*
- *ACUMs should be considered in all young women presenting with severe menstrual pain symptoms after menarche.*

Key question: What are the diagnostic criteria for an accessory cavitated uterine malformation?

ACUMs are almost certainly underdiagnosed, due to a lack of awareness by patients and clinicians, as well as the absence of widely agreed-upon diagnostic criteria. Failure to diagnose ACUMs will often condemn women to years of debilitating pain while trialling empirical, often ineffective, treatments. Many will undergo unnecessary investigations, procedures and operations in an attempt to diagnose and treat their pain. There may also be additional psychological consequences from experiencing ongoing, debilitating symptoms without a clear explanation. Failure to diagnose ACUMs denies women the opportunity for surgical excision, which in most cases substantially reduces or even completely cures the pain symptoms.

Several criteria have been proposed for the diagnosis of ACUMs, as detailed below.

Acién et al.[10]

1. Isolated accessory cavitated mass,

2. Normal uterus (endometrial cavity), tubes, and ovaries,

3. Surgical case with excised mass and with pathological examination,

4. Accessory cavity lined by endometrial epithelium with glands and stroma,

5. Chocolate-brown–coloured fluid content,

6. No adenomyosis (if uterus removed), but there could be small foci of adenomyosis in the myometrium adjacent to the accessory cavity.

Takeuchi et al.[22]

1. Solitary myometrial cyst measuring >1 cm surrounded by hypertrophic endometrium, independent of the uterine lumen,

2. Found in women ≤30 years of age,

3. Associated with severe dysmenorrhea.

Chun et al.[30]

1. Age of onset of severe dysmenorrhea within 5 years after menarche or ≤18 years of age,

2. No history of suspected endometrial or uterine injuries (delivery, myomectomy or dilatation and curettage),

3. Presence of a cystic lesion ≥0.5 mm indicated by imaging studies or observed during surgery.

Naftalin et al.[25]

1. Solitary cavitated lesion with a,

2. Myometrial mantle and,

3. Echogenic contents in the anterolateral wall of the myometrium beneath the insertion of the round ligament,

4. Ruling out obstructive congenital anomalies, such as communicating and non-communicating horns is crucial to diagnosis.

Timmerman et al.[31]

1. A uterine abnormality, presenting as a cavitated lesion surrounded by a myometrial mantle, in continuity with the anterolateral uterine wall, and located beneath the insertion of the round ligament and the interstitial portion of the fallopian tubes.

2. The appearance on imaging reflects the surrounding rim of functional endometrium and the haemorrhagic content of the cyst.

3. To distinguish ACUMs from other uterine abnormalities, a normal uterine cavity should be visualised.

There is, unsurprisingly, substantial overlap between these diagnostic criteria but there are specific criteria that apply to most cases but are not ubiquitous. Acién et al.'s.[23] criteria describe a normal uterus (endometrial cavity), tubes and ovaries as a criterion, although not indispensable. More specifically, they state that the patient must not have adenomyosis apart from small foci of adenomyosis surrounding the ACUM. Women may often however have coincidental uterine or ovarian pathology such as fibroids, a dermoid cyst or even adenomyosis elsewhere in the uterus that would not need to influence the diagnosis of an ACUM. Further, Acien's criteria include surgical excision of the ACUM for a definitive diagnosis, but there are increasing numbers of case descriptions of women with ACUMs not undergoing surgical excision. Increasing imaging quality means that the diagnosis can be confidently reached without a requirement for surgical excision. Nevertheless, as the original description of ACUMs, Acién et al.'s.[23] criteria have formed the basis of all the subsequent descriptions.

Both Takeuchi et al.[22] and Chun et al.'s[30] diagnostic criteria include stipulations about age. While these criteria help focus on the younger age group in which women with ACUMs frequently present, there are many case reports that describe women with ACUMs presenting outside of these age-related criteria. Chun et al.[30] go on to state that no history of suspected endometrial or uterine trauma should have occurred, including delivery. However, there are multiple case reports of women with ACUMs being diagnosed despite having had children or having previously undergone uterine surgery. More recent diagnostic criteria by Naftalin et al.[25] and Timmerman et al.[31] have focused more on the imaging appearance of ACUMs while still maintaining Acién et al.'s[23] original focus on the importance of ensuring that other uterine anomalies with similar appearances to ACUMs are excluded. These criteria have evolved over time as more has been learnt about ACUMs. Mindful that there remains a great deal about ACUMs that we do not yet know, it is important that diagnostic criteria account for this uncertainty and do not become overly prescriptive.

Key points

- *In order to diagnose an ACUM, the following criteria should be fulfilled:*
- *An isolated cavitated lesion located in the anterolateral myometrium, in the proximity of the round ligament.*
- *The cavity is lined by endometrial tissue and typically filled with haemorrhagic/menstrual fluid.*
- *The cavity is surrounded by a myometrial mantle with concentric orientation of myometrial fibres.*
- *They are typically associated with a normal uterine cavity.*

Additional notes

- While large ACUMs may enlarge to *involve* the posterolateral myometrium, because they are thought to originate from the gubernaculum, they should predominantly be within the anterolateral myometrium.
- ACUMs are found within the myometrium but the extent of their involvement with the myometrium can vary. They can be completely embedded within the myometrium or substantially outside the myometrium with minimal myometrial involvement. A grading system could be used to describe this based on the FIGO classification of type 4, type 5 and type 6 fibroids, as this will inform the extent of surgical dissection necessary, as well as the risk of uterine cavity breach.[32]

Key question: What are the diagnostic tools for diagnosing accessory cavitated uterine malformation?

Transvaginal ultrasound is the primary diagnostic tool in gynaecology and, in expert hands, is sufficient to diagnose ACUMs with confidence. Nevertheless, not all gynaecologists or sonographers will have the experience or confidence to diagnose ACUMs on ultrasound alone. Magnetic resonance imaging (MRI) is important in these circumstances, and with expert radiologists, the diagnosis can be made with confidence. Furthermore, given that the population in which ACUMs will be suspected often includes young women and girls in whom transvaginal ultrasound might not be appropriate, MRI should be considered in preference to transvaginal ultrasound. Consideration can also be given to transrectal ultrasound, which gives equivalent views to transvaginal ultrasound, although it may also not be appropriate or considered acceptable by the patient.

Ultrasonography

On ultrasound, ACUMs are visualised as cavitated lesion with a myometrial mantle and echogenic contents seen in the antero-lateral wall of the myometrium or within the broad ligament (Figure 3). While the myometrial mantle will likely be of similar echotexture to the surrounding myometrium, the concentric orientation of its muscle

fibres means that it can be clearly distinguished from it. The endometrial lining will often be visible. The fluid within the cavity should be echogenic and is most often seen as being of "ground glass" echogenicity, equivalent to the altered blood content seen in endometriomas. The contents have also been reported as hyperechogenic.

3D ultrasound can also be useful in confirming the diagnosis, although it can be difficult to get a single clear image of both the uterine cavity and the ACUM within it, because they are rarely in the same plane. Coronal 3D ultrasound image should reveal a circular cavity adjacent to the otherwise normal uterine cavity with no communication between the two cavities (Figure 4). 3D ultrasound is also crucial to excluding other uterine anomalies, and so in women with ACUMs, the main uterine cavity will be visible with both uterine horns.

Key point

- *In expert hands, the diagnosis of ACUM can confidently be made on transvaginal or transrectal ultrasound.*

Magnetic resonance imaging

On MRI, ACUMs will be seen to have a central cavity, surrounded by a well-defined ring with low T1 and T2 signal enhancements, which is similar to that of the junctional zone (Figures 5, 6). The surrounding myometrial mantle has been described as thickened and hypointense on T2-weighted images, which demonstrates myometrial hypertrophy. In addition, the cavities had a thin inner lining

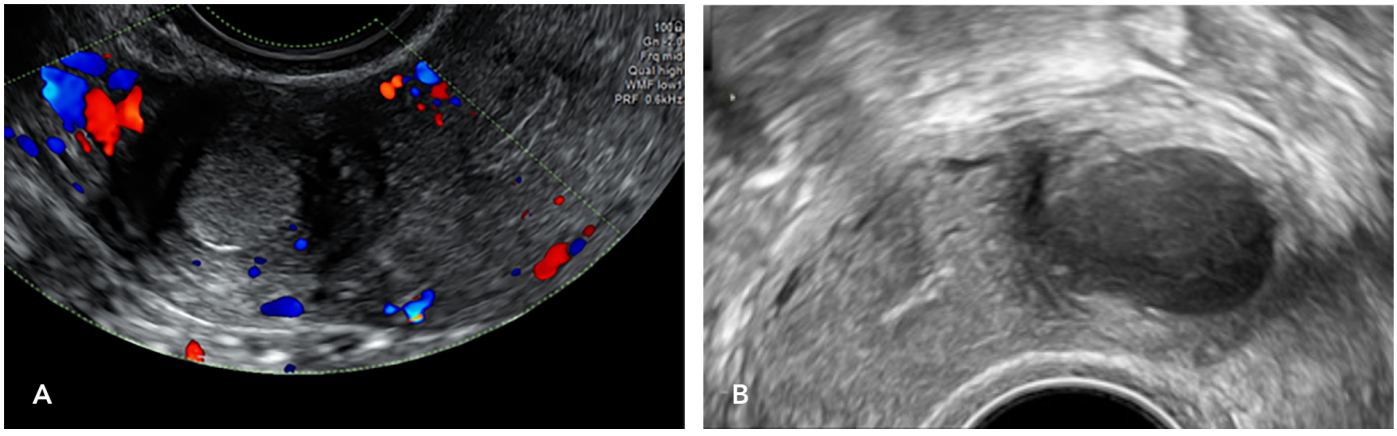

Figure 3A, B. 2D Ultrasound images of ACUMs in the left lateral myometrium showing the myometrial mantle and haemorrhagic content that can be hyperechogenic **(A)** or "ground glass" in appearance **(B)**.

ACUM: Accessory cavitated uterine malformation.

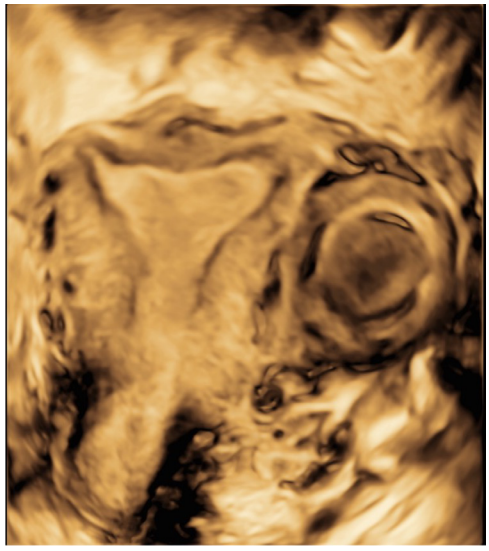

Figure 4. 3D ultrasound image of ACUM in the left lateral myometrium.

ACUM: Accessory cavitated uterine malformation.

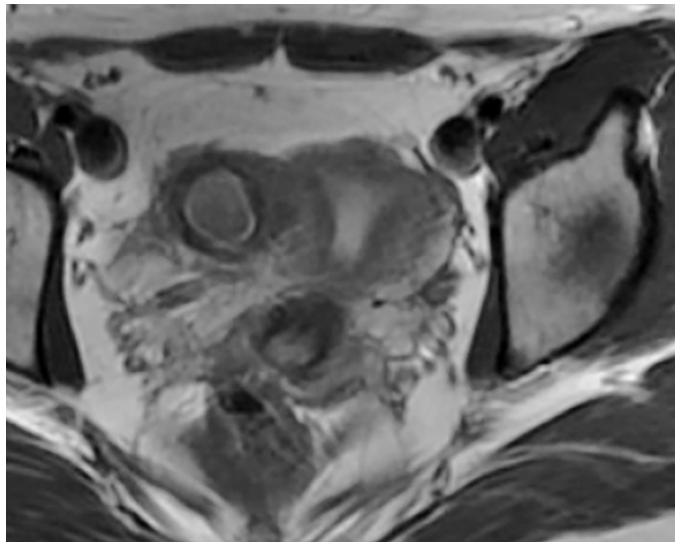

Figure 5. MRI of ACUM in the right lateral myometrium.

MRI: Magnetic resonance imaging, ACUM: Accessory cavitated uterine malformation.

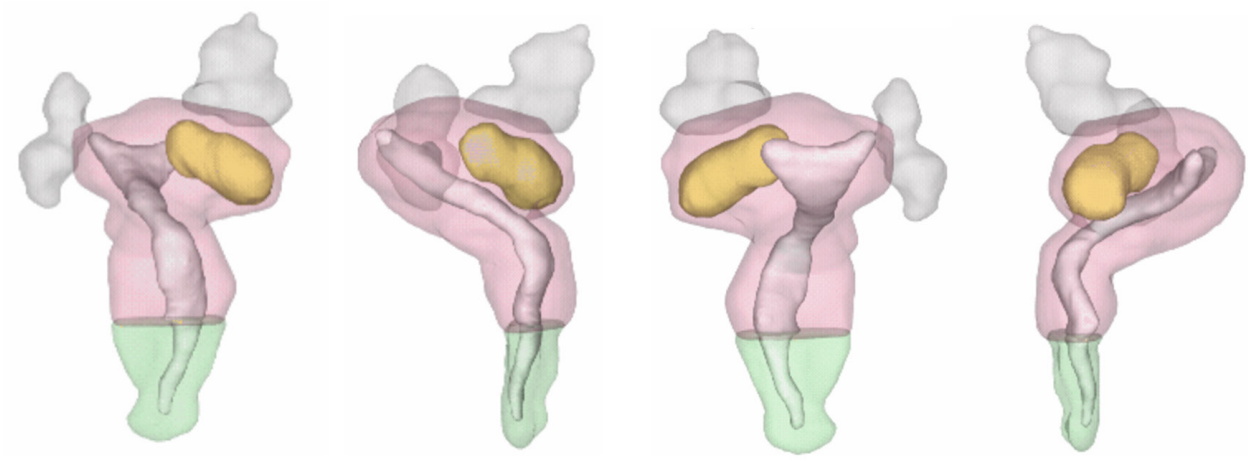

Figure 6. Three-dimensional reconstruction of ACUM based on MRI.
ACUM: Accessory cavitated uterine malformation, MRI: Magnetic resonance imaging.

that moderately enhanced after gadolinium contrast and appeared hyperintense on T2-weighted images, indistinct from endometrium. The internal content of the cavities displays high T1 signal intensity, which persists after fat saturation and is indicative of haemorrhagic content. Some lesions will demonstrate T2 shading, which is seen in ovarian endometriomas.

Key point

- *If there is diagnostic uncertainty after ultrasound examination, consideration should be given to using MRI.*

Histology (microscopy)

Microscopically, the cavity of the lesion is lined with functional endometrium consisting of glands and stroma and blood is seen within the cavitation (Figure 7). Studies report that the endometrial tissue within ACUMs positively stains for CD10, oestrogen receptors (ER) and progesterone receptors (PR), which are markers of normal endometrium. They also reported that the myometrial mantle of the ACUMs contained smooth muscle cells that stained positive for desmin, ER, and PR. The myometrium surrounding the cavitated lesion may be hypertrophic and will often contain foci of adenomyosis.

Key point

- *Not all histopathologists are familiar with ACUMs so it is important to let them know what that you suspect an ACUM and ensure they are aware of their histopathological features.*

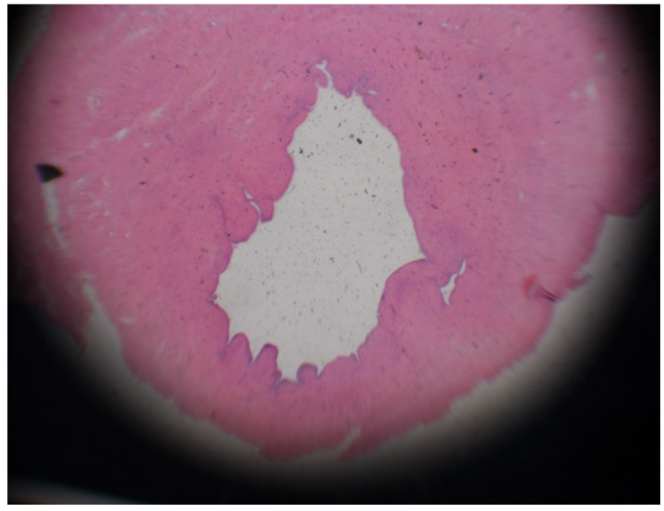

Figure 7. Microscopic pathologic image of ACUM.
ACUM: Accessory cavitated uterine malformation.

Differential diagnoses

Obstructive congenital uterine anomalies are key differentials of ACUMs and, therefore, excluding them is crucial to making the diagnosis. Regardless of the imaging modality used, it is important to demonstrate that there is no connection to either the uterine cavity or to the Fallopian tubes and that there are two normal interstitial portions of the Fallopian tubes. Those without sufficient expertise in ultrasound and MRI may consider other more invasive investigations, such as saline infusion sonography (SIS), hysterosalpingography (HSG), hysterosalpingo sonography using saline or foam (HyCoSy/HyFoSy) or hysteroscopy, to exclude other congenital anomalies, but these modalities should only be required in rare circumstances.

Other important differentials of ACUMs include cystic adenomyomas, unicornuate uteri with functioning rudimentary horns, complete septate uterus with unilateral cervical aplasia (Robert's uterus) and degenerating fibroids. It is particularly important to differentiate these entities because the management options and strategies vary greatly. Knowledge of their different features can help distinguish them (Table 2). Other potential differentials that could be confused with ACUMs are endometriomas that are adherent to the lateral aspect of the uterus and, more rarely, ectopic pregnancies, including interstitial, intramural and rudimentary horn pregnancies.

Key point

- *As exclusion of other uterine anomalies is crucial to the diagnosis, in the rare circumstances where ultrasound and MRI have failed to clarify the morphology of the uterine cavity, consideration could be given to more invasive tests such as saline infusion sonohysterography, HyCoSy/HyFoSy or hysteroscopy.*

Part III: Treatment and Counselling

Key question: What are the clinical indications and available treatment options for accessory cavitated uterine malformation?

Treatment aims to alleviate pain and to restore normal anatomy. Reported ACUM management options range from medical treatment to surgery. Factors that influence decision-making include the severity of symptoms, age, and patient preferences.[25,33,34]

Surgical treatment

Surgery is considered the definitive treatment for ACUM and has shown excellent results in symptom relief, pregnancy prognosis and long-term management.[10,22-25,28,34-36] There is no direct evidence to guide the timing of ACUM surgery or on the role of preoperative gonadotropin-releasing hormone (GnRH) agonist therapy.

Table 2. Features of accessory congenital uterine malformations and relevant differential diagnoses.

	Accessory cavitated uterine malformations	**Cystic adenomyomas**	**Rudimentary horn with functioning endometrial cavity**	**Complete septate uterus with unilateral cervical aplasia (Robert uterus)**	**Degenerated fibroids**
Location	Located in the anterolateral myometrium, in proximity to the round ligament	Located in the myometrium	Located at the lateral cornual aspect or lateral and distinct from the myometrium	Located in the lateral aspect of the uterus with a thin septum between cavities that can be bulging	Can be located anywhere in the myometrium
Pathophysiology	Have a myometrial mantle and endometrial lining	Absence of myometrial mantle	No myometrial mantle	Will not have a myometrial mantle that is distinct from the surrounding myometrium	Fibroid pseudo capsule and heterogeneous aspect
Relation to the uterine corpus	Typically bulges outside the uterine corpus	Typically, entirely within the myometrium	It can be separate from the main uterine body or not, but the uterine cavity will be unicornuate.	Typically, within the uterine corpus	Could be within the body of the uterus or pedunculated
Content	Typically, echogenic cavity content	Often anechoic cavity content	There is usually not hematometra found because the content refluxes into the abdomen	Typically, echogenic content	Can be echogenic or anechoic content
Age	Commonly found in young women or teenagers	Commonly found in older parous women	Can be found in any age group	Commonly found in young women or teenagers	Can be found in any age group

Surgical approaches include laparoscopy, robot-assisted laparoscopy, and laparotomy[10,23,37] and they involve the excision of the ACUM.

Irrespective of the surgical approach, a systematic approach is required. Firstly, incision and circumferential enucleation of the ACUM is performed with or without preceding injection of dilute vasopressin along the uterine-ACUM interface for haemostasis. It should be noted that finding the cleavage plane can be challenging, as the typical pseudocapsule present in fibroids will not be found in ACUM. Assisted by ancillary instruments, such as a tenaculum or suction device, the procedure is completed by transecting the ACUM from its attachment and closing the uterine defect with sutures.

Considering that ACUM is a benign condition, its contents are not thought to pose any threat if they leak. Thus, various techniques, such as morcellation and specimen retrieval in endo bags, have been described for removing specimens of ACUM.[31]

Adhesion barrier agents can be used during surgery to prevent postoperative adhesions.[35]

The boundaries of an ACUM can sometimes be imprecise and so some authors have described using intraoperative ultrasound to help with lesion localisation and excision,[31] also using intraoperative 3-dimensional ultrasonography, which not only can clearly locate the nodule but also show the thickness of the myometrium overlying the cystic cavity.[36]

For older patients who do not desire future pregnancies, hysterectomy may be recommended as it offers permanent relief from dysmenorrhea. Total laparoscopic hysterectomy is a common, safe, and minimally invasive option for women with benign gynaecological conditions like ACUM.[33]

Medical treatment

Medical treatments for ACUM generally focus on pain relief and symptom management and are based on non-steroidal anti-inflammatory drugs (NSAIDs) and analgesics or on hormonal treatments [include continuous oral contraceptive pills (OCPs)],[34-43] the levonorgestrel-releasing intrauterine system (LNG-IUS, e.g., Mirena), and gonadotropin-releasing hormone agonists (GnRHa).[22,38]

These therapies may temporarily reduce symptoms, allowing patients to defer or avoid surgery or to help them manage their symptoms while awaiting surgery.[44] It is unclear whether factors such as age at the start of treatment, the size of the ACUM, or other morphological characteristics influence the success of medical treatment.[31] However, if medical treatment is not effective, conservative minimally invasive surgery should be considered, always considering fertility preservation in young patients.[40]

Sclerotherapy and radiofrequency ablation

An alternative treatment is sclerotherapy with ethanol, as described by Merviel et al.[45]

The procedure typically involves general anaesthesia and ultrasound guidance to insert a needle through the vaginal wall and into the ACUM. After aspirating the cyst's contents, 96% ethanol is injected to fill the cavity for about 15 minutes, then drained.

This method can offer temporary relief from symptoms but is rarely a permanent solution. Risks include leakage of the sclerosing agent into the peritoneal cavity.

More recently, lauromacrogol has also been introduced as a sclerosing agent for ACUM.[46] This compound offers the dual benefits of sclerotherapy and local anaesthesia, although its long-term efficacy and safety remain under investigation.

Radiofrequency ablation has also been used with similar results as ethanol sclerotherapy in terms of symptom relief.[47,48]

Key points

- *Treatment aims to restore uterine anatomy through excision of the ACUM and to alleviate symptoms.*
- *ACUM typically requires treatment in case of severe dysmenorrhea or chronic/recurrent pelvic pain.*
- *Surgical management, consisting of ACUM removal from the myometrium and suturing of the uterine defect, is the definitive treatment, and it has shown nearly complete remission of symptoms. Options include laparotomy, laparoscopy, and robot-assisted laparoscopy. A minimally invasive approach should be preferred when possible.*
- *Medical management including administration of NSAIDs, OCP, LNG-IUS, and GnRH agonists. Medical management provides temporary relief but is often not a definitive solution.*
- *Sclerotherapy is an alternative for those who wish to avoid surgery, though it may lead to recurrence.*

Key question: What are the optimal skills and facilities to remove the accessory cavitated uterine malformation while protecting the uterine myometrium wall?

The surgical management of ACUM requires a meticulous approach to achieve complete lesion excision while preserving myometrial integrity. Optimal outcomes depend on precise surgical techniques, surgeon expertise in minimally invasive gynaecologic surgery, and selective use of intraoperative imaging guidance when necessary.

Key points

- *Ability to accurately estimate the penetration depth in the myometrium to remove the lesion while minimising risks.*
- *Use of intraoperative ultrasound, including 3D ultrasonography, for precise localisation and excision of the ACUM.*
- *Surgical skills and experience to apply proper surgical techniques including careful enucleation of the ACUM using mechanical, monopolar or bipolar energy, with various tools assisting in the dissection and suturing (especially for laparoscopy/robotics).*

Key question: What is the best timing of surgery for accessory cavitated uterine malformation?

The optimal timing for surgical intervention in ACUM remains poorly defined due to limited evidence, but clinical decisions should prioritise symptom severity, reproductive goals, and patient priorities.

Key point

- *There is no direct evidence to guide the timing of ACUM surgery.*

Key question: What is the recommended interval before attempting pregnancy after surgery?

There is no direct evidence to guide decision making on the interval before embarking on pregnancy.

Key point

- *After surgery for ACUM, a recommended waiting period of 4-6 months is advised before attempting pregnancy; this allows the proper healing of the myometrium.*

Key question: What is the recommended mode of delivery for future pregnancy?

The mode of delivery following ACUM excision lacks standardised guidelines due to insufficient outcome data, necessitating individualised decision-making based on surgical characteristics and obstetric context. Delivery planning should account for the depth of myometrial resection during ACUM excision, analogous to the FIGO classification for fibroids (e.g., FIGO type 4–5 lesions involving >50% myometrial thickness may warrant heightened surveillance for uterine rupture).

Key point

- *There are no data to determine the optimal mode of delivery after ACUM excision. Caesarean sections and vaginal deliveries are described in literature. In determining the mode of delivery after ACUM excision, consideration should be given to the depth of myometrial involvement/FIGO type of ACUM.*

Conclusion

There remains a great deal that is unknown about ACUMs, which provides challenges for clinicians managing patients with this malformation. The embryological origin remains unclear, although it´s possibly related to a gubernaculum dysfunction or abnormal traction. Existing classification systems, except for Acién´s, while widely utilised, do not adequately incorporate ACUM. To diagnose an ACUM, the following criteria should be fulfilled: to be an isolated cavitated lesion located in the anterolateral myometrium, in the proximity of the round ligament, with a cavity lined by endometrial tissue and typically filled with haemorrhagic/menstrual fluid. They should be surrounded by a myometrial mantle with typical concentric orientation of the myometrial fibres, with a normal uterine cavity. Current management strategies prioritise complete surgical excision of the lesion, preferably via minimally invasive techniques, to achieve symptom resolution. There is a paucity of high-quality evidence to guide clinical decision-making regarding aspects of optimal surgical intervention and, more specifically regarding the management of future pregnancies.

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REVIEW ARTICLE

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Ovarian remnant syndrome: an unsuspected diagnosis

Irene Colombi, Gabriele Centini, Francesco Giuseppe Martire, Alessandro Ginetti, Alberto Cannoni, Lucia Lazzeri, Filiberto Maria Severi, Errico Zupi

Department of Molecular and Developmental Medicine, Obstetrics and Gynaecology, University of Siena, Siena, Italy

ABSTRACT

Background: Ovarian remnant syndrome (ORS) is a rare condition defined by the presence of residual tissue of ovarian origin, histologically confirmed in a woman with a previous salpingo-oophorectomy, usually as a result of difficult surgery in the presence of adhesions.

Objectives: To evaluate the existing literature on ORS.

Methods: A narrative review was performed. A search for relevant articles was carried out in PubMed for the period from January 2014 to July 2024. Three original cases of ORS are also reported.

Main Outcome Measures: All available literature on the subject was analysed and articles relevant to the topic of the review were included. Additional articles were reviewed to provide an overview of the issue.

Results: A total of 10 different cases of ORS found in the literature were analysed, together with 3 original cases.

Conclusions: The presence of distorted anatomy and extensive adhesions may lead to an increased risk of residual ovarian tissue. Residual ovarian tissue may sometimes evolve into a malignant lesion. When difficult oophorectomy is suspected, the surgeon must proceed with caution to complete oophorectomy. Strict follow-up is essential to detect ORS.

What is New? This is the first narrative review including cases described in the literature and three new original cases. Our work provides a comprehensive and global view of this condition and may help in clinical practice to reduce the risk of ORS through appropriate surgical planning and possibly early diagnosis of the syndrome.

Keywords: Ovarian remnant syndrome, endometrioid ovarian carcinoma, ultrasound

Introduction

Ovarian remnant syndrome (ORS) is a rare condition defined by the presence of residual tissue of ovarian origin histologically confirmed in a woman with a previous salpingo-oophorectomy.[1] Generally, it is consequent to difficult oophorectomy in the presence of adhesions which may be subsequent to multiple surgical intervention, pelvic inflammatory disease or endometriosis, which may result in inadvertent incomplete removal of the ovarian tissue.[1] According to a previous study[1] endometriosis is the most frequent indication for oophorectomy in women with subsequent ORS. The main presenting symptoms of this rare condition are pain and the presence of a pelvic mass but sometimes it can be an incidental finding during a routine pelvic transvaginal scan.

In the literature, data concerning the incidence of ORS are limited and for the majority based on case reports and case series, moreover malignant transformation is very rarely descripted.

The aim of this narrative review is to examine the current literature on this rare topic and add new data

Corresponding Author: Prof. Lucia Lazzeri, Department of Molecular and Developmental Medicine, Obstetrics and Gynaecology, University of Siena, Siena, Italy
E-mail: lazzeri13@unisi.it **ORCID ID:** orcid.org/0000-0002-9513-1980
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reporting three different cases of ORS, demonstrating how challenging the diagnosis can be and how the presentation can vary, highlighting the need to perform regular transvaginal ultrasound (TVS) also in women with previous salpingo-oophorectomy and suspect ovarian pathology also in these women. Our hypothesis is that it may be possible to find ultrasound features that may be alarming and lead the clinician to suspect this pathology, by carefully studying cases of ORS reported in the literature.

Methods

A search for relevant articles was carried out in PubMed for the period from January 2014 to July 2024. The keywords used were "ovarian remnant syndrome". Only publications written in English were included, and only studies published within the time period relevant to the research question were included in the review.

Exclusion criteria were as follows:

We excluded studies that did not fulfil the defined inclusion criteria; duplicated studies; non-peer-reviewed articles; grey literature; or reports that lacked scientific rigor.

We found 55 publications, of which 1 was excluded because the full text was not available. A total of 54 publications were identified for inclusion in the review. All titles and abstracts were carefully evaluated. In the end, 23 manuscripts were excluded because they didn't focus on the topic of the current review, and 21 others were excluded because they were animal studies.

The process followed the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[2] The protocol was not registered.

To provide an accurate description of the current state of the art and background of ORS, a further electronic search of the online medical database MEDLINE (accessed via PubMed) was performed to evaluate the existing literature on this condition. The titles and abstracts of the articles were carefully screened to select those relevant to our research question. We also conducted a thorough review of the bibliographies of the selected articles to identify additional publications for inclusion. All selected articles were carefully assessed for both relevance and scientific merit by three independent reviewers (I.C., A.G. and A.C.). Figure 1 shows a flow diagram of the literature search. Nine articles were selected for review (Table 1).[3-11]

Case Series

Case 1 Endometrioid Ovarian Cancer: A 6-year Diagnosis

We present a case of an endometrioid ovarian carcinoma appeared in the context of a misdiagnosed ORS recognized after 6 years in the Hospital Le Scotte of the University of Siena. All ultrasonographic pictures are reported in the timeline in Figure 2.

The patient was a 65-year-old woman, with normal body mass index (BMI) (24.89) who had been in menopause for 52 years without showing any gynaecological symptoms. There was no evidence of malignancy in the patient's family and personal history. The patient had two spontaneous deliveries and had previously undergone a laparotomic appendicectomy during reproductive age.

In 2015, throughout a routine gynaecological evaluation with TVS, a multilocular cyst was detected in the left ovary,

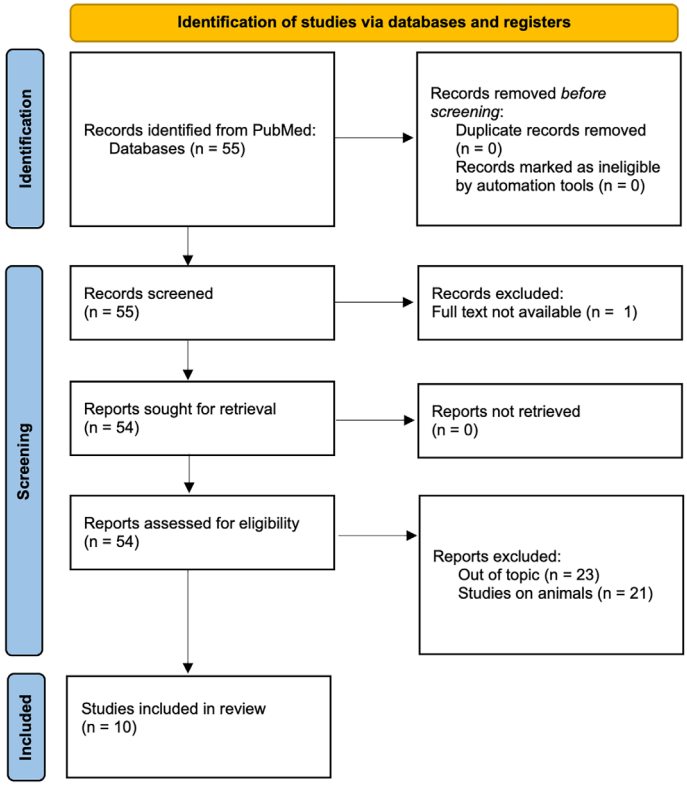

Figure 1. PRISMA 2020 flow diagram which includes searches of PubMed. Literature search diagram. A total of 55 papers filled the search string. Of these, 1 article was excluded because the full text was not available. In addition, 23 were excluded because they were out of topic and 21 were excluded because they were studies on animals. A total of 10 papers were eligible for review.[2]

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Table 1. Main characteristics of ORS cases reported in the literature analysed in the review.

Author, journal, year of publication	Previous surgery and indication	Age at diagnosis of ORS	Case description	Treatment	Histological examination
Vilos et al.[3], J Minim Invasive Gynecol, 2015 Case 1	Total abdominal hysterectomy and bilateral salpingooophorectomy Indication: extensive endometriosis Subsequent persistent right adnexal cyst that removed by laparotomy (endometriotic cyst)	50-year-old	- Right-sided pelvic pain - CT MRI revealed right adnexal cyst of 4.5x3.4x2.4 cm; severe right hydro-uretero-nephrosis - CA-125 negative	Medically treated because of complex medical and surgical history (leuprolide acetate 3.75 mg). At 12 months, the cyst, pain, and hydro-uretero-nephrosis were resolved	NA
Vilos et al.[3], J Minim Invasive Gynecol, 2015 Case 2	Total abdominal hysterectomy followed by bilateral salpingo-oophorectomy (BSO) Indication: endometriosis	45-year-old	- Left-sided flank and pelvic pain - Ultrasound and CT identified a left adnexal cyst measuring 6x5x4 cm and moderate hydro-uretero-nephrosis	Medically treated (leuprolide acetate 3.75 mg together with oestradiol 1 mg)	NA
Gupta and Gupta[4], J Midlife Health, 2016	Bilateral salpingooophorectomy	56-year-old	- Access to the emergency department with persistent nausea, vomiting and abdominal pain - CT revealed distended abdomen with hypoactive bowel sounds. Small, irregular soft tissue mass in proximity to site of narrowing and acute angulation of the ileal loop	Exploratory **laparotomy**: ascites, small bowel dilated, stricture in the proximal ileum with an adhesive band, causing near complete obstruction, small bowel mesenteric nodule	Histopathology of the mesenteric nodule associated with small bowel confirmed the presence of ovarian tissue
Chan et al.[5], Cardiovasc Intervent Radiol, 2017	Total abdominal hysterectomy for adenomyosis and fibroids and bilateral salpingooophorectomy for endometriosis. Subsequent lysis of adhesions and attempted removal of left ovarian remnant tissue adherent to the nearby colon	44-year-old	- Chronic, constant, dull, left-sided pelvic pain - Computed tomography angiography revealed soft tissue mass in the left oophorectomy site with a volume of cc 12.5	Ovarian artery embolization	NA
Weiner and D'Andrea[6], Breast J, 2018	Bilateral salpingooophorectomy ER + breast cancer	40-year-old 6 months after BSO	- PET revealed right adnexal cystic lesion - MRI showed 2.5x9x1.1 cm left adnexal soft tissue area and two right adnexal cystic lesions	**Laparoscopy** (retained ovarian tissue)	Benign ovarian tissue with focal endometriosis
Wei et al.[7], Breast J, 2019	Laparoscopic-assisted vaginal hysterectomy and bilateral salpingooophorectomy Indication: pathogenic variant in BRCA2 in women with stage IIIA HR-positive invasive ductal breast cancer	32-year-old premenopausal woman	- Menopausal symptoms - Serum estradiol concentration 226 pg/mL - MRI showed a complex 2.5x3.1x3.8 cm right adnexal mass and a 1.4x1.3 cm	Laparoscopy	Ovarian parenchyma in the right ovarian remnant

Table 1. Continued.

Author, journal, year of publication	Previous surgery and indication	Age at diagnosis of ORS	Case description	Treatment	Histological examination
Tien et al.[8] Medicine (Baltimore), 2022	Total abdominal hysterectomy and bilateral salpingooophorectomy Indication: leiomyoma	73-year-old 30 years after BSO	- Dull lower abdominal pain for three years - No remarkable findings on TVS - On TA US cystic lesion 53.x3.3 cm in the lower abdominal region - CT of the pelvis revealed a multilocular cystic mass - CEA 3.5 ng/mL and CA-125 70.4 U/mL	Laparoscopic enterolysis and tumour excision (paraintestinal cyst with a smooth surface measuring 5×3 cm with omental adhesion to the anterior pelvic wall)	Ovarian serous cyst adenofibroma
Wills et al.[9], Am Surg, 2022	Total abdominal hysterectomy with bilateral salpingo-oophorectomy Indication: unknown	68-year-old	- Abdominal pain - CT demonstrated multiple abdominal and pelvic masses, the measured 16.1×15.1×12.1	Exploratory laparotomy and mass excision (multiple masses within the small bowel mesentery)	Serous cystadenomas
Xiao and Li[10], Asian J Surg, 2023	Prophylactic total hysterectomy and bilateral adnexectomy Indication: ovary mass and a history of breast cancer	69-year-old 2 years after BSO	- Mass at the left corner of the vaginal stump without any clinical symptoms - TVS showed a 3.7×3.3×3.9 cm septate cystic mass at the left corner of the vaginal stump, with slightly strong echo in the capsule - CA125, CA199, CEA were normal	Laparoscopic exploration and mass resection (mass bulged at the left edge of vaginal stump)	Ovarian borderline endometrioid cystic fibroma
Yao et al.[11], BMC Womens Health, 2023	Unilateral salpingo-oophorectomy Indication: umbilical cord entanglement during childbirth	47 years old 19 years before oophorectomy	- Dull lower abdominal pain for the six months preceding her presentation - Tumour mass located on the right posterior uterine wall, of 40×50 mm size - TVS showed hyperechogenic area measuring 9×10 mm in the posterior wall of the myometrium, an isoechoic area measuring 24×18 mm in the left wall of the myometrium, as well as heterogeneous hyperechogenicity measuring 48×50 mm in the anterior myometrium - CT revealed a rounded soft tissue mass approximately 46x40 mm in size within the right wall of the myometrium - CA125 181.4 U/mL, HE4 55.6 pmol/L, CA199 15.9 U/mL, CA153 10.6U/mL, CA72-4 3.5 U/mL, CEA 1.93 ng/mL, AFP 2.7 ng/mL, SCC 1.5 ng/mL	Transabdominal hysterectomy with left adnexectomy (pale-yellow mass measuring approximately 50×40×30 mm with a nodular appearance)	Clear cell carcinoma

ORS: Ovarian remnant syndrome, ER: Emergency room, HR: Hormone receptor, CT: Computed tomography, MRI: Magnetic resonance imaging, PET: Positron emission tomography, TVS: Transvaginal ultrasound, NA: Not applicable.

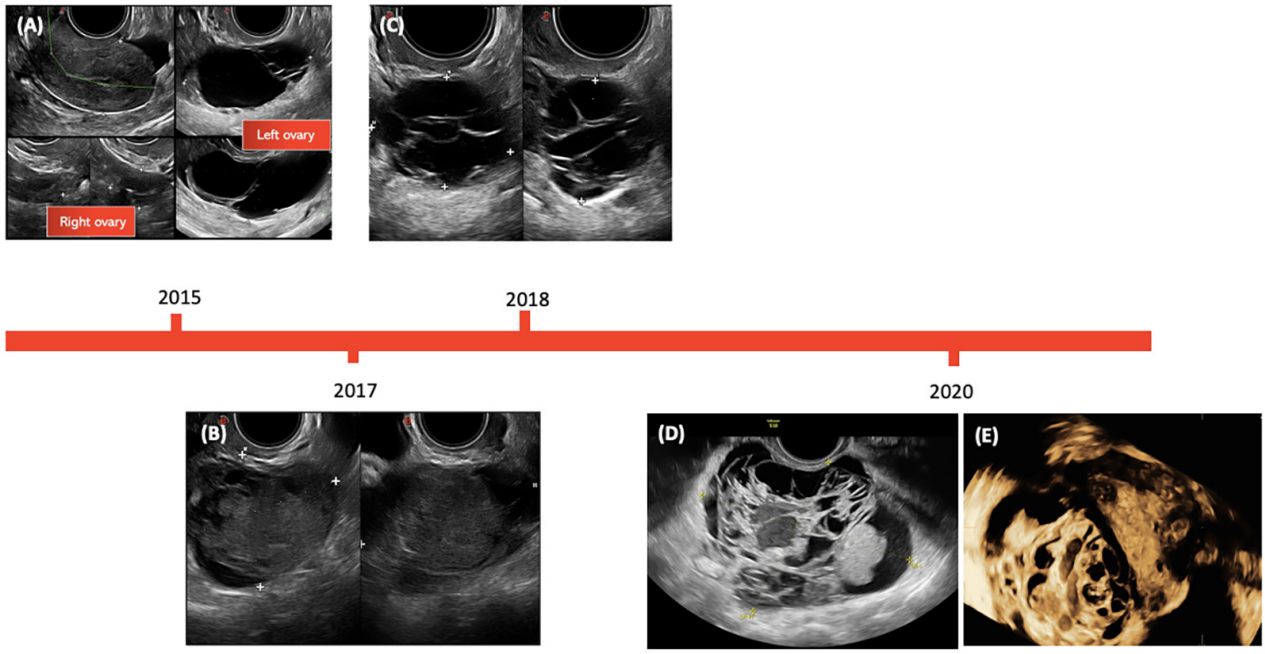

Figure 2. A-E) Ultrasonographic pelvic assessment during follow-up (case 1).

with a diameter of 74×41x56 mm, smooth internal walls, anechoic content, with colour score 1 and no crescent sign. Right ovary, uterus and endometrium appeared normal (Figure 2A).

The patient was admitted to our hospital to undergo laparoscopic bilateral salpingo-oophorectomy (BSO). The surgical report described a 70 mm cyst with fluid content that completely occupied the left adnexa and fibrotic adhesions between the colon and the adnexa retracting the uterus on the left side. No macroscopical lesions of the right adnexa and the uterus were described. The cyst was sent to histological exam, and the diagnosis was serous cystadenoma.

In 2017, the patient reported pelvic discomfort. With TVS a 71x49x62 mm solid tumour was detected located in the Douglas on the left side. The lesion was characterized by a mixed partially anechoic and partially hyperechoic echogenicity, with regular external walls, with colour score 3. The uterus and endometrium were regular. No lesions were visualized in the other side of the pelvis (Figure 2B).

The patient was admitted again to our hospital and underwent a laparotomy with the exeresis of a 60 mm retroperitoneal mass. In the surgical report it was described the presence of firm adhesions between sigmoid-colon, left ureter and left infundibolopelvic ligament which have been gently removed. The histological examination described the presence follow-up walls with hemosiderin deposits suggestive of endometrioid cystadenoma. There was no need for further intervention and the patient was discharged with an annual follow-up visit.

In 2018, the patient underwent a follow up TVS and it was again detected a 36x29x31 mm multilocular cyst in the left adnexal region with anechoic content, smooth internal walls, not vascularized (colour score 1) (Figure 2C). Unfortunately, no tumour markers were carried out as the cyst was not investigated as ovarian cancer. We believe that with the benefit of hindsight they would be useful to guide the diagnostic process.

The referring gynaecologist decided on expectant management until, in 2020, the patient was admitted to our outpatient department for follow-up assessment. A 80x62 mm multilocular solid cyst was detected attached to the posterior uterine wall, the lesion was high vascularized at colour Doppler (colour score 2-3) (Figure 2D); its sonographic characteristics were completely different from the previous TVS.

Based on the previous history of BSO and the position of the cyst attached to the uterus, a uterine malignancy was considered in differential diagnosis (Figure 2E).

In 2021 the patient undergone a total laparotomic hysterectomy with contextual omentectomy, pelvic lymphadenectomy, rectal discoid resection and ureteral reimplantation. The invasiveness of the surgery, particularly the discoid resection, was due to the

numerous adhesions that made it impossible to dissect the lesion.

The final histologic exam diagnosed endometrioid ovarian carcinoma. The surgery was considered to be complete, and the patient did not have to undergo chemotherapy.

The patient is still under follow-up and the gynaecological assessment is negative for ovarian cancer relapses.

Case 2 Vanishing Ovarian Cyst

We present the case of a 67-year-old female patient with spontaneous menopause at the age of 52 and with a BMI of 28.1. She underwent laparotomic left ovariectomy for a dermoid cyst in 1989. Her past medical history included a previous grade IV postpartum vaginal laceration suture and a laparoscopic cholecystectomy in 2023. Prior to menopause, she reported regular, non-painful menstrual cycles. She had a long history of oestro-progestin therapy for contraception, and history of one vaginal birth.

At her annual ultrasound examination in 2023, a unilocular cyst, with anechogenic content, avascular was described on the right ovary with a maximum diameter of 1.5 cm, unchanged since 2010. The left adnexal region showed no echogenic tumefactions.

In 2024 she complained of pain in the left iliac fossa and hypogastrium with a feeling of weight in the abdomen, especially with rectal pressure.

Because of the reported symptomatology, she underwent magnetic resonance imaging, which revealed a pelvic cyst with a maximum diameter of 6.5 cm, polylobulated with modest diffuse post-contrast enhancement in the retrouterine area.

In March 2024 she underwent TVS. On TVS the right ovary appeared normal, with the known small cyst of the same size as on previous examinations. On retrouterine inspection, there was a solid multilocular cyst measuring 65x42x63 mm, which was vascularized in its solid component, with colour score 2. The presence of vascularized tissue raised the suspicion of endometrioid carcinoma or alternatively mucinous intestinal carcinoma in a possible residual ovarian syndrome. In April 2024, a further ultrasound scan was performed, and the cystic formation was no longer visible. Instead, only solid, avascular tissue resembling postmenopausal ovarian parenchyma was observed with a maximum diameter of 2 cm. Given the previous suspicion of malignancy and the postmenopausal state, the patient was referred for right oophorectomy, peritoneal washing and exeresis of pelvic mass. In May 2024 the patient underwent laparoscopy, during which the regular uterus was visualized, with a regular right adnexus with a small cyst, while the left adnexus was absent. Posterior to the uterus, a 2 cm pelvic mass was observed, which was much smaller than on the previous ultrasound scan. Ultrasonographic pelvic assessment is reported in Figure 3. The histological examination revealed a serous cystadenoma of the right ovary, while the retrouterine formation was recognized as a fragment of ovarian parenchyma with recent haemorrhagic extravasation with associated simple cyst. In the postoperative ultrasound the adnexal fields were regular bilaterally. The patient did not require further treatment and is being followed up regularly. According to the histological report, the symptoms and the appearance of the cyst, it is reasonable to hypothesize that there has been a resumption of ovarian tissue activity despite menopause of a fragment of parenchyma remained in the Douglas, with the development of a functional formation with probable blood extravasation inside it, responsible for the internal projections visible on ultrasound control.

Case 3 the Concealed Ovary

We present the case of a 52-year-old female patient who underwent laparoscopic right adnexectomy and left salpingectomy in March 2021 for an occasionally diagnosed ovarian cyst detected on annual TVS. Her personal medical history was silent. The patient had

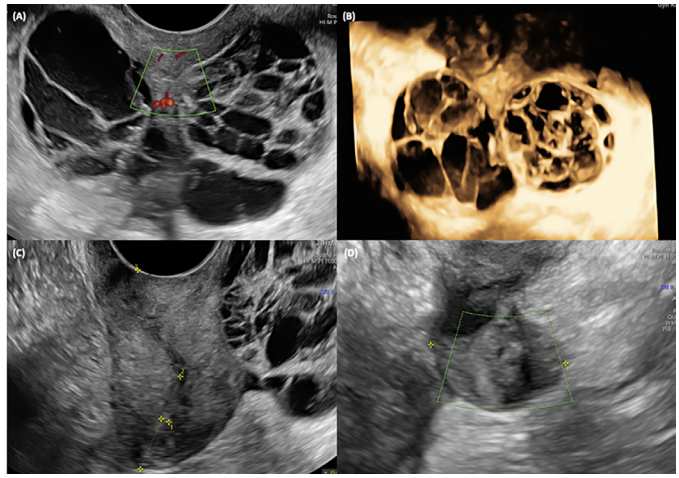

Figure 3. Ultrasonographic pelvic assessment (case 2). A solid multilocular cyst with a vascularized central solid part is observed on power Doppler (A). 3D appearance of the mass (B). The cyst was located posterior to the uterine body and cervix as clearly visible in the longitudinal scan of the uterus (C). The Pouch of Douglas was obliterated. Picture D shows the ultrasound appearance of the mass in May 2024, with the cyst no longer visible, appearing as ovarian parenchyma.

no previous surgical intervention and was completely asymptomatic.

On preoperative ultrasound, the patient presented with a unilocular cyst with anechoic content, non-vascularized on power Doppler with a maximum diameter of 8 cm. The diagnostic hypothesis suggested a serous cystadenoma. At surgery, the uterus had irregular external contours consistent with uterine fibromatosis. The left ovary appeared macroscopically normal and was attached to the ipsilateral uterosacral ligament. The right ovary appeared enlarged in volume and completely occupied by an 8 cm cyst with fluid content and regular walls, attached to the uterosacral ligament and the anterior wall of the rectum. During surgery, careful lysis of the peritoneal adhesions was performed and a right adnexectomy and left salpingectomy were performed.

Histological examination revealed an oedematous connective wall of Müllerian origin, salpinx and ovarian tissue with areas of endometriosis.

On follow-up 6 months later, a normal ovary was observed on the left and tissue compatible with an ovarian remnant on the right iliac fossa. Given the asymptomatic presentation, careful ultrasound follow-up was indicated. Ultrasonographic pelvic assessment is reported in Figure 4.

Discussion

The incidence of ORS is still unknown. The presence of distorted anatomy and extensive adhesions is associated with unfavourable surgical condition which may lead to an increased risk of ovarian tissue remenants.[12,13]

Patients often present with chronic pelvic pain, dyspareunia, cyclic pelvic pain, dysuria and tenesmus, caused by the growth and compression of the embedded functional ovarian tissue but they could also be asymptomatic[12] thus clinical history is fundamental in the diagnosis of ORS and a previous ovarian surgery must be recorded.

Small pieces of ovary may be functional and grow under hormonal stimulation[8] and neovascularisation may occur.[12]

The ORS can be suspected with imaging techniques, typically a pelvic mass consistent with an ovarian remnant can be recognized in a woman who has previously undergone unilateral or bilateral oophorectomy[10] but the diagnosis is only histological after surgical removal of the suspected lesion.[8]

The surgical excision of the ovarian remnant may be challenging due to the presence of adhesions, bleeding and distorted anatomy thus the procedure must be performed by an experienced surgeon and must be radical to avoid recurrences[10] mainly because the residual ovarian tissue carries a risk of malignant transformation.[14]

In addition to anatomical distortion, a potential risk factor associated with ORS is the extension of ovarian stroma up to 1.4 cm into the infundibulopelvic ligament beyond the visible margin. Therefore, in order to prevent ORS, it is necessary to perform high ligation of the infundibulopelvic ligament, retroperitoneal dissection, and excision of all peritoneum and tissue adherent to the ovary.[15]

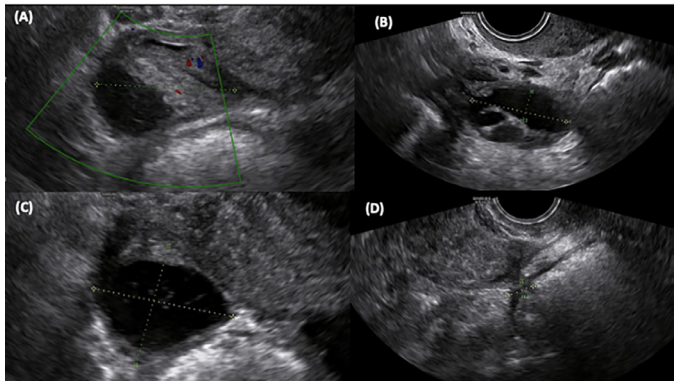

Figure 4. Ultrasound scan at 6 months (case 3). Residual ovarian tissue with follicular activity is observed (A-C). A nodule of deep endometriosis infiltrating the anterior wall of the rectum is visible in the posterior compartment (D).

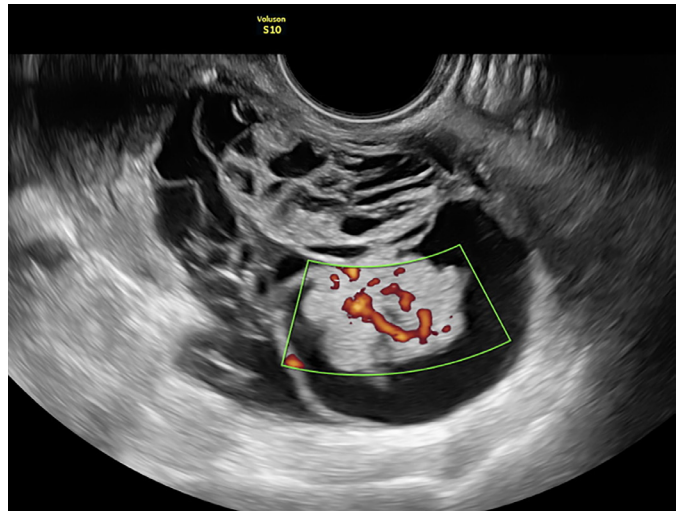

Figure 5. Ultrasonographic aspect of the endometrioid ovarian cancer in the context of ORS. It appears as a large, unilateral, multilocular-solid tumour, with anechoic cystic fluid. A large central solid component located within locules can be observed corresponding to a cockade-like sign.

ORS: Ovarian remnant syndrome.

Once a residual ovary is diagnosed, laparoscopy, laparotomy and robotic surgery can be used if surgical treatment is chosen. In a 2012 study of 223 patients with ORS, 83.9% underwent laparotomy, 8.5% laparoscopy and 7.6% robotic surgery. The laparoscopic and robotic approaches were associated with less blood loss than laparotomy and were also found to be associated with fewer postoperative complications and shorter length of stay.[16]

For patients who are at high risk of surgical complications or who are asymptomatic with no risk factor, conservative medical management of ORS has also been suggested. If symptoms occur, oral contraceptives, gonadotropin-releasing hormone analogues and medroxyprogesterone may be used to suppress the potential ovarian function of the remaining tissue, as well as pelvic radiation therapy. However, conservative strategies should only be reserved for cases where there is a histological diagnosis confirming ORS and excluding the risk of malignancy.[8]

One of the main causes of the presence of altered pelvic anatomy and presence of adhesions is endometriosis.

Endometriosis is a diffuse disease, characterized by the presence of endometrial tissue outside the uterine cavity, that affects about 5% of women and involves multiple pelvic organs such as the ovaries, pelvic peritoneum, pouch of Douglas, rectum, rectosigmoid, rectovaginal septum, uterosacral ligaments, vagina and bladder with different degrees of severity.[17] It usually causes painful symptoms such as dysmenorrhoea, dyspareunia, dysuria, dyschezia or chronic pelvic pain, but sometimes it can be asymptomatic and may only be discovered during surgery. Nowadays, awareness of the disease has increased, and imaging techniques and knowledge have improved. TVS is the first-line imaging technique in the diagnosis of endometriosis.[18] Allowing improved and quicker detection of the disease due to its wide availability, non-invasiveness and lower cost. Ultrasonographic features of lesions have been extensively described by the International Deep Endometriosis Analysis group.[17] Although endometriosis is a benign disease, malignant transformation of the lesions is possible, in particular, it is associated with a higher risk of clear cell and endometrioid ovarian cancer, 3.4 times and 2.3 times respectively.[19]

Endometrioid carcinoma is the second most frequent ovarian carcinoma in women with a mean age at presentation of 55-58 year and up to 50% of cases develop in patients with endometriosis; it carries a 5-year survival rate of more than 70%.[20] Macroscopically, endometrioid ovarian carcinoma appear as a unilateral tumour with a mean size of 150 mm.[20] The ultrasonographic characteristic of this kind of tumours are widely described, they generally appear as multilocular-solid tumours, with low-level echogenicity of the cyst fluid, but they also can be described as solid masses.[20]

In case 1, with the benefit of hindsight, we can recognize in the cyst of our case most of the main characteristic features of an endometrioid ovarian carcinoma (Figure 5): a large, unilateral, multilocular-solid tumour, with anechoic cystic fluid and, if we look carefully, we can recognize a large central solid component located within locules, which may correspond to the cockade-like appearance described by Moro et al.[20]

As mentioned above, given the patient's clinical history, the previous adnexectomy and the tight connection between the cyst and the uterine wall, in the differential diagnosis was considered a malignant pathology of the uterus, in particular a uterine sarcoma was suspected, which however has distinct ultrasonographic features. Generally, sarcomas have an irregular shape, with heterogeneous echogenicity, cystic areas and necrosis, and are highly vascularized[21] but in complicated cases these features can be superimposable to those of an ovarian neoplasm, and they may be misinterpreted.

Unfortunately, in our case, we cannot know whether there was a diagnostic mistake in ultrasonographic evaluation and in the reading of the first histologic examination or whether the malignant transformation occurred later. Given the presence of adhesions described in the first surgery, we can speculate that the patient in the case described may have had undiagnosed endometriosis that exposed her to an increased risk not only of ORS but also of neoplastic transformation of the ovarian tissue remained in the pelvis.[22]

In this case, diagnosis may be delayed because of failure in recognizing ORS which was not suspected because of the patient's previous history of bilateral oophorectomy.

Moreover, in those patients, ovarian remnant tissue may be mistakenly confused with a leiomyoma,[11] uterine sarcomas and adenomyomas. In most of case report in literature authors conclude, as we do, that the diagnosis is generally missed because of the patient's previous surgical history.

ORS can present with multiple histopathological diagnoses from endometrioid, clear cell but also borderline endometrioid cystic fibroma,[10] mucinous adenocarcinoma,[23] ovarian serous cystadenofibroma.[8]

Surgical inattention, such as incomplete removal of ovarian tissue or morcellation in the pelvic cavity during a difficult oophorectomy, increases the risk of ORS through the dissemination of ovarian fragments into the pelvis.[24]

In women with previous surgery, endometriosis or other conditions associated with the development of pelvic adhesions, it's fundamental for the surgeon to consider the possibility of a difficult oophorectomy and carefully proceed to a complete ovarian remove, a high ligation of the pelvic infundibulum ligaments and retroperitoneal dissection may be considered to avoid the risk of ORS.[11]

It is preferable to remove the ovary in one block, possibly within a bag, from a larger laparoscopic port, colpotomy or mini-laparotomy, but if this is not possible and fragmentation is used, it is important to collect all the fragments and wash the pelvic cavity thoroughly. In case incomplete oophorectomy is suspected, the patient should be closely monitored to recognise the development of the syndrome in advance[24] and to early recognize the presence of anomalies in the adnexal area for the risk of malignant transformation.[11]

Conclusion

ORS is a rare condition which must be suspected in case of incidental detection of pelvic mass in a woman with previous bilateral oophorectomy. The presurgical evaluation of the risk of adhesions and an accurate excision of the ovarian tissue during the initial surgery will reduce the risk of ORS.

This condition could be a completely incidental finding that is occasionally discovered during a routine ultrasound scan. If the syndrome is diagnosed, several aspects must be taken into account, from the presence of symptoms, the ultrasonographic aspect of the cyst and the patient's preference, in order to choose the correct management, from expectant management to surgery, balancing the risks and benefits of each choice. If second surgery is required, it is important that it is carried out by a team of experienced surgeons to reduce the risk of recurrences.

A possible limitation of this paper is that due to the paucity of data in the literature, it is not possible to draw conclusions. Other potential limitations of this work may be related to eventual selection bias, we attempted to include all cases described in the literature, however it is possible that some papers named with keywords not included in our search string were not selected. However, by comparing our work with similar previous papers, we have found that the cases described are common to all studies, so we can assume that the number of erroneously omitted cases is limited.

The present paper with our case series contributes to the total number of reports and may help to provide new information on how this syndrome may manifest. We would also like to raise awareness of this possibility in a woman who has had a previous oophorectomy and is found to have a pelvic mass.

Suspect ovary even if the ovaries have been removed!

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Transparency: The manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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REVIEW ARTICLE

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Optimising ergonomics in minimally invasive gynaecological surgery: a comprehensive review and practice recommendations

Dimitrios Balafoutas[1,2], Ralf Joukhadar[2], Nikos Vlahos[1]

[1]2nd Department of Obstetrics and Gynaecology, University of Athens, Aretaieion Hospital, Athens, Greece
[2]Department of Obstetrics and Gynaecology, Spital Männedorf, Zurich, Switzerland

ABSTRACT

Background: Modern minimally invasive gynaecological surgery greatly contributes to women's health; however, it can be physically demanding for surgeons. A plethora of available data shows that the optimisation of ergonomics in the operating room (OR) is crucial for the health and efficiency of surgeons.

Objectives: To provide an overview of the importance of ergonomics and clinically useful, concise recommendations.

Methods: A literature review with critical analysis of available data.

Main Outcome Measures: Impact of ergonomics on the prevalence of musculoskeletal disorders (MSDs), fatigue levels, efficiency and subjective comfort among surgeons.

Results: Evidence suggests that MSDs are highly prevalent among minimally invasive gynaecological surgeons and that several ergonomic interventions can greatly reduce muscle strain and improve clinical practice, with the most important being the planning of brief intraoperative breaks, the selection of proper laparoscopic instruments and the positioning of the operating table and monitor at the correct height. The adoption of robotic surgery can also improve surgical ergonomics. Clinical practice recommendations for ergonomic improvement in gynaecological laparoscopy based on the existing evidence are provided.

Conclusions: Surgeons must be aware of the optimal ergonomic settings in the OR and impose measures to reduce risks and achieve a comfortable environment.

What is New? A comprehensive, praxis-oriented review with exact ergonomic advice for minimally invasive gynaecological surgeons.

Keywords: Ergonomics, laparoscopic, musculoskeletal disorders, operative setting, robotic, surgeon health, surgical efficiency

Introduction

Minimally invasive gynaecological surgery is currently used for the diagnosis and treatment of various disorders. Despite its benefits for the patients, this approach can be physically demanding and can lead to musculoskeletal injuries among surgeons, nurses, and other healthcare workers.[1] Therefore, interventions that reduce these risks are needed. Ergonomics is the science of designing and arranging the workplace, equipment, and tasks to fit the capabilities and limitations of the human body. In the context of laparoscopy, ergonomics can play a

Corresponding Author: Dimitrios Balafoutas, MD, 2nd Department of Obstetrics and Gynaecology, University of Athens, Aretaieion Hospital, Athens, Greece; Department of Obstetrics and Gynaecology, Spital Männedorf, Zurich, Switzerland
E-mail: dbalafoutas@yahoo.com **ORCID ID:** orcid.org/0000-0002-6256-2127
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crucial role in reducing the physical strain and improving the performance of surgical teams.[2] This is crucial for surgeons' career longevity and quality of life, because performing laparoscopic surgery has been shown to cause fatigue, strain and injury irrespective of age, experience and handedness.[3]

This review aims to explore the current knowledge on ergonomics for gynaecological laparoscopy. We investigate the hypothesis that specific ergonomic interventions can reduce the prevalence of musculoskeletal disorders (MSDs) among surgeons and improve their overall surgical performance. Moreover, we summarise concise recommendations regarding the optimal ergonomic settings based on available data.

Methods

Search Strategy and Study Eligibility

The systematic search was conducted in the ScienceDirect, PubMed/Medline, and Google Scholar databases without any restriction on the publication date. The preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines were used.[4] The protocol for this review was registered at PROSPERO (CRD42023452153). The search focused on studies that evaluated ergonomic or surgeon strain parameters during laparoscopic surgery. The following keywords were used: (laparoscopic OR robotic) AND (ergonomics OR ergonomic) AND (gynecological OR gynecologic), (laparoscopic OR robotic) AND musculoskeletal AND (gynecological OR gynecologic). The search was performed in October and November 2023.

Inclusion criteria were surgeons as subjects (primary operators and assistants). Exclusion criteria were work-related MSDs among hospital staff outside the operating room (OR). The main outcomes to be considered were the avoidance of musculoskeletal injury of surgeons, the reduction in fatigue and the improved efficiency and operative time. Randomised controlled trials and prospective or retrospective randomised cohort studies were included. Because of the narrative character of this review and the need to suggest optimal ergonomic recommendations and ideas, review articles and society guideline websites were also included. Only full-text articles were included. Inaccessible articles and articles in languages other than English were excluded.

Data Extraction

Articles from the initial database search were searched for duplicates. Two hundred thirty-four articles were screened by titles and abstracts for irrelevant articles. After assessing content according to the inclusion/exclusion criteria, articles were scanned by the authors for relevant information and supplemented with online scientific committee sources and two book chapters. Finally, 86 sources were included. Study design, baseline characteristics, modality of surgery (laparoscopic or robotic) and exact setting, OR table height, OR setup and surgeon positioning were extracted for comparison from full-text articles. No missing data was defined.

Strategy For Data Synthesis

Narrative synthesis assessing the quality of studies and bias.

Evidence

Research Tools: Research tools that have been utilised to study surgical ergonomics can be broadly categorised into subjective and objective instruments.[5] Subjective tools include validated questionnaire scales that study discomfort in specific body regions or subjective assessment of the mental and physical workload, performance and frustration.[6] Objective tools include electromyography measurements of muscle activity and fatigue[7] and kinematic tracking through video[8] or special sensors, like accelerometers.[9] With the above research tools, valuable information about the ergonomic risk factors, as well as the common musculoskeletal problems in surgeons, could be obtained.

Ergonomic Risk Factors in Gynaecological Laparoscopy: Laparoscopy requires surgeons and staff to maintain prolonged static postures, awkward body positions, and repetitive movements, which can result in MSDs such as neck pain, back pain, shoulder pain, and hand-arm vibration syndrome. A systematic review showed that the average prevalence of physical complaints among laparoscopic surgeons was 74% and that the prevalence of MSDs is higher in minimally invasive surgeons than in any other occupational group.[10] Several task-related factors affect the risk for MSDs in laparoscopy, such as instrument design, equipment placement, and surgical technique, as well as individual factors, such as age, gender, and physical fitness.

Gynaecological surgeons are especially prone to MSDs because of the additional musculoskeletal strain due to the parallel exposure to vaginal surgery.[11] During vaginal surgery, the assistant stands holding retractors beside the primary surgeon with excessive trunk rotation and prolonged asymmetrical upper extremity strain. A study

comparing the frequency and duration of strenuous body postures between assistant and primary surgeons demonstrated that while both experience high durations of trunk lateral bending and neck and shoulder deviations, the assistant surgeons spent a greater percentage of working time in trunk flexion compared to the primary surgeon.[12] In operative laparoscopy, data suggest that surgical assistants face significant ergonomic stress, just as operating surgeons do.[13]

Many instruments, common in advanced minimally invasive gynaecological surgery, i.e. endoscopic needle-drivers, demonstrate reduced degrees of freedom, enhanced fulcrum effect, and magnification of minimal tremor.[14] Moreover, conventional laparoscopic instruments create an inefficient transfer of force and an uneven lever effect towards the fingers of the surgeon, which can result in pain, fatigue, and neuropraxia.[15]

Minimally invasive surgery involves more internal shoulder rotation, elbow flexion and wrist supination than open surgery, and larger ranges of motion are required of the upper extremities due to the instrument length.[16] A quantitative study of laparoscopic surgeons' movements in live surgical environment utilizing video analyses demonstrated that surgeons spent a median of 98 % (range 77-100%) of surgical time with their neck rotated at >21° (range 0°-52°) with shoulder flexion at 45°-90° for 35% vs. 0% (P<0.001) and elbow flexion at >120° for 31 vs. 0 % (P<0.001) of total surgical time.[17] The non-dominant arm was subjected to more extreme positions for significantly longer periods of time compared to the dominant arm. Power morcellation was associated with the additional strain of multiple instrument insertions and removals, however, this technique is used less in recent years in many parts of the world following considerations of cancer cell dissemination. Short heighted surgeons, in particular (reference height 170 cm), spend more time in these extreme joint and posture positions.[18]

Hand size significantly affects the ergonomics of laparoscopic instruments and can lead to an increased risk of MSDs.[19] Available data suggest that smaller hand dimensions and glove size, as well as female sex, are associated with a higher probability of MSDs.[14] Indeed, various endoscopic surgery instruments, i.e. staplers, are designed for a minimum hand size. A study furthermore reported that the most appropriate instrument size for surgeons with a given hand size is not the same for male and female individuals, but needs to be established separately for each sex, ideally by developing smart instruments whose usability is not affected by the gender of the user.[20] Unfortunately evidence suggests that this also applies to the current disposable laparoscopic devices that do not fit the needs of female laparoscopic surgeons.[21] Indeed, women are still more likely to describe the laparoscopic instruments as uncomfortable to handle and seek more frequent treatment for MSDs. In a recent study, women were found to have 5.37 times the odds of physical complaints attributed to the use of laparoscopic instruments (odds ratio: 5.37; 95% confidence interval: 2.56-11.25).[22] Because of the rapidly increasing number of women entering the field of operative gynaecology, these limitations are likely to gain importance in the future.

Common Musculoskeletal Disorders in Surgeons

The overall risk of work-related musculoskeletal symptoms in surgeons has been calculated at up to 90%.[23,24] The highest levels have been recorded among surgeons who perform complex minimally invasive gynaecological surgery,[25] with 52% of the individuals reporting persistent pain in an online survey. The neck, shoulders, and wrists are the most investigated areas for MSDs, followed by the ankle, knee, back, upper back, elbow, lower back, thumbs, mid-back, fingers, and hips.[26] Interestingly, the prevalence of MSDs seems to increase with the number of years of laparoscopic practice.[27]

Neck and Shoulder Pain

Neck and shoulder pain are common complaints among surgeons, with studies reporting prevalence rates ranging from 56% to 85%.[28] The repetitive use of upper extremities during surgery, the prolonged static postures, and the awkward positioning are all risk factors for developing neck and shoulder pain. The ergonomic impact of laparoscopy on surgeons has been studied at the level of specific muscles through electromyograms. The activation patterns of deltoid, trapezius, biceps, pronator teres, flexor carpi ulnaris, and extensor digitorum superficialis muscles have been analysed during simulated laparoscopic tasks. Proximal arm and shoulder muscles were impacted the most.[29]

Low Back Pain

Low back pain is another common musculoskeletal complaint among surgeons. A descriptive, cross-sectional study showed prevalence rates of up to 68%.[28] The prolonged standing or sitting in awkward positions

during surgery, as well as the repetitive nature of surgical tasks, can contribute to the development of low back pain. Currently, limited evidence shows that exercise programs can reduce the prevalence of pain, however, most surgeons experience ongoing symptoms.[30]

Carpal Tunnel Syndrome

Carpal tunnel syndrome is a common hand and wrist injury among surgeons, with prevalence rates up to 34%. Repetitive hand movements, awkward hand positions, and forceful gripping of instruments are all risk factors for developing carpal tunnel syndrome. An online questionnaire study found that, while ergonomic interventions, such as adjustable instrument handles and padded gloves, could reduce the incidence of carpal tunnel syndrome, most surgeons were unaware of the possible ergonomic solutions and didn't consider adopting any appropriate preventive measures.[31]

Lower Extremities

Posture-related MSDs of the lower extremities, especially in the knee and ankle/foot regions, appear to be common among surgeons, with reported prevalence up to 65%.[32] Increased prevalence of varicose veins has been well-documented[33] and standing places significant pressure on the joints of the hips, knees, ankles and feet and without significant movement, the lubrication of the synovial joints is diminished, causing increased wear. These MSDs are of particular importance for the surgeons' quality of life, because they appear to have a maximum impact on their leisure activities.[1]

Interestingly, the MSDs experienced by surgeons seem to have implications on clinical practice, with up to 30% of surgeons reporting that they consider their symptoms as a factor in choosing the operative approach.[34]

Ergonomic Interventions for Gynaecological Laparoscopy

Ergonomic interventions across a diverse range of industries in modern working environments have been shown to decrease lost workdays and sick leave,[35] and to improve efficiency and employee satisfaction.[36] In general terms, ergonomic improvements in the occupational setting have been proven to be cost-efficient[37] Despite this evidence, limited ergonomic interventions have been implemented for surgeons until recently.[38]

Ergonomic interventions can help reduce the physical strain and MSDs associated with laparoscopy. Fortunately, there are available effective ergonomic guidelines which are proven to reduce the risk of MSDs.[39] Some of the commonly used ergonomic interventions in laparoscopy include the following:

Intraoperative Breaks: During training and clinical practice, surgeons often develop a high level of concentration on patient outcomes, which frequently leads to neglecting their own needs during operations. Therefore, even microbreaks of some seconds are uncommon in laparoscopic surgery. However, current data suggest that work breaks during complex laparoscopic surgery can reduce psychological stress and preserve performance without prolongation of the operation time compared with the traditional work scheme. A randomised clinical trial found that regular intraoperative breaks did not prolong the operation (176 vs. 180 min, $P>0.05$) and the surgeon's cortisol levels, as an indicator of stress during the operation, were reduced by 22 ± 10.3% ($P<0.05$).[40] Another prospective study concluded that muscular fatigue and loss of accuracy can almost completely be prevented by microbreaks: In an experiment with surgeons under increasing fatigue, manual accuracy, measured by mistakes made when following a predetermined path on a board and discomfort, measured by a visual analogue scale, were vastly eliminated by microbreaks.[41] In a multi-centre cohort study, discomfort in the shoulders of surgeons incorporating microbreaks was significantly reduced, while distractions and flow impact were minimal, with the majority of surgeons reporting that they would alter their clinical routine after the exposure to the study.[42]

Regarding surgeon body positioning during prolonged laparoscopy, avoiding prolonged extreme body and trunk positions seems to be crucial. Laparoscopic surgery allows for more head/neck positioning flexibility in comparison with open surgery because the monitors can be adjusted. Preferably, the neck should have a small degree of flexion from 15° to 25°, while the shoulders should be below 20° of abduction and 40° of internal rotation.[43] The elbows should have a flexion of 90°-120°, and the wrists should not exceed 15° of deviation or flexion in any direction.[44] The positioning of foot pedals should be placed in an ergonomically favourable position, directly to the side of the working foot and should enable the knees to be soft and unlocked, feet hip-width apart, and body weight equally distributed. Surgeons should limit foot dorsiflexion to below 25° over the pedal and, if possible, utilise shoes without extreme external width, which can minimise the risk of accidental pedal and energy engagement.

The Alexander technique, a process of psychophysical re-education of the body to improve postural balance and coordination initially described in open surgery, has also been adopted in operative laparoscopy with positive impact in ergonomics and, interestingly, also in laparoscopic skills assessment scales.[45] The optimal body positioning for gynaecological laparoscopy is shown in Figure 1.

The design of laparoscopic instruments and equipment can significantly impact the physical strain and the performance of surgeons and staff. Ergonomically designed instruments, such as those with angled handles, adjustable tension and ergonomic grips, can reduce the strain on the hand, wrist, and forearm muscles and improve the precision and control of surgical movements. Especially those that minimise wrist flexion and rotation, and ulnar deviation should be selected.[46] Equipment placement, such as the position of monitors, can also impact the posture and neck flexion of surgeons and staff. Additionally, the selected instruments should be appropriate for the surgeon's anthropometry and the exact intended task.[47] Laparoscopic suturing and knotting constitute a special ergonomic challenge, where the camera angle and the distance between the working trocars play a crucial role. The ideal geometry has been proposed in an in vitro model study. An isosceles triangle between the instruments, with an angle between 25° and 45° and an angle of <55° between the instruments and the horizontal, facilitates faster and more relaxed suturing.[48]

In recent years, handheld robotic laparoscopic instruments have been developed. While lacking the motorised arm support of the full-scale robotic platforms, these instruments aim to improve ergonomics in complex laparoscopic tasks like intracorporeal suturing.[49] Indeed, the design of these instruments enables up to 360° rotation and some degree of three-dimensional articulation and can be combined with several end effectors, possibly reducing prolonged awkward wrist positions for the surgeon.[50] Furthermore, proximal interphalangeal flexion of the thumb and the metacarpophalangeal and proximal interphalangeal flexion of the index finger seem to be reduced with handheld robotic assistance.[51]

Structured Training and Education: Proper training and education can improve the ergonomic awareness and skills of surgical teams and reduce the risk of MSDs. Training programs can include instruction on proper body mechanics, postures, and movements, as well as exercises to improve strength, flexibility, and endurance. A recent electromyography study found that trained individuals had lower muscle activation (P<0.05), muscle workload (P<0.05) and better bimanual dexterity than the trainee surgeons at baseline.[52]

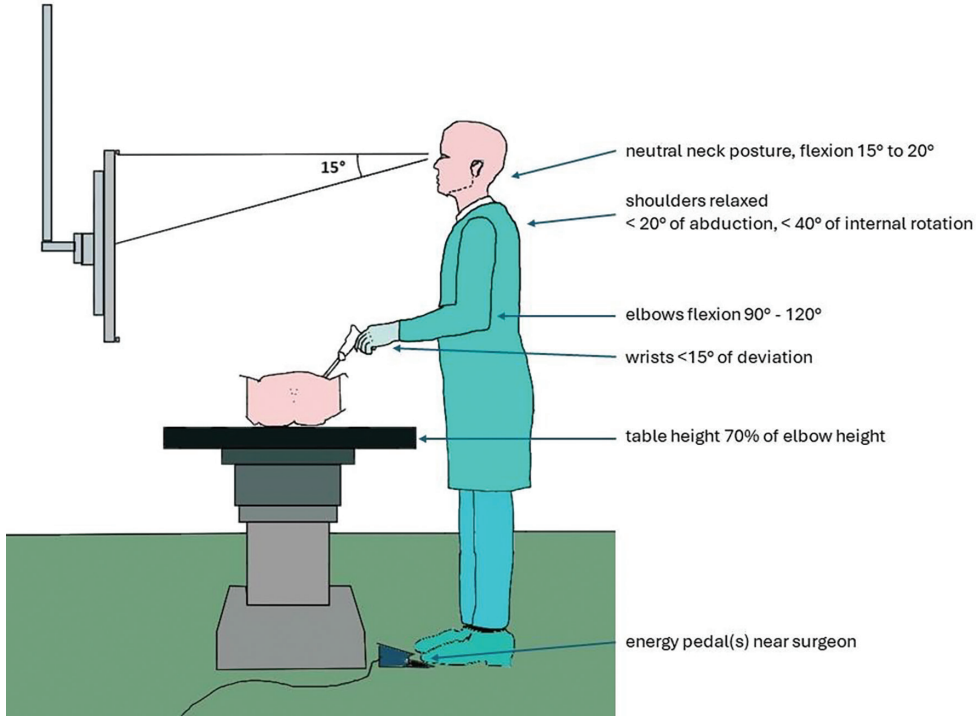

Figure 1. Recommended posture and setting for gynaecological laparoscopy.

Environmental Modifications: Environmental modifications, such as adjustable lighting, temperature control and noise reduction, can improve the comfort and well-being of surgical teams and reduce the risk of MSDs. Modern laparoscopic ORs are equipped with multiple ceiling-suspended flat-screen monitors that facilitate versatile positioning around the operative field. The exact adjustment of each monitor in location, height, and inclination within a comfort distance and in the direct field of vision of each surgeon can reduce eyestrain and improve posture during prolonged operations.[44,53] The correct placement of the endoscopic image, as a sole intervention, has been shown to decrease the operative time by 10%, even for procedures that do not require complex suturing skills.[54] In the case of intracorporeal knot tying, a randomised controlled trial could demonstrate that both knot quality ($P<0.01$) and execution times ($P<0.01$) could be improved with the monitor straight in front of the operator at the level of the hands.[55] This finding contrasts with the common perception of the OR staff that the monitor should be at the level of the eyes or higher. Indeed, the optimal height zone appears to lie 15 degrees lower than sight level. The direct ergonomic impact of monitor positioning could be highlighted in a study utilising electromyography and ultrasonic position transmitters, which compared several monitor angles (display at 0°, 17.5°, and -35°) and clearly proved that muscle effort increased with viewing angle.[56]

Recent data suggest that proper workload management, such as task rotation, can reduce the physical strain and fatigue associated with laparoscopy. Task rotation can help distribute the physical demands across different body regions and reduce the physical strain.[57,58] In particular, surgeons and assistants switching sides of the table to balance the strain on the upper extremities has been proposed.[59]

Proper holding and manipulation of laparoscopic instruments are essential for successful laparoscopic surgery. Incorrect handling of the instruments can lead to tissue damage, prolong the surgery, and increase the risk of complications. The surgeon should hold the laparoscopic instrument in a relaxed and comfortable grip, using the thumb and index finger. The grip should be firm enough to control the instrument, but not so tight as to cause hand fatigue. The other fingers should be relaxed and not holding the instrument, as this can cause unnecessary tension and strain.[60] Using the dominant hand can improve the surgeon's dexterity and control over the instrument, reducing the risk of tissue damage and other complications. The surgeon should use their wrist and fingers to manipulate the laparoscopic instrument, rather than their shoulder or elbow. This can reduce the risk of shoulder and neck strain, as well as improve the surgeon's control over the instrument (fine positioning).[61]

The height of the operating table is an important factor to consider during laparoscopic surgery, as it can affect the surgeon's posture and increase the risk of musculoskeletal injuries. The optimal height of the operating table for laparoscopic surgery depends on several factors, including the surgeon's height, the type of procedure, and the size of the patient. Generally, the operating table height should be adjusted to ensure that the surgeon's elbows are at a comfortable and neutral position when holding laparoscopic instruments.[62] OR tables were designed for open operations and are too high for many surgeons performing laparoscopic surgery. The ergonomically optimal operating surface height for laparoscopic surgery has been previously assessed in a study performed in a pelvic-trainer setting, with the strain being measured with questionnaires and electromyography.[44] The optimal patient height during a laparoscopic procedure is suggested to be 0.7× to 0.8× surgeon elbow height, which allows joints to stay in their neutral position for more than 90% of the operation duration. This proposed formula results in heights with an average of only 77 cm, whereas for open surgery, the equivalent lies at about 122 cm. Usual operating tables have a range of 73-122 cm, which, given the extra height of the supine patient, would be too high for 95% of minimally invasive surgeons.[63] While a stool is available in every setting, this solution is not sufficient in all scenarios. Energy devices require the surgeon's pedals and balance of the surgeon, and with the parallel use of various pedals, can be demanding.

Special Equipment which Aims Solely to Improve Surgeons' Comfort is Available: Special ergonomic chairs with adjustable heights should be readilyavailable.[64] For prolonged operations, a randomised controlled trial has shown that robot-assisted camera holders can decrease the strain of the assistants.[65] The OR staff should ensure that the lights are adequately dimmed to ensure glare reduction and display contrast enhancement, while simultaneously allowing safe movements throughout the room.[66] Cables and tubes usually clutter the floor of the OR, creating physical hazards for operators and staff. Organising the cables at the beginning of surgery, as well

as ceiling-mounted boom systems for cables outside of the direct proximity of surgeons, can enhance safety and reduce physical obstacles, hence improving ergonomics. Whereas it has been proven that surgeons can effectively block out noise, it is preferable to reduce noise in the OR to improve communication within the team, especially in emergencies.[67] Additionally, when planning ergonomics for complex gynaecological laparoscopy, it is important to organise both patient and equipment placement to facilitate conversion to laparotomy or patient resuscitation.

Ergonomic Factors of Robotic Surgery

Robotic surgery is a minimally invasive surgical technique that uses robotic systems to perform surgical procedures. It offers several ergonomic benefits over traditional open or laparoscopic surgery, which can improve surgical outcomes and reduce the risk of injuries for the surgical team. At the same time, robotic surgery creates new challenges and special issues that must be addressed.

The customizability of the surgeon's console can greatly improve surgeon ergonomics, resulting in less overall back, shoulder, neck, and wrist pain.[68] A recent prospective cohort study suggested adjusting the console to achieve the most neutral neck angle and lowering the viewfinder until visibility into the device is uninhibited while sitting up straight, usually at a viewing angle of approximately 15° below the horizontal.[69] Back flexion should be less than 15°, while neck flexion should not exceed 25°, which is a low-risk posture as assessed in MSDs risk assessment validated tools.[8] Robotic surgeons should be instructed that the head should rest lightly on the console headrest to avoid forehead pain and increased neck strain.[70] Forearms should rest on the console armrests to cater for a more relaxed soldier position and free flexion of the elbows.[71] It is important to frequently utilise the clutches that enable the free adjustment of the controls to keep the hands in the neutral position ("sweet spot" in the robotic surgery argot).[46] The recommended surgeon positioning for ergonomic improvement in robotic surgery is shown in Figure 2.

Reduced Physical Strain and Fatigue

Robotic surgery systems allow for more ergonomic positioning for the surgical team, which can reduce physical strain and fatigue. The surgeon sits at a console that is typically located away from the patient, allowing for a more comfortable, neutral posture. This can reduce the risk of musculoskeletal injuries, such as neck and back pain, which are common in traditional laparoscopic surgery. A survey of physical discomfort and symptoms following open, laparoscopic, and robotic surgery found that surgeons experienced significantly less physical strain and fatigue during robotic-assisted surgery compared to laparoscopic surgery.[72] Additionally, the forearms can rest on the armrest of the console and are hereby protected from gravity strain.[73]

Improved Visualization

Robotic surgery systems offer improved visualisation of the operative field, which can reduce the risk of errors and complications. The systems provide high-definition 3D imaging, which allows for better depth perception and visualisation of anatomical structures. This can reduce the need for awkward head positions or repeated instrument exchanges and can improve ergonomics for the surgical team. Several studies found that through the tremor-free 3D immersive optics, robotic surgery provided better visualisation of the surgical field compared to laparoscopic surgery.[74,75]

More Precise Instrument Control

Robotic surgery systems offer more precise instrument control, which can reduce the risk of errors and complications. Robotic instruments are designed to mimic the movements of the surgeon's hand and wrist, allowing for greater dexterity and control.[76] This can reduce the need for excessive force or repetitive motions, which can reduce the risk of injuries caused by hand and wrist strain. Currently, the use and demand for robotic medical and surgical platforms are increasing, and new technologies are continuously being developed with promising possible ergonomic advantages for surgeons.[77]

Importantly, MSDs persist in robotic surgery, albeit at a lower rate than in laparoscopic surgery.[78] In the field of gynaecology, a large survey reported 54% of participating gynaecologic robotic surgeons experiencing physical symptoms or discomfort.[79] Discomfort in the fingers and neck was the most reported problem. In a online questionnaire survey robotic surgery was found to be more likely than either open or laparoscopic surgery to lead to eye or finger symptoms, and more likely than open surgery (but not laparoscopic surgery) to lead to thumb symptoms.[72] Additionally, prolonged sitting without lumbar support creates greater intradiscal strain than standing.[80] A further ergonomic limitation of robotic surgeons affects bedside assistant surgeons, who are exposed to unnatural positions under the threat of

sudden motion of the robotic arms. In one study, 73% of bedside assistants reported discomfort, stressful positioning of the upper extremities, trunk, neck, and shoulder.[81] A further study reported that robotic assistance is associated with worse neck posture, but lower overall and mental workload compared to the console surgeon.[82] Importantly, a questionnaire survey reported that only a small percentage of robotic surgeons (17%) received ergonomic training prior to practice.[38]

In conclusion, robotic surgery offers several ergonomic benefits over traditional open or laparoscopic surgery. It allows for more ergonomic positioning for the surgical team, improved visualisation of the operative field, more precise instrument control, and reduced smoke and noise exposure. These benefits can improve surgical outcomes and reduce the risk of injuries for the surgical team. However, more studies are needed to explore the long-term effects of robotic surgery on the ergonomics and health of the surgical team.

Based on the mentioned evidence, we propose an ergonomics checklist for the minimally invasive gynaecological surgeon (Table 1) to safeguard his/her own well-being and the well-being of the surgical team.

Discussion

Even though, when confronted with questionnaires, surgeons answer that ergonomics should be part of minimally invasive gynaecological surgery training, less than 20% of surgeons report ergonomic training during residency and fellowship, and less than two-thirds of surgeons with one-time training in ergonomics incorporate those principles into practice.[83,84]

Work-related MSDs have an enormous impact on work absenteeism and decreased productivity.[85] Moreover, they have a negative impact on the healthcare professionals quality of life.[86] Entering the OR, gynaecological minimally invasive surgeons follow guidelines and standard operating procedures to ensure patient safety. Unfortunately, surgeon safety has received little attention in the demanding and developing field of minimally invasive surgery, creating an environment in which "patients benefit while surgeons suffer".[84] Hence, we propose that proper ergonomics are integrated in the preoperative team-time-out checklists of minimally invasive gynaecological surgery. Additionally, and in this context, "we should stand by our surgical assistants"[87] and ensure that all our colleagues, including, in particular, the second assistant, frequently seated between the legs do have proper ergonomic conditions and unhindered vision of the monitors. In robotic surgery, care should

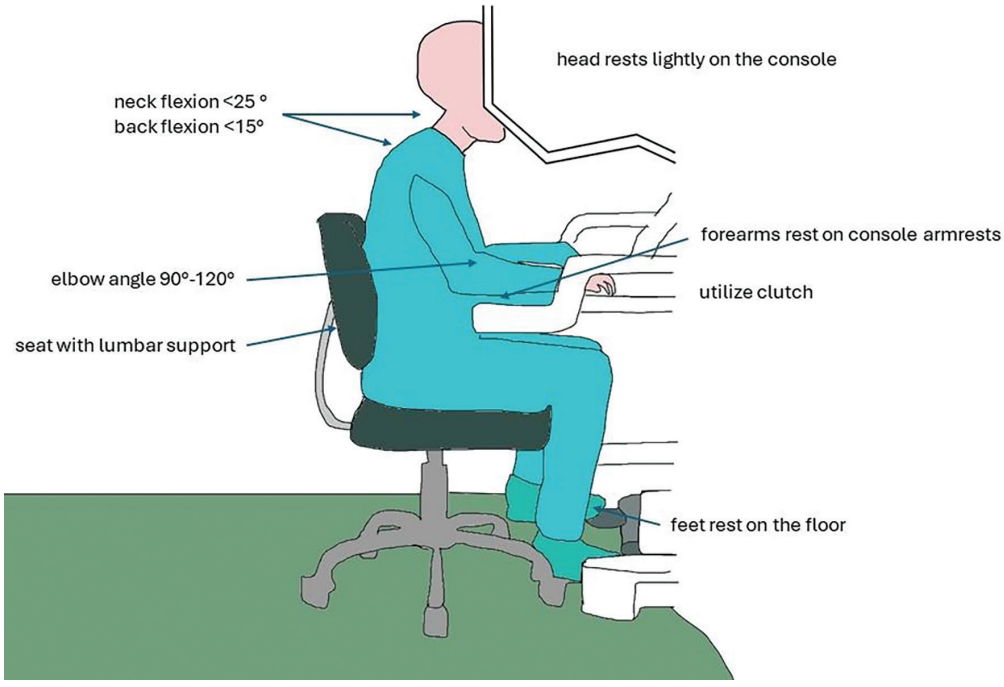

Figure 2. Recommended posture for gynaecological robotic surgery.

Table 1. Proposed ergonomic checklist for minimally invasive gynaecological surgery.
Patient positioning, room settings
Patient positioning, i.e. arms should not interfere with the surgeon
The operating table must be adjusted to optimise the surgeon's posture, and avoid using stools
The monitor should be slightly below eye level, at the level of hands, to maintain a neutral neck posture
Instrumentation
Ergonomically designed and familiar instruments, which use trigger locks and ratchets, should be used to minimise sustained gripping
Surgeon positioning
Keep your back straight, shoulders relaxed, and feet flat on the floor
The wrists should be straight and not bent, with the hands and fingers relaxed. when available, use the instruments' rotation
Organizational
Surgeons should take regular, preferably preplanned breaks during long procedures to rest and stretch their muscles
If possible, switch to robotics for complex operations
In robotics, follow the exact console instructions for ergonomic adjustment
Communicate ergonomic difficulties, encourage assistants to speak out

be taken that the assistants are not threatened by the sudden movements of the robotic arms.

The American College of Surgeons Division of Education established a Surgical Ergonomics Committee to systematically address the ergonomic challenges experienced by surgeons and improve their ergonomic well-being.[66] A well-documented recommendations bulletin with detailed general and technique-specific recommendations has been issued in 2022.[88] Worldwide, many hands-on laparoscopic training courses focus on ergonomic improvements and teach the proper OR settings.

Rehearsal of surgical techniques through simulation training enables tutors to demonstrate the appropriate posture and surgical technique as well as the correct utilisation of surgical instruments, hence significantly contributing to ergonomic improvements.[89] In this context, it is possible to assess ergonomics from video recordings during simulation training using automated movement assessment tools. The results can enable trainees to improve their posture and skills at the very early stages of their surgical career.[90]

Switching to robotic-assisted laparoscopy can be seen as an ergonomic upgrade in most scenarios. Additionally, current robotic surgical systems facilitate the central collection of real-time surgical data. These data can be analysed and, given the ability to integrate multiple sources simultaneously and the advances in artificial intelligence, console ergonomics are likely to be further improved to fit most surgeons.[91] However, the availability of this infrastructure is still scarce due to cost.

This report focuses on the importance of improved ergonomics for surgeons' well-being. However, it has been shown that many incidents which affect patient safety can be attributed to poor ergonomics of healthcare personnel.[92] Even though there is high-quality data that demonstrates that workplace ergonomics improve outcomes, especially in healthcare, the direct effect of improvements in laparoscopy ergonomics on complication rates is yet to be measured.

In modern healthcare, financial cost arises as an important factor in decisions and planning. Providing the training, settings and infrastructure for optimal ergonomics in the high-tech setting of modern ORs will, inevitably, commit financial resources. Therefore, the decision makers acceptance of ergonomic improvements in minimally invasive gynaecological surgery will increase if this improvement proves to be cost-effective. Indeed, ergonomic interventions have proven themselves cost-effective through predictive cost-benefit analyses in most industries and can be seen as a safety intervention.[93] Hopefully, future regulatory changes in occupational safety will facilitate these improvements internationally.

Strengths and Strengths and Limitations of the Study

There are obvious limitations in the applicability of recommendations on optimal ergonomics in minimally invasive gynaecological surgery: Exceptions should be

made to fit the anthropometric differences between surgeons or special situations such as pregnancy or obesity, as well as the target anatomy of the patient.[94] Additionally, some interventions will not be possible in some institutions due to financial reasons.

Conclusion

This review has demonstrated the importance of ergonomics in minimally invasive gynaecological surgery and that general recommendations regarding ergonomic interventions are possible. Along with our commitment to the well-being of the patients, it is our responsibility as physicians to ensure optimal conditions for our working environment.

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REVIEW ARTICLE

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Improving efficacy and safety of surgery in benign gynaecology: the case for indocyanine green

Rebecca Mallick, Bomee Kim, Ian Nouvel

Department of Obstetrics and Gynaecology, University Hospitals Sussex NHS Foundation Trust, Princess Royal Hospital, Lewes Road, Haywards Heath, UK

ABSTRACT

Indocyanine green (ICG) with near-infrared imaging is a valuable adjunct in minimally invasive gynaecological surgery, enhancing anatomical visualisation and surgical precision. This narrative review synthesises current evidence on ICG's clinical applications, safety, and practical implementation in benign gynaecology. ICG supports bladder and ureteric identification, cavity integrity checks, and assessment of bowel and ovarian perfusion. It also aids detection of endometriosis lesions, though diagnostic accuracy remains variable. ICG is safe and feasible, with growing evidence supporting its role across a range of procedures. Further research is needed to standardise protocols, assess cost-effectiveness, and support broader adoption in clinical practice.

Keywords: Fluorescence imaging, ICG, indocyanine green, ureteric identification, perfusion, surgical safety

Introduction

Indocyanine green (ICG) is a versatile compound with a well-established safety profile and growing applications in minimally invasive surgery, particularly for assessing vascular perfusion and visceral integrity.[1,2] When illuminated with near-infrared (NIR) light, ICG emits infrared fluorescence, detectable by specialised imaging equipment. The introduction of NIR imaging with laparoscopic and robotic cameras has accelerated the adoption of ICG in minimally invasive surgeries. This paper aims to consolidate the growing body of evidence on ICG in benign gynaecology and provide practical guidance for its safe use, addressing the current lack of comprehensive, clinically focused reviews on the topic. By doing so, we seek to increase user confidence, reduce intra-operative complications, promote earlier recognition of injuries, and prevent severe long-term sequelae. Practical techniques for safely integrating ICG into practice will also be detailed, highlighting its potential to improve surgical outcomes.

Methods

Study Design

A comprehensive literature review was conducted to evaluate the clinical applications, efficacy, and safety of ICG in benign gynaecological surgery. The study synthesised data from clinical trials, systematic reviews, feasibility studies, and case reports to assess ICG's role in improving surgical precision, reducing complications, and enhancing anatomical and pathological detection.

Search Strategy and Data Sources

A systematic search of the literature was performed using databases such as PubMed, Embase, and Cochrane Library. The search included peer-reviewed

Corresponding Author: Rebecca Mallick, MBChB, FRCOG, Department of Obstetrics and Gynaecology, University Hospitals Sussex NHS Foundation Trust, Princess Royal Hospital, Lewes Road, Haywards Heath, UK
E-mail: r.mallick@nhs.net **ORCID ID:** orcid.org/0000-0001-7516-9132
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articles using a combination of Medical Subject Headings and keywords related to "Indocyanine Green," "ICG fluorescence," "benign gynaecology," "laparoscopic surgery," "robotic surgery," "endometriosis," "tubal patency," "ureteric injury," and "vascular perfusion."

Inclusion Criteria

Studies on ICG in benign gynaecological procedures were included, encompassing various research types such as trials, case reports, and reviews. These studies evaluate its effectiveness, safety, and feasibility in surgery, with a focus on surgical precision, anatomical identification, blood flow, and complication rates.

Exclusion Criteria

Studies exclusively focused on gynaecological oncology, non-English articles without translation, reviews without original data, and research lacking clear outcome measures were excluded.

Data Extraction and Analysis

The extracted data included study design and sample size, the type of benign gynaecological procedure performed, and details on dosage, route of administration, and imaging techniques used. Outcomes assessed encompassed efficacy in anatomical identification, complication rates, surgical precision, safety, diagnostic accuracy, and postoperative recovery.

Limitations and Biases in Study Methodology

A narrative synthesis of the findings was performed, categorising results by the specific surgical application of ICG, including bladder demarcation, ureteric identification, bowel and ovarian perfusion assessment, tubal patency testing, and endometriosis lesion detection.

Indocyanine Green Administration Protocols

Standardised ICG dosing and administration techniques were identified from the literature and summarised in Table 1. The protocols included intravenous, intrauterine, intravesical, intravaginal, and intra-fibroid injection methods. The primary objective was to provide practical guidance for clinicians to ensure consistent and safe application of ICG in benign gynaecological surgery.

Ethical Considerations

As this study involved a review of existing literature, no ethical approval was required. However, ethical considerations from the included studies were reviewed to ensure compliance with international clinical research standards.

Results

ICG has versatile applications across various surgical disciplines, including hepatopancreatobiliary, colorectal, cardiac, ophthalmic, and gynaecological oncology surgery.[1,3] Once administered intravenously, ICG remains largely unmetabolised and undergoes rapid hepatic clearance by liver parenchymal cells into bile. Studies indicate that approximately 95% of intravenously administered ICG remains plasma-bound, allowing it to stay predominantly within the intravascular compartment. This property minimises its absorption and impact on surrounding tissues, making it an effective and safe tool for intraoperative imaging.[4]

ICG is generally accepted as a safe, non-toxic substance, with approval from international regulatory bodies for use in medical diagnostics.[5,6] Adverse effects are rare. In a prospective study involving 1,226 patients, only five cases of moderate to severe reactions were reported, and no deaths were associated with ICG administration.[7] These reactions included non-fatal anaphylaxis and urticaria, which were promptly recognised and treated without long-term consequences. The primary precaution with ICG administration is to avoid its use in patients with known iodide allergies.[6]

ICG is manufactured as a dry powder, typically distributed in 25 mg vials, and reconstituted in sterile water to create a 2.5 mg/mL solution. This solution can be administered via various routes, such as intravenous. Once prepared, the solution remains stable for use throughout the operative day. However, when exposed to daylight at room temperature, its fluorescence intensity declines by 8–16% per day during the first three days. To maintain maximum efficacy, ICG solutions should be stored at low temperatures (approximately 4 °C) and protected from light. Due to spectral instability, ICG should only be dissolved immediately before use.

Intravenous administration of ICG to assess tissue perfusion and viability typically involves a dose of 2.5 mg per bolus, administered slowly to minimise the risk of adverse reactions. Due to ICG's hepatic clearance, lower doses are preferred for patients with impaired liver function. In healthy individuals, ICG has a half-life of approximately 3–4 minutes, with rapid clearance from the bloodstream within 15–20 minutes via the liver and excretion into bile. This quick clearance makes ICG ideal for procedures requiring immediate vascular imaging or perfusion assessment, as it provides real-time information

without lingering effects.[6] Additionally, the rapid half-life enables repeated dosing without the risk of false positives.

For similar applications, intravenous methylene blue has been explored. However, methylene blue is associated with greater adverse effects and false negatives due to its metabolite, leukomethylene blue, being colourless.[5,8] This further underscores ICG's superiority for real-time vascular and perfusion imaging.

Clinical Uses of Indocyanine Green

ICG is a well-established technique for sentinel lymph node detection in gynaecological oncology, as demonstrated in the landmark FILM trial, which identified ICG as superior to methylene blue due to its high uptake and enhanced visualisation in laparoscopic procedures.[3] In addition to its superiority over methylene blue, ICG has also demonstrated superior detection rates when compared with technetium-99m (Tc99m) with methylene blue dye. In a meta-analysis by Baeten et al.[9], ICG was associated with significantly higher bilateral sentinel lymph node detection rates compared to Tc99m (88.6% vs 76.5%, $P<0.001$), supporting its emerging role as a preferred tracer in minimally invasive sentinel lymph node mapping procedures. Beyond sentinel lymph node detection, ICG has been explored in a variety of experimental applications, including assessing vaginal cuff perfusion, identifying nerves during nerve-sparing radical hysterectomies, and evaluating the viability of flap reconstructions in vulval cancer.[10,11] Although these methods are limited to small-scale case series and reports, they highlight the broad potential scope of ICG in advancing surgical practice.

With laparoscopic and robotic approaches now the preferred methods for abdominal surgery in benign gynaecological cases, ICG has emerged as an invaluable tool for demarcating key anatomical structures, minimising intra-operative complications and ultimately expediting recovery and reducing adverse surgical outcomes. Numerous case reports, case series, and video publications have demonstrated the use of ICG in benign gynaecology. However, there remains limited guidance and consensus on its use. Current applications include:

- **Demarcating the bladder and assessing bladder wall integrity:** Particularly useful post-hysterectomy or during complex surgeries to avoid injury.

- **Ureteric identification and vascularity assessment:** Enhances safety during pelvic dissections.

- **Identification of the uterine cavity and integrity assessment:** Post-myomectomy or adenomyomectomy.

- **Delineation of vaginal mucosa:** Improves precision in vaginal surgeries.

- **Assessing tubal patency:** Facilitates minimally invasive evaluation of fallopian tube function.

- **Assessing bowel perfusion in complex endometriosis surgery:** Ensures vascularised anastomoses and reduces complications.

- **Assessing ovarian perfusion in acute torsion:** Aids in determining ovarian viability and guiding surgical decisions.

- **Identification of endometriotic implants:** Enhances visualisation of diseased tissue during excision procedures.

These examples underscore ICG's growing role in benign gynaecology, though further research and standardised guidelines are needed to optimise its application

Demarcating the Bladder and Assessing Bladder Wall Integrity Post Hysterectomy/Complex Surgery

The incidence of bladder injury during laparoscopic hysterectomy is estimated to be 0.02–0.7%,[12] often occurring when the posterior bladder dome is reflected from the lower uterine segment during development of the utero-vesical (UV) fold prior to colpotomy. Adhesions at the UV fold are common following caesarean sections. Studies report adhesions in approximately 24% of patients after one caesarean delivery and up to 83% after three caesarean deliveries,[13] adding technical challenges and increasing the risk of urinary tract injury during hysterectomy.

With the increasing incidence of caesarean deliveries and adhesions, intra-operative ICG fluorescence serves as a crucial adjunct to safe surgical practice by clearly demarcating the bladder edge, enhancing the surgeon's confidence, and reducing the risk of bladder injury (Figure 1a). This is achieved by diluting 25 mg of ICG into 200 mL of sterile water and instilling the required volume into the bladder via a urinary catheter and bladder syringe (Table 1).

Historically, cystoscopy or bladder inflation with saline or methylene blue dye has been used to assess bladder injury. However, saline is colourless and may fail to detect small leaks, while methylene blue can disrupt visual clarity, particularly in cases of leakage. In contrast, ICG fluoroscopy provides superior visualisation, as the

NIR light can be turned off as needed[14-17] and avoids unwanted staining of the pelvic cavity. Yoshida Ueno et al.[15] have standardised the 'ICG-washout' technique (where instillation and subsequent drainage of ICG from the bladder allows for improved identification of the bladder dome) ensuring adequate safety margins during colpotomy. Additionally, real-time ICG fluorescence has been successfully applied in the robotic excision of bladder wall endometriosis, facilitating precise resection while preserving uninvolved bladder tissue.[16] A further case report described ICG-guided bladder nodule shaving in deep infiltrating endometriosis (DIE), demonstrating how fluorescence imaging can assist in delineating the nodule and ensuring complete excision with minimal collateral damage.[17]

Delineation of Vaginal Mucosa

Intravaginal dye is a well-established technique for highlighting the edges of the vaginal mucosa to ensure precise vault closure, with studies estimating a reduction in dehiscence rates by 0.64%–1.35%.[18] This technique is particularly valuable not only for vault closure but also in cases requiring resection of full-thickness endometriotic nodules (Figure 1b). While methylene blue has traditionally been used for this purpose, ICG offers a safe and cost-effective alternative that enhances visualisation during laparoscopic surgery by providing superior fluorescence under NIR light (Table 1).

Menezes and Rao[19] demonstrated that vaginal ICG application can effectively delineate the rectovaginal plane in patients with distorted pelvic anatomy, significantly improving real-time anatomical visualisation and easing surgical navigation during complex endometriosis surgery.

Sarofim et al.[20] replaced traditional tactile guidance during laparoscopic sacrocolpopexy with direct injection of ICG into the vaginal walls to identify optimal dissection sites on the anterior and posterior compartments. Fluorescence imaging enabled precise localisation without the need for vaginal manipulation or tactile cues, simplifying the procedure and supporting future robotic adaptations.[20]

A further novel application of ICG was recently described by Khazali et al.[21] In this case, an endometriotic vaginal nodule was 'tattooed' with ICG by injecting 1 mL of a 2.5 mg/mL ICG solution (prepared by diluting 25 mg of ICG in 10 mL of sterile saline) trans-vaginally into the vaginal mucosa just below the nodule margin. This technique allowed clearer visualisation of the nodule, facilitating precise excision while preserving normal vaginal tissue.

Identification of the Uterine Cavity and Assessing Integrity Post Myomectomy/Adenomyomectomy

A common concern with myomectomy is the potential risk of uterine rupture in subsequent pregnancies. Although rare, uterine rupture is associated with significant maternal and foetal mortality. Further studies are needed to determine intra-operative factors influencing the risk of rupture; however, the breach of the endometrial cavity during myomectomy is an important consideration. This factor should be addressed when counselling patients about the timing and mode of delivery in future pregnancies.[22] Intra-operative identification and repair of endometrial defects are therefore crucial to reduce the risk of complications.[23]

ICG is well absorbed by endometrial tissue but minimally by myometrium or fibroid tissue, effectively delineating the endometrial border and aiding in the prevention of cavity breaches during myomectomy. This also facilitates the identification and closure of small breaches. To

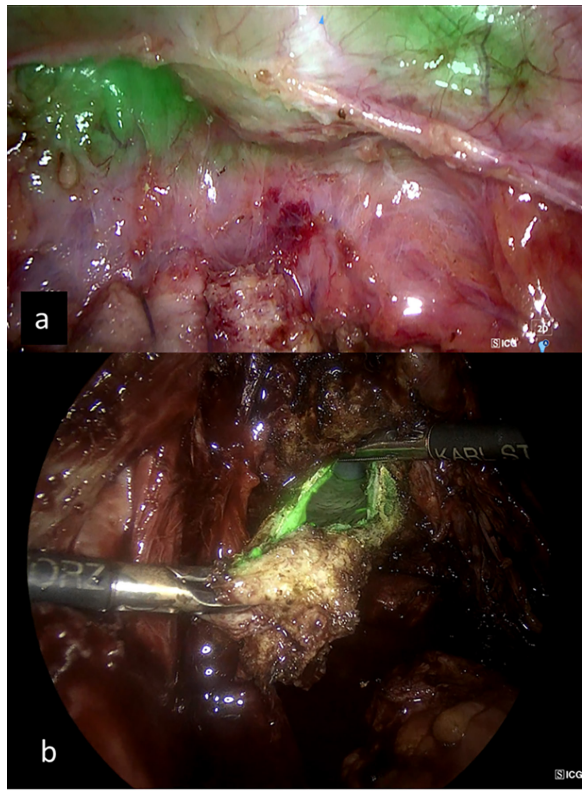

Figure 1. a) ICG instilled in the bladder following total laparoscopic hysterectomy to rule out bladder injury. b) Vaginal ICG to aid demarcation in a full thickness vaginal wall nodule resection.

ICG: Indocyanine green.

achieve this, ICG is injected through the cervix using a uterine manipulator or injector (Table 1). The ICG rapidly absorbs into the endometrial tissue, clearly marking the cavity. Any fluorescence leakage observed during the procedure or during a final inspection indicates a breach of the endometrial cavity, enabling prompt repair.[23]

Naem et al.[24] proposed a novel use of ICG during myomectomy. They hypothesised that injecting ICG directly into a myoma could help clearly delineate the borders of the pseudo capsule. This technique may facilitate easier identification of fibroid boundaries, enabling successful complete resection while minimising blood loss.[24]

Laparoscopic or robotic niche repair is a challenging gynaecological procedure with variable outcomes. Krentel et al.[25] described a novel use of ICG to clearly demarcate the uterine niche prior to laparoscopic surgery. The use of ICG eliminates the need for a secondary stack system and concomitant hysteroscopy. The authors highlight several benefits, including immediate niche visibility, the ability to clearly identify resection margins, and the avoidance of unnecessary adhesiolysis and tissue preparation. These advantages may streamline the procedure and improve surgical precision and highlighting yet another potential use of ICG.

Assessing Tubal Patency

The tubal dye test is a key component in evaluating subfertility and has traditionally been performed using methylene blue dye. ICG offers several advantages over methylene blue, enabling real-time visualisation of tubal patency through fluoroscopic transillumination. Unlike methylene blue, ICG can be administered prior to operative manipulation, reducing the risk of false negatives caused by tubal spasm (Figure 2).[21,26,27] Additionally, ICG remains transparent under normal lighting, avoiding unwanted staining of pelvic organs that could hinder the surgical procedure. The same technique is employed by injecting ICG through the cervix using a uterine manipulator or injector (Table 1).

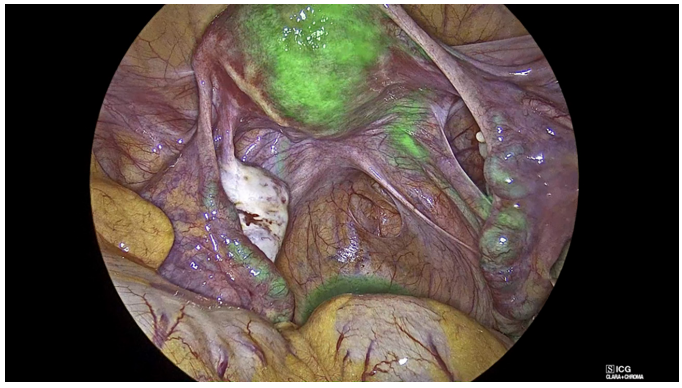

Figure 2. ICG tubal dye test prior to excision of endometriosis via uterine manipulator.

ICG: Indocyanine green.

Ureteric Identification and Assessment of Ureteric Vascularity

Although ureteric injuries during pelvic surgery are uncommon, they carry significant morbidity. Approximately 70% of iatrogenic ureteric injuries are not identified intra-operatively and are diagnosed in the post-operative period.[28] In gynaecological surgery, ureteric injuries are most likely to occur in cases of significant anatomical distortion, such as deep invasive endometriosis and cervical or broad ligament fibroids. Prophylactic ureteric stenting, a strategy debated in the past as a means of reducing intra-operative complications, is generally considered disadvantageous for preventing injuries. Current consensus suggests it should be reserved for a select group of high-risk patients.[29] Ureteric stent insertion, while necessary in many cases may be associated with increased morbidity. A review of >50,000 cases described common complications such as bladder irritability, haematuria, back/loin pain and urinary tract infections.[30] Less common, but more severe complications included stent migration, stent obstruction and ureteric perforation.

ICG and ureteric mapping provide a safe and effective way to assess ureteric location and integrity in real time during complex pelvic surgeries. Real-time visualisation enhances surgical confidence and reduces the risk of unnoticed ureteric injuries. This is achieved via cystoscopy and ureteral catheterisation (Figure 3a), delivering 4–12 hours of fluorescence. In our practice, a 25F rigid cystoscope and 6F ureteric catheters are used, with 5 mL of dilute ICG (25 mg in 10 mL sterile water) instilled 1–2 cm into the ureteric orifice. Using smaller catheters and limiting insertion depth minimises risks associated with larger stents, offering a safer approach.

A pilot RCT, the ICE trial (Indocyanine Green versus Conventional Ureteric Stenting in Endometriosis Surgery), will compare ICG-guided ureteric identification with stenting. The study will assess whether ICG can reduce operative time, post-operative pain, and stent-related morbidity.[31]

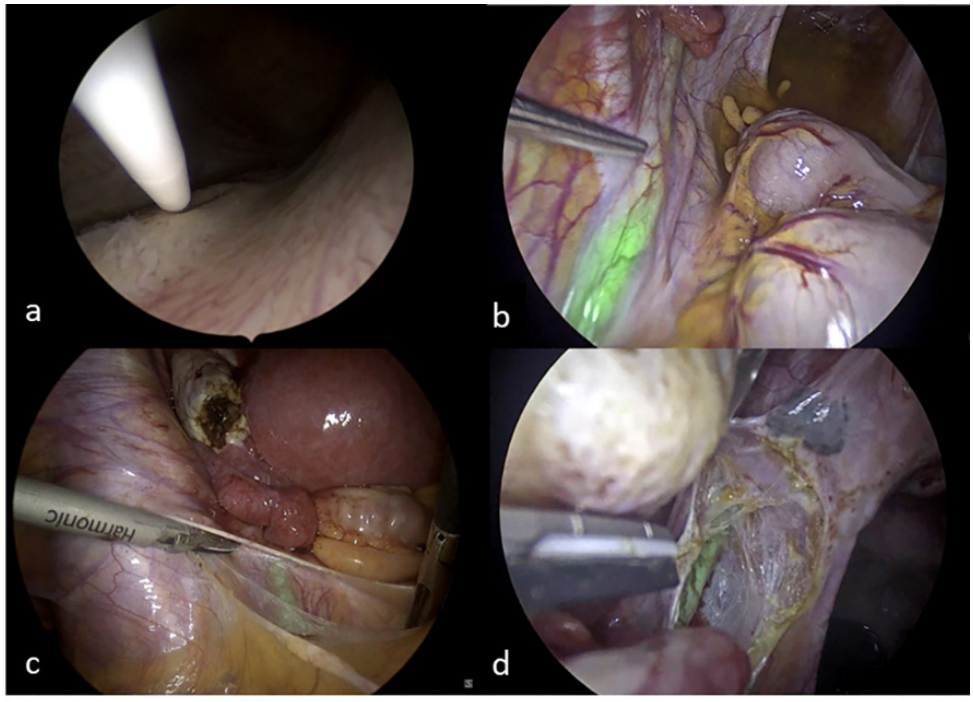

Figure 3. Stepwise fluorescent visualisation of the ureter in laparoscopic excision of endometriosis. a) Cystoscopy-guided ureteric catheterisation for ICG administration, b) identification of the ureter prior to ureterolysis, c) ureterolysis in frozen pelvis guided by ICG, d) ureterolysis and excision of endometriotic nodule on the left USL.

ICG: Indocyanine green, USL: Uterosacral ligament.

The first reported use of ICG for ureter identification was by Lee et al.[32] during robot-assisted ureteroureterostomies, demonstrating its value in real-time ureter visualisation and distinguishing healthy from diseased tissue without complications. In gynaecology, Park and Farnam.[33] used ICG with NIR imaging for ureter mapping during endometriosis surgery, enhancing localisation of lesions, surgical precision, and reducing tissue damage. Similarly, Siddighi et al.[34] reported a 100% success rate in ureter visualisation without intra- or post-operative complications. Mandovra et al.[35] validated ICG as a reliable, cost-effective, and user-friendly tool for pelvic surgeries in a cohort of 30 cases.

ICG is a valuable tool for assessing ureteric vascularity after complex dissections via intravenous administration, enabling the detection of adventitial de-vascularisation and tissue hypoperfusion for prompt diagnosis and intervention. Raimondo et al.[36] evaluated NIR-ICG imaging during endometriosis and ureterolysis procedures, reporting an average procedural time of 5.4 minutes for 31 ureters with no adverse events. NIR-ICG was particularly effective in identifying ischemic areas undetectable under standard lighting, facilitating critical intraoperative decisions such as stent placement. The method was reproducible amongst the surgical team, with excellent clinical and radiological outcomes. The authors concluded that NIR-ICG is a safe, efficient, and reliable technique for assessing ureteral vascular integrity, enhancing decision-making in complex surgical cases.

Assessing Bowel Perfusion in Segmental Bowel Resection for Deep Infiltrating Endometriosis

DIE often affects multiple pelvic and abdominal organs, necessitating complex multidisciplinary surgical management. For symptomatic patients with advanced bowel involvement, treatment options include bowel shaving, disc excision, or segmental bowel resection. However, the complexity of these procedures increases the risk of long-term morbidity, particularly in cases of bowel ischaemia and anastomotic leaks.

Studies have highlighted the clear benefits of utilising intraoperative ICG to assess bowel vascularity and integrity, particularly in colorectal disease.[37] A meta-analysis by Liu et al.[38] reviewed over 4,000 patients and demonstrated a significantly reduced anastomotic leak rate in the ICG group [3.8% vs. 7.8%, odds ratio: 0.44; 95% confidence interval (CI): 0.33–0.59; $P<0.00001$]. Furthermore, a more recent systematic review and meta-analysis by Elmajdub et al.[39] reported a 45% reduction in anastomotic leaks.

Table 1. Summary of ICG administration route and suggested dosage.

Use	Administration	Dilution	How it is given	References
Bowel vascularity Ureteric vascularity Ovarian vascularity Endometriosis identification	IV	25 mg ICG in 10 mL sterile water 2.5 mg/mL 1 mL injection = 2.5 mg	3 mL (7.5 mg) followed by a 10 mL saline flush Boluses can be repeated	31,32,35,36,38,42,47
Tubal patency Cavity check	Into uterus	25 mg ICG diluted into 50 mL sterile water	Via uterine manipulator	21,26,27
Ureteric visualisation	Into ureteric orifices	25 mg ICG in 10 mL sterile water 5 mL into each ureter	6F ureteric catheters and 25F cystoscope	28-30
Demarcation of bladder/check bladder injury	Into bladder via catheter	25 mg ICG diluted into 200 mL sterile water	Via bladder syringe	15
Vaginal mucosa	Intravaginal application e.g. swab in vagina	25 mg ICG in 10 mL sterile water	10 mL of 2.5 mg/mL	19-21
Fibroid capsule	Intra-fibroid injection	25 mg ICG in 10 mL sterile water	3 mL of 2.5 mg/mL	24

ICG: Indocyanine green, IV: Intravenous.

Although data specific to endometriosis is limited, the first documented use of ICG during bowel resection for endometriosis was reported in 2018 by Seracchioli et al.[40] They described the intravenous use of ICG to delineate a precise dissection plane between well-perfused healthy bowel and hypovascular endometriotic nodules. Before resection and anastomosis, ICG allowed for a visual assessment of the blood supply to the anastomosis, potentially reducing post-operative risks. A feasibility study by Raimondo et al.[36] evaluated the use of NIR-ICG imaging to assess bowel vascularisation and guide the transection line following full-thickness bowel resections (segmental and discoid) for endometriosis in 32 patients. No adverse reactions to ICG were reported, and the average assessment time was 3–5 minutes. The study demonstrated excellent intraoperator agreement, and the authors concluded that NIR-ICG imaging for anastomotic perfusion assessment after discoid or segmental resections for rectosigmoid endometriosis is a feasible, safe, and reproducible method.

An example of the assessment of bowel vascularity is demonstrated in Figure 4, where ICG has been administered intravenously to reveal adequate perfusion (Table 1).

ICG also appears to have a role in endometriosis bowel shave surgery for assessing bowel integrity and identifying potential ischaemic areas. Bourdel et al.[41] conducted a study involving 21 patients undergoing laparoscopic surgery for DIE and rectal shaving, aiming to use intravenous ICG to assess the vascularity of shaved areas and potentially reduce postoperative complications such as fistulas. Intravenous ICG was administered following the shave procedure, and fluorescence was visually assessed using a Likert scale.

The results showed no adverse reactions to ICG, with 81% of patients demonstrating very good fluorescence at the rectal shave site. In one case, additional sutures were placed, which improved fluorescence. No post-operative bowel complications occurred. The authors concluded that ICG fluorescence imaging is feasible in endometriosis surgery and may serve as a valuable tool to enhance patient safety in bowel surgery for endometriosis.

Assessing Ovarian Perfusion in Acute Torsion

In cases of ovarian torsion, the decision between oophorectomy, detorsion, or cystectomy largely relies on the surgeon's visual assessment of the ovary intraoperatively. While this decision-making process has significant implications, no standardised guidance or assessment techniques currently exist to evaluate ovarian perfusion and salvageability. Nicholson et al.[42] conducted a feasibility study using ICG in 12 confirmed cases of surgical ovarian torsion. ICG fluorescence was visualised

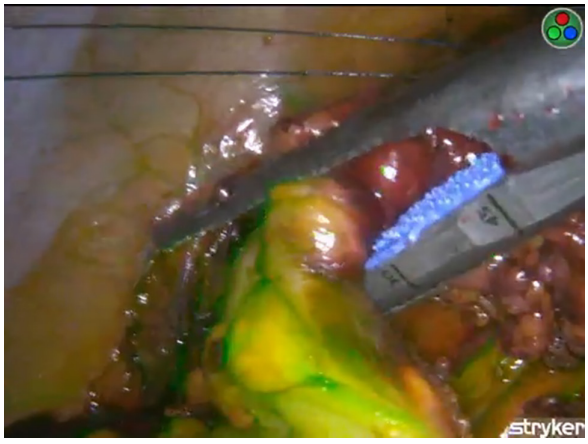

Figure 4. Assessing bowel vascularity with intravenous ICG prior to anterior resection.

ICG: Indocyanine green.

in the detorted adnexa in 10 out of 12 cases following intravenous administration, enabling partial or total ovarian conservation, even in a case where preoperative Doppler flow was absent.[42]

The evidence suggests that ICG can provide clinically valuable information during laparoscopy, reserving oophorectomy for cases of established necrosis, indicated by the absence of ICG fluorescence.[43] This approach has the potential to reduce unnecessary oophorectomies in young women, which can have devastating long-term consequences.

Identification of Endometriotic Implants

During endometriosis surgery, one of the most significant challenges remains the accurate diagnosis of endometriosis, despite advancements in surgical techniques. These challenges arise from the polymorphic and diverse appearance of endometriosis within the pelvis. This variability can lead to misdiagnosis, underestimation of disease depth, and incomplete removal of nodules. Such outcomes may contribute to disease progression and increased recurrence rates.[37]

Recurrence rates for endometriosis vary widely, ranging from 5% to 50%, depending on several factors. Therefore, any adjunct that aids in detecting endometriosis, particularly subtle disease during laparoscopy, is essential. Given the high degree of neovascularisation associated with endometriotic nodules, ICG may play a role in improving detection. However, the evidence in the current literature remains variable.

Cosentino et al.[44] conducted a single-centre prospective study evaluating 27 patients. The study aimed to assess the use of NIR-ICG during laparoscopic surgery for identifying endometriosis lesions. NIR-ICG was found to effectively detect both visible and occult endometriotic lesions, with a positive predictive value of 97.8% and a negative predictive value of 82.3%. However, not all lesions were identified, and the authors concluded that NIR-ICG should complement, rather than replace, white-light evaluation.

The Gre-Endo trial, a prospective single-arm study by Turco et al.[45], evaluated the use of NIR imaging with ICG for the detection of endometriosis lesions during surgery. After an initial exploration using white light (WL) mode, patients received an ICG injection and were subsequently examined using NIR mode. Lesions were classified based on their visualisation with WL, NIR-ICG, or a combination of both.

Of the 240 lesions identified, 207 (86.2%) were detected with WL imaging, with 200 confirmed as true positives. The remaining 33 lesions (13.8%) were only identified with NIR-ICG and were all confirmed as pathological, indicating a 100% detection rate for occult lesions using NIR-ICG.

The authors concluded that NIR-ICG imaging, both alone and in combination with WL, is highly effective for intraoperative detection and fluorescence-guided excision of endometriosis. Additionally, NIR-ICG enabled the removal of occult lesions that might otherwise have been missed, potentially reducing postoperative pain and the risk of disease persistence and relapse.

Conversely, a systematic review and meta-analysis by Zhuang et al.[46] evaluated the diagnostic efficacy of intraoperative ICG imaging compared to traditional WL imaging. The analysis included six studies and found that, although ICG imaging may assist in visualising occult endometriosis lesions, it did not demonstrate superior diagnostic accuracy over WL imaging. The sensitivity for WL was reported at 0.88 (95% CI: 0.81–0.93), compared to 0.64 (95% CI: 0.36–0.84) for ICG. Similarly, the specificity for WL was 0.85 (95% CI: 0.49–0.97), compared to 0.88 (95% CI: 0.66–0.97) for ICG.

Furthermore, Siegenthaler et al.[47] conducted a prospective study evaluating the role of NIR-ICG imaging in endometriosis detection. While ICG identified additional lesions beyond standard WL imaging, only one was histologically confirmed as endometriosis. The authors concluded that NIR-ICG has limited diagnostic value but may aid in resecting

Table 2. Summary of clinical applications of indocyanine green (ICG) in benign gynaecological surgery.

Application	Purpose	Route of administration	Key benefit	References
Bladder demarcation	Identify bladder margins and assess injury	Intravesical (via catheter)	Reduces risk of bladder injury during dissection	15
Ureteric visualisation	Intraoperative mapping of ureters	Intracystic → ureteric catheter	Enhances safety in complex pelvic surgery	35
Ureteric vascularity assessment	Assess blood supply post-dissection	Intravenous	Detects ischaemia and guides stenting decisions	36
Uterine cavity during myomectomy	Detect endometrial breach	Intrauterine (via manipulator)	Enables repair to reduce uterine rupture risk	23
Tubal patency assessment	Confirm tubal patency	Intrauterine (via manipulator)	Real-time visualisation without pelvic staining	27
Vaginal mucosa delineation	Improve vault closure or endometriotic excision	Intravaginal injection or swab	Enhances visualisation and surgical precision	21
Fibroid pseudo capsule delineation	Define resection planes during myomectomy	Intramyoma injection	Minimises bleeding and aids complete resection	24
Uterine niche identification	Mark niche for laparoscopic repair	Intrauterine	Improves accuracy, avoids need for hysteroscopy	25
Ovarian perfusion in torsion	Assess salvageability	Intravenous	Supports ovary-sparing decisions	42
Bowel perfusion (endometriosis resection)	Assess anastomotic vascularity	Intravenous	Reduces risk of post-operative leak	37
Endometriotic lesion detection	Identify occult or deep nodules	Intravenous	Improves completeness of excision	47

deep-infiltrating nodules by improving visualisation and defining tissue borders.

Although there is no definitive consensus, and further randomised controlled trials are needed, ICG appears to be a helpful adjunct in improving the diagnosis of endometriosis and increasing the identification of more subtle lesions.

Discussion

ICG has emerged as a versatile and valuable tool in minimally invasive gynaecological surgery, providing real-time imaging to enhance precision and reduce intraoperative risks. ICG's expanding use in benign gynaecology represents a promising frontier in minimal access surgery, given its fantastic safety profile comparable to conventional diagnostic dyes.[6,7] The advantages of ICG have been discussed in several contexts, including improved visualisation of anatomical structures, more accurate assessment of tissue perfusion, and the ability to make real-time decisions on interventions.[42,48]

The benefits of ICG fluoroscopy are best described in colorectal surgery, where a systematic review undertaken by a panel of experts commissioned by the European Association for Endoscopic Surgery outlined a strong body of evidence to support its use in several surgical procedures, including laparoscopic cholecystectomy and bowel resection surgery.[49]

In this context, administration of ICG to assess vascular perfusion of bowel adventitia has shown a reduction in operative complications and length of hospital admission, and a further budget impact analysis predicted an overall reduction in cost. Further described in this study is a qualitative evaluation of the clinicians' perceptions of intra-operative ICG fluoroscopy, which revealed greater confidence in anatomical identification and described ICG techniques as 'easy to use'. In this context, the use of NIR imaging has the potential to reduce the surgeon's cognitive load and shorten the learning curve for trainee surgeons by providing enhanced visualisation that supports safe procedural navigation to avoid visceral injuries. This facilitates hands-on learning in a controlled and safer environment, allowing trainees to gain experience and confidence while minimising patient risk.

ICG use in benign gynaecology remains limited by the lack of standardised guidelines and the variability in application techniques. So far, few studies have assessed the direct benefit of ICG versus WL or methylene blue

assessment and impact on overall patient morbidity and mortality, particularly in benign gynaecological conditions. Presented in this study are the conventional dosing of ICG utilised in many settings, yet targeted research is needed to establish optimal protocols and dosing strategies to ensure consistent and safe results across different surgical settings. Additionally, accessibility of equipment capable of NIR fluorescence imaging is crucial for the effective implementation of ICG in clinical practice.

While standard dosing protocols for ICG are well established, the visibility and efficacy of fluorescence can vary depending on the imaging platform. Differences in fluorescence sensitivity, signal intensity, and image clarity have been reported between systems, largely due to variability in both hardware and software design.[50] Surgeons should be familiar with their specific equipment and may need to tailor ICG dosage or timing to optimise fluorescence-guided imaging in real time.

Moving forward, developing standardised guidelines and increasing surgeon familiarity with ICG in benign gynaecological surgery could lead to significant improvements in patient safety and postoperative recovery. By addressing these gaps, ICG can become an integral part of gynaecological surgery, enhancing surgical precision and improving outcomes in complex cases.

Strengths and Limitations

This review offers a comprehensive synthesis of current evidence on ICG use in benign gynaecology, aiming to address gaps in practical guidance and support wider adoption in clinical practice. We recognise that the quantitative effects of ICG need further investigation with large-scale prospective studies and randomised controlled trials. The recently launched ICE trial,[31] which directly compares ICG with conventional ureteric stenting, exemplifies the type of evidence needed to fully harness the benefits of ICG in benign gynaecology. Future study of the cost-benefit of ICG fluorescence imaging in laparoscopy is imperative to wider application in clinical practice.

Conclusion

ICG is a valuable adjunct in minimally invasive benign gynaecological surgery, enhancing visualisation, surgical precision, and intraoperative safety. Its applications span tissue perfusion assessment, prevention of urinary tract injuries, and improved detection of endometriosis and ovarian or bowel vascularity. With a strong safety profile and increasing access to NIR imaging, ICG has the potential to improve outcomes across a range of procedures. However, high-quality studies are still needed to define its role in routine practice. Ongoing research, such as the ICE trial,[31] will help clarify its comparative benefits and support evidence-based integration.

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VIDEO ARTICLE

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A combined endoscopic and ultrasonographic approach to a complex U4a uterine anomaly

Gaby Moawad[1], Brunella Zizolfi[2], Danilo Borrelli[2], Giuseppe D'Angelo[2], Fabiola Nardelli[2], Serena Guerra[2], Attilio Di Spiezio Sardo[2]

[1]Department of Obstetrics and Gynecology, The George Washington University, Washington; Center for Endometriosis and Advanced Pelvic Surgery, Washington, DC, USA
[2]Department of Public Health, University of Naples Federico II, Naples, Italy

ABSTRACT

Background: Uterine malformations are congenital anomalies arising from abnormal Müllerian duct development during embryogenesis. These can be linked to vaginal cysts, resulting in complex malformations. One rare form is the unicornuate uterus, where only one duct develops, leading to complications like severe pain due to a rudimentary, non-communicating horn.

Objectives: To describe a combined approach using ultrasound, hysteroscopy, and robotic-assisted laparoscopy for complex uterine anomalies.

Participant: A 30-year-old nulliparous woman with unilateral kidney agenesis and acute pelvic pain referred to our centre.

Intervention: 2D ultrasound suggested a complex malformation. 3D ultrasound and magnetic resonance imaging confirmed a U4a uterus. Hysteroscopy revealed a hemicavity with one tubal ostium. Robotic-assisted laparoscopy enabled right salpingectomy and removal of the rudimentary horn while preserving the ovary. Intraoperative ultrasonography guided the drainage of vaginal cysts. As a result, vaginal cysts were drained, and the rudimentary horn was removed with ovarian preservation. The patient was discharged without complications and spontaneously conceived a healthy pregnancy 8 months later.

Conclusions: Unicornuate uterus with non-communicating horn and renal agenesis is a rare condition. A combined approach using ultrasound, hysteroscopy, and robotic-assisted laparoscopy allows comprehensive evaluation and treatment.

What is New? This is the first reported case of simultaneous and synergistic use of hysteroscopy and robotic-assisted laparoscopy for complex genital malformations under ultrasonographic guidance.

Keywords: Unicornuate uterus, hysteroscopy, robotic-assisted laparoscopy, complex genital malformations, non-Müllerian anomalies

Introduction

The prevalence of unicornuate uterus is approximately 0.1% in the general female population, 0.5% in infertile women, and 2% in those with a history of miscarriage.[1] A unicornuate uterus may be associated with a rudimentary horn, which can be either communicating or non-communicating. One in 35 cases is associated with hematometra due to obstruction of a non-communicating rudimentary horn. The rudimentary horn may or may not contain functional endometrium.[2,3]

Corresponding Author: Brunella Zizolfi, M.D., Ph.D., Department of Public Health, University of Naples Federico II, Naples, Italy
E-mail: brunellazizolfi@hotmail.it **ORCID ID:** orcid.org/0000-0002-3409-7504
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Diagnosis of obstructive Müllerian anomalies typically occurs in adolescence due to blood retention and pain; however, mild menstrual pain may delay diagnosis.

In complex genital malformations, Müllerian anomalies can coexist with non-Müllerian anomalies due to defects in mesonephric duct remnants.[4-7]

We present the case of a 30-year-old nulliparous woman with unilateral kidney agenesis who experienced acute pelvic pain. She was diagnosed with a unicornuate uterus [European Society for Gynaecological Endoscopy/ European Society of Human Reproduction and Embryology (ESGE/ESHRE) U4a classification], featuring a non-communicating horn and associated vaginal cysts.

This case demonstrates the benefit of combining transvaginal ultrasound (2D/3D), hysteroscopy, and robotic-assisted laparoscopy for comprehensive diagnosis and treatment. Ultrasonography provided essential preoperative guidance, while hysteroscopy and laparoscopy facilitated surgical management, including the identification and drainage of vaginal cysts and removal of the rudimentary uterine horn while preserving fertility. This case is notable for being the first to treat a complex uterine anomaly using simultaneous hysteroscopy and laparoscopy under ultrasonographic guidance.

Methods

A 30-year-old nulliparous patient was referred to our centre due to the onset of severe abdominal pain. Her medical history was notable for right unilateral renal agenesis. Additionally, she reported a pattern of light menstruation interspersed with prolonged periods of amenorrhea. Both her personal and family medical histories were unremarkable. From a professional standpoint, she was a classical ballet dancer. Following a thorough clinical and laboratory evaluation, the patient underwent ultrasound assessment, initially with 2D imaging, followed by 3D ultrasound for further anatomical delineation. As an adjunct diagnostic modality, magnetic resonance imaging (MRI) of the abdomen and pelvis was also performed. The diagnostic workup was further complemented by performing an inpatient hysteroscopy using a 5-mm continuous-flow hysteroscope.

Results

Initial 2D ultrasound suggested a complex uterine malformation with a non-communicating rudimentary horn, hematometra, and vaginal cysts. 3D ultrasound and MRI confirmed a Class U4a uterus, as per the ESGE/ESHRE classification. Hysteroscopy revealed a hemicavity with a single tubal ostium. Robotic-assisted laparoscopy successfully facilitated the removal of the rudimentary horn and right salpingectomy. Retroperitoneal access allowed for direct visualization of the ureter to rule out other urological anomalies.

Intraoperative ultrasonography enabled precise identification of the vaginal cysts. The caudal vaginal cyst was drained via a minor incision using a 5Fr electrode, resulting in the release of thick, dark mucus. A separate cranial vaginal cyst was also emptied without complications. The patient was discharged the next day with no adverse events.

Eight months after the surgery, the patient spontaneously conceived and is currently carrying a healthy pregnancy.

Discussion

A unicornuate uterus with a non-communicating rudimentary horn is a rare Müllerian anomaly associated with endometriosis, pelvic pain, and infertility. In this case, Herlyn-Werner syndrome, a complex urogenital anomaly, was excluded through vaginoscopy, which confirmed the absence of an atretic hemivagina anterolateral to the patent vagina. Similarly, imaging ruled out Wunderlich syndrome, as no blind-ending hemivagina was detected. Heller[8] described how mesonephric duct developmental anomalies can lead to Gartner's duct retention, resulting in vaginal cysts, as observed in this patient.[9-11] Acién suggested that mesonephric anomalies may contribute to renal agenesis due to failed ureteral bud sprouting.[12,13] Notably, laterality was evident in our patient's anomalies, including right-sided vaginal cysts, a cavitated non-communicating rudimentary horn, and renal agenesis. The failure of the Wolffian duct's inductive function on the Müllerian duct contributes to uterine duplication and ipsilateral renal agenesis. This developmental mechanism may explain the observed laterality of the anomalies.[14] A combination of ultrasound, vaginoscopy, and robotic-assisted laparoscopy provides a comprehensive approach to diagnosing and treating complex malformations. Bermejo et al.[15] highlighted that 3D ultrasound is comparable to MRI imaging. However, we opted for MRI to rule out any additional urological anomalies.

We chose to drain the cysts due to the patient's new onset of dyspareunia. Imaging and hysteroscopy

showed that the cysts were not large enough to require excision, as noted by Thapa and Regmi[16] Based on the cysts' appearance and according to the findings from Bats et al.[17], we ruled out malignancy risk. To minimize invasiveness, particularly in a young patient, we opted for cyst drainage. This involved creating a wide opening in the cyst wall and selectively coagulating the cyst bed using a 5Fr bipolar electrode for both incision and coagulation. The endoscopic approach enhanced safety through direct visualization, while intraoperative ultrasound offered real-time guidance for identifying and draining vaginal cysts, especially for the second cyst with a more cranial development.

Pre-surgical imaging revealed poorly defined anatomical planes, raising concerns about potential access to the abdominal cavity during hysteroscopic drainage of the vaginal cysts, which were also in continuity with each other. Therefore, we opted for a robotic approach, which, in addition to the inherent advantages of laparoscopy—minimized blood loss, accelerated recovery, and next-day discharge—provides enhanced precision and control, particularly in cases with complex or unclear anatomical structures. Furthermore, the dual endoscopic approach provided definitive treatment in a single procedure, avoiding further surgeries. Moreover, the patient later achieved a spontaneous pregnancy, demonstrating the success of this multidisciplinary approach in preserving fertility.[18]

The patient sought care after experiencing her first episode of severe pelvic pain. Her prolonged amenorrhea, likely a result of the intense physical and emotional demands of her career as a professional classical ballet dancer, may explain why the condition went undetected until adulthood.

This is the first reported case of treating a complex female genital malformation using simultaneous vaginoscopy and laparoscopy under ultrasonographic guidance, presenting a promising approach for similar cases in the future.

Conclusion

A unicornuate uterus with a non-communicating rudimentary horn and ipsilateral renal agenesis represents a rare and complex clinical condition. In this case, the combination of Müllerian and non-Müllerian anomalies required a multidisciplinary approach involving 2D/3D ultrasound, hysteroscopy, and robotic-assisted laparoscopy.

This approach allowed for comprehensive evaluation and treatment, ensuring preservation of the patient's fertility and leading to a favourable outcome, including a spontaneous pregnancy. Intraoperative ultrasonography provided crucial real-time guidance, particularly for the identification and management of vaginal cysts.

To our knowledge, this is the first reported instance of simultaneous hysteroscopy and laparoscopy under ultrasonographic guidance for treating such a rare and complex malformation. This combined approach offers an effective and minimally invasive solution for managing congenital uterine anomalies and associated conditions.

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Data sharing: The data that support the findings of this study are available from the corresponding author upon reasonable request. Restrictions apply to the availability of these data due to confidentiality agreements and the sensitive nature of patient information.

Transparency: The authors affirm that this manuscript is an honest, accurate, and transparent account of the case reported. All relevant details have been included, and no important information has been omitted. The patient's identity has been protected in accordance with ethical standards.

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Video 1. https://youtu.be/0VOispgg3cE

VIDEO ARTICLE

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Laparoscopic management of caesarean scar pregnancy in 10 steps

Nikolaos Kathopoulis, Konstantinos Kypriotis, Athanasios Douligeris, Michael Panagiotopouloz, Ioannis Chatzipapas, Athanasios Protopapas

1st Department of Obstetrics and Gynecology, University of Athens, Alexandra Hospital, Athens, Greece

ABSTRACT

Background: Caesarean scar pregnancy (CSP) is a pathologic entity with rising incidence over recent years. So far, there are many treatment methods and protocols suggesting surgical or medical interventions and their combinations. More and more laparoscopic surgery is applied to treat scar pregnancy with excellent results. A proper surgical strategy is a key point for optimal surgical outcome.

Objectives: To present a standardised technique for the laparoscopic management of CSP.

Participant: Patients with CSP having the indication of laparoscopic treatment.

Intervention: The video presents a systematic approach of the laparoscopic treatment of CSP clearly divided into 10 steps: 1. Prepare the surgery; 2. Inspection of the pelvis; 3. Bladder dissection; 4. Preventive haemostasis; 5. Hysterotomy; 6. Evacuation of conception products; 7. Excision of niche scar tissue; 8. Evacuation of the uterine cavity; 9. Suturing of the uterine defect; 10. Removal of the uterine artery clips. The main outcome measures are the efficacy of the laparoscopic management of CSP and the postoperative uterine reconstruction in terms of ultrasonic measurement of the isthmic myometrial layer thickness. Patients are released from the hospital the day after the surgery, and a follow-up ultrasound is scheduled three months post-operatively. In the case presented in the video, the myometrial wall is increased from 3 mm preoperatively to 13 mm three months postoperatively.

Conclusions: The main advantage of this technique is the ability to treat CSP, remove the uterine isthmocele, and reconstruct the lower uterine segment simultaneously. The 10 steps proposed in a logical sequence may shorten the surgery's learning curve and reduce possible complications.

What is New? We present a systematic approach that provides a safe and easily reproducible technique for managing CSP.

Keywords: Caesarean scar pregnancy, ectopic pregnancy, laparoscopy, uterine niche

Introduction

Caesarean scar pregnancy (CSP), characterised by the implantation of the gestational sac into the isthmocele formed after a previous caesarean section, is increasingly being recognised, with its incidence estimated to reach up to 4% of all ectopic pregnancies.[1,2] Myometrial dehiscence and development of secondary fibrosis during the healing process predispose to implantation of the conceptus into the newly formed defect, defined as uterine niche.[3] Uterine rupture may be the result of pregnancy progression in untreated cases, leading to massive uterine bleeding.[4] Early diagnosis and prompt management are imperative to establish favourable outcomes in these patients.[5]

Corresponding Author: Nikolaos Kathopoulis, PhD, 1st Department of Obstetrics and Gynecology, University of Athens, Alexandra Hospital, Athens, Greece
E-mail: doctor@kathopoulis.gr **ORCID ID:** orcid.org/0000-0002-0031-809X
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Given the rarity of CSP, which challenges the ability to conduct reliable, high-quality studies, there is a lack of consensus on a standard treatment, although more than 30 medical and surgical protocols have been proposed so far.[6] Expectant management, methotrexate administration (local or systematic), uterine artery embolisation, high-intensity focused ultrasound, dilation and curettage, hysteroscopy, laparoscopy, and their combinations have all been proposed to detect the best treatment intervention.[7,8] Over the last decade, the laparoscopic approach has been reported more often to effectively treat CSP, claiming high success and minimal complication rates.[9] Moreover, uterine reconstruction and resection of the uterine niche reduce the recurrence of CSP. Laparoscopic management of CSP is a demanding operation requiring advanced surgical skills. We report a standardised approach, clearly divided into 10 steps, with an aim to make the procedure easily reproducible.

Methods

The video presents a systematic approach to the laparoscopic treatment of CSP, clearly divided into 10 steps: 1. Prepare the surgery; 2. Inspection of the pelvis; 3. Bladder dissection; 4. Preventive haemostasis; 5. Hysterotomy; 6. Evacuation of conception products; 7. Excision of niche scar tissue; 8. Evacuation of the uterine cavity; 9. Suturing of the uterine defect; 10. Removal of the uterine artery clips. Patients included in the video are women with indications for laparoscopic management of CSP. All patients have given written consent for publication of the video and participation in this study.

When preparing for the surgery, an ultrasound scan by a sonographer specialised in gynaecological pathology is mandatory to establish the correct diagnosis. It is important to measure the residual myometrial thickness of the uterine isthmocele accurately. Thorough counselling for the patient regarding the benefits and complications of each management option helps in agreeing the therapeutic plan. During the pelvic inspection, an assessment of the ectopic pregnancy is performed, mainly focused on ectopic size, bulging, and blood supply while identifying the main anatomic landmarks. Vesico-uterine dissection starts by dividing the peritoneum from one round ligament to the other. In many cases, this step may be challenging for the surgeon as, due to previous c-sections, the bladder is firmly adherent to the uterus (Figure 1). A few measures of preventive haemostasis may be applied to control bleeding. Temporary uterine artery clipping and intra-myometrial diluted Vasopressin (0,16 IU/mL) are two effective interventions to reduce myometrial bleeding.[10] After hysterotomy, the evacuation of conception products follows to remove all trophoblastic remnants, trying not to lacerate the adjacent endometrium (Figure 2). The scar tissue of the isthmocele is then excised to prepare the uterine isthmus for reconstruction, and a suction curettage may be applied to remove all trophoblastic tissue adjacent to the uterine fundus. The uterine defect is closed using interrupted or running sutures (Figure 3).

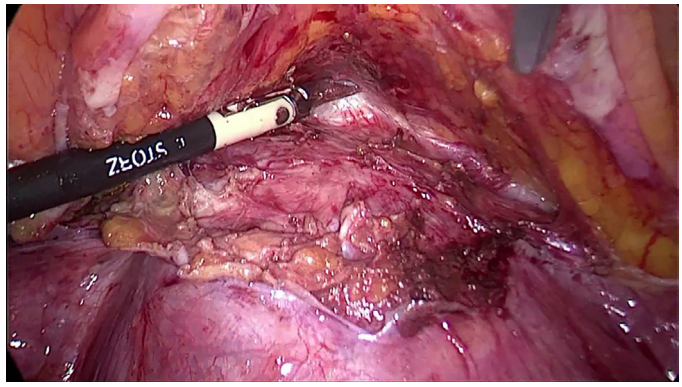

Figure 1. Bladder dissection up to the cervix.

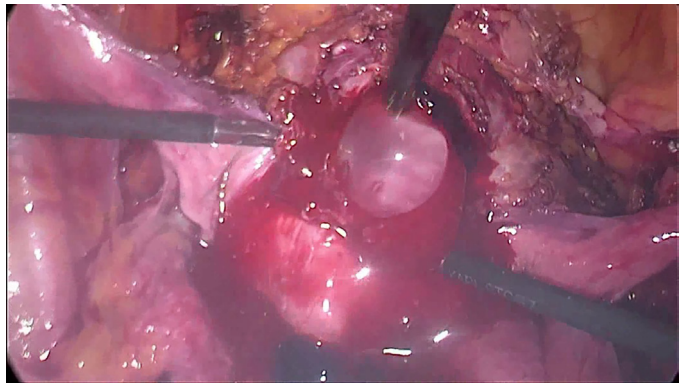

Figure 2. Extraction of the conception products from the uterus.

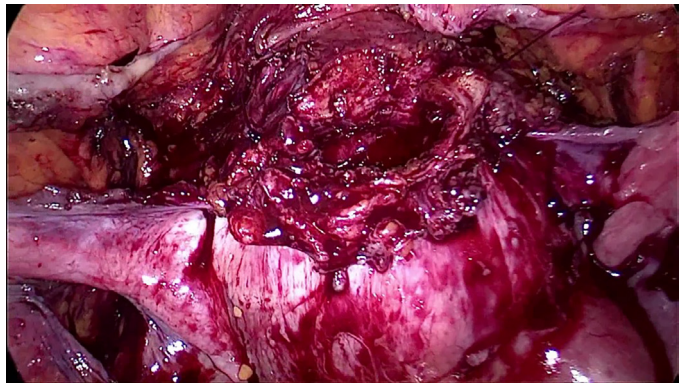

Figure 3. Suturing of the uterine defect to reconstruct the uterus after isthmocele removal.

We propose two-layer sutures to increase postoperative myometrial thickness. Finally, the clips of the temporary uterine artery clipping are removed.

Results

The technique described aims to reduce intraoperative blood loss, treat CSP and reconstruct the lower uterine segment with a low complication rate. Patients are discharged from the hospital the day after the surgery, and a follow-up ultrasound is scheduled three months postoperatively. Ultrasonic evaluation primarily focuses on the thickness of the myometrial wall where the isthmocele was located prior to surgery. In the case presented in the video, the myometrial wall thickness increased from 3 mm preoperatively to 13 mm postoperatively, showing that laparoscopy is an appropriate approach with excellent myometrial thickness restoration without residual isthmocele.

Discussion

In this video article, we propose a 10 step laparoscopic treatment of CSP. The steps are divided and presented clearly, leading to a more standardised approach for experienced surgeons to take. The systematic approach of gynaecologic surgery in 10 steps has already been described for other indications such as myomectomy, lymph node dissection, ovarian cyst excision or sclerotherapy, and promontofixation.[11-14] The 10 steps help to perform each part of the surgery in a logical sequence, contributing to increasing the procedure's ergonomics and making it easier to adopt and learn.[15] Another goal of the teaching video is to help surgeons to shorten the learning curve of the operation performed.

Besides the standardised surgical steps, our video highlights some important surgical techniques for facilitating the operation. Bladder dissection is, in our opinion, the most difficult step of the surgery due to a previous caesarean section. During this dissection, the surgeon has to take care to follow the avascular plane and avoid the enlarged neovasculature that commonly accompanies the CSP. If the surgical plane is lost, the surgeon may instil normalsaline in the bladder to help recognise the plane and facilitate dissection. Moreover, it is helpful to spend some surgical time to temporarily ligate the uterine artery, an intervention that, in our experience, reduces intraoperative blood loss during hysterotomy, which follows afterwards. Finally, suturing of the uterine defect after niche removal is imperative to increase the postoperative myometrial thickness, predisposing to reduced recurrence of isthmocele and future CSP. We propose two layers of interrupted sutures, but the suturing strategy is up to the surgeon's preference, as there is no evidence supporting any specific suturing technique. However, other suturing techniques could be applied depending on the surgeon's preference. The first and second sutures are placed in the left and right corners and are used as guide sutures.

The strength of our technique lies in its ability to present 10 clearly divided surgical steps that are easy to follow. Moreover, it may simultaneously address both CSP and uterine isthmocele, which is very important, especially in women who desire future fertility. Uterine niche is a pathology well-known for its negative impact on future fertility, as the blood accumulated in the uterine cavity may be embryotoxic, alter the cervical mucus, and reduce uterine receptivity either mechanically or through disturbance of cytokine cascades.[16]

Conclusion

The systematic approach provides a safe and easily reproducible technique for managing CSP. Moreover, the main advantage is the ability to treat CSP, remove the uterine isthmocele, and reconstruct the lower uterine segment simultaneously. The 10 steps proposed in a logical sequence may shorten the surgeon's learning curve and aim to lower the complication rate.

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Informed Consent: All included patients gave written consent for their anonymised data to be used in research.

Data sharing: Data and related information are available from the corresponding author upon request.

Transparency: The authors affirm that the manuscript is an honest, accurate, and transparent account of the studies assessed.

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Video 1. Laparoscopic management of caesarean scar pregnancy in 10 steps.

https://youtu.be/gOn-PNmLL_M

VIDEO ARTICLE

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A total endoscopic levonorgestrel-releasing intrauterine system (LNG-IUS) placement: a novel approach for obese patients with early-stage endometrial cancer

Ursula Catena[1], Emma Bonetti[2], Omer Moore[3], Eleonora La Fera[1], Federica Bernardini[1], Giorgia Dinoi[1], Giovanni Scambia[1-4], Francesco Fanfani[1-4]

[1]Fondazione Policlinico Universitario A. Gemelli, Department of Woman and Child Health and Public Health, Rome, Italy
[2]University of Brescia, Department of Clinical and Experimental Sciences, Brescia, Italy
[3]Laniado Hospital, Sanz Medical Center, Clinic of Obstetrics and Gynecology, Netanya, Israel
[4]Università Cattolica del Sacro Cuore, Rome, Italy

ABSTRACT

Background: Endometrioid adenocarcinoma is a common endometrial cancer, linked to excess oestrogen exposure. Obesity, a major risk factor, can lead to unopposed oestrogen and endometrial cancer. Surgery is the standard treatment for early-stage disease. However, obese patients with a high body mass index (BMI) may be unsuitable due to surgical risks.

Objectives: We present a novel completely endoscopic technique for placing a levonorgestrel-releasing intrauterine system (LNG-IUS) in an obese patient with early-stage endometrioid adenocarcinoma (FIGO 2009 stage IA, grade 1) who was not a surgical candidate due to multiple comorbidities.

Participant: An 82-year-old obese woman (BMI: 48.9 kg/m^2) with abnormal uterine bleeding was referred to our gynaecological department. Endometrial thickening, without spread beyond the uterus, was observed by transvaginal ultrasound and magnetic resonance imaging, and final diagnosis of early stage endometrioid adenocarcinoma was confirmed by hysteroscopic endometrial biopsy. Due to her high-risk status and anatomical challenges, initial management involved oral medication and regular biopsies. After a year of presence of a stable disease, a new technique for LNG-IUS placement was attempted.

Intervention: The LNG-IUS was successfully placed within the uterine cavity using a 5 mm XL Bettocchi hysteroscope and a 5 Fr grasping forceps, without needing vaginal speculum or cervical grasping. The patient tolerated the procedure well. Follow-up at six months was negative, without signs of recurrence.

Conclusions: This case demonstrates the feasibility and safety of a total endoscopic LNG-IUS placement as an alternative for obese patients with early-stage endometrioid adenocarcinoma who are not surgical candidates.

What is New? This is the first description of a total endoscopic technique for LNG-IUS placement performed without speculum or anesthesia.

Keywords: Early-stage endometrial cancer, levonorgestrel-releasing intrauterine system, LNG-IUS, obesity, hysteroscopy

Corresponding Author: Emma Bonetti, MD, University of Brescia, Department of Clinical and Experimental Sciences, Brescia, Italy
E-mail: emmabonetti@outlook.it **ORCID ID:** orcid.org/0009-0005-0836-5260
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Introduction

Endometrioid adenocarcinoma is the most prevalent type of endometrial cancer and is directly associated with an oestrogen-related pathway.[1] Obesity is a key risk factor because fat tissue actively produces aromatase, an enzyme that actively converts androgens into oestrogen. When this excess oestrogen goes unopposed by progesterone, it can trigger pre-cancerous changes in the endometrium, ultimately progressing to endometrial cancer.[2] The gold standard treatment for early-stage endometrioid adenocarcinoma is surgery, typically involving total hysterectomy, bilateral salpingo-oophorectomy, with lymph nodes assessment.[3] However, obese patients with a high body mass index (BMI) may be unsuitable for radical surgery due to surgical and anaesthesiologic risks.[4] Therefore, alternative treatment options such as radiotherapy or hormone therapy are often considered for this high-risk patient population.[5] This paper explores a promising alternative management strategy for obese patients diagnosed with early-stage endometrioid adenocarcinoma. It describes a novel, minimally invasive technique for placing levonorgestrel-releasing intrauterine system (LNG-IUS) using 5 mm XL Bettocchi hysteroscope (Karl Storz, Tuttlingen, Germany), with 5 Fr grasping forceps. This innovative approach has the potential to offer a safer and more comfortable treatment option for high-risk patients who are not candidates for surgery and with anatomical challenges which make the standard LNG-IUS insertion technique impractical.

Methods

An 82-year-old woman with morbid obesity (BMI: 48.9 kg/m^2) was referred to our gynaecological department, in Fondazione Policlinico Gemelli IRCCS of Rome (Italy), for abnormal uterine bleeding. She underwent two previous caesarean sections and experienced menopause at 55 years old. The ultrasound evaluation revealed an endometrial thickening. Computed tomography scan and magnetic resonance imaging confirmed the endometrial thickening confined to the uterine cavity, without spread beyond the uterus. The patient underwent an office hysteroscopy with multiple endometrial biopsies obtained using a 5 Fr grasping forceps. Histopathological examination confirmed final diagnosis of early stage endometrioid adenocarcinoma (FIGO 2009 stage IA, grade 1). Due to her comorbidities, the patient underwent a preoperative evaluation by anaesthesiologists who classified her as "high-risk", according to Boyd and Jackson[6] criteria and assigned her an American Society of Anaesthesiologists (ASA) physical status classification of III.[7] Consequently, surgery was not considered the most suitable treatment option due to the potential risks associated with anaesthesia and the procedure itself. Considering the patient's anatomical limitations, including a long and narrow vaginal canal and a small cervix, likely resulting from her two prior caesarean sections, standard LNG-IUS placement within the uterine cavity was not feasible. Initial management included a daily oral dose of 160 mg megestrol acetate and outpatient hysteroscopic endometrial biopsies every three months. However, after one year the disease was stable. We present a step-by-step video demonstration of a novel completely endoscopic technique for placing LNG-IUS performed by an expert surgeon.

Results

The procedure was performed in an outpatient setting at Digital Hysteroscopic Clinic - Class Hysteroscopy in Fondazione Policlinico Gemelli, without anesthesia.[8] A 5 mm XL Bettocchi hysteroscope, 36 cm in length, with a 30° forward oblique lens (Karl Storz, Tuttlingen, Germany), was used. Hysteroscopic examination revealed focal endometrial thickening with atypical vascularization. To avoid using vaginal speculum and cervical grasping, the surgeon removed LNG-IUS from its inserter and introduced 5 Fr grasping forceps into the working channel of the hysteroscope. The surgeon closed the spiral arms and grasped them with 5 Fr grasping forceps. By manoeuvring the hysteroscope and forceps in a coordinated way, the LNG-IUS was then carefully pushed vaginoscopically towards the vagina and cervix. The saline solution distended the vagina creating a clear pathway for placement and the LNG-IUS was correctly positioned at the uterine fundus. The entire procedure was well-tolerated, and the patient was discharged a few minutes later. After six months of LNG-IUS treatment, follow-up transvaginal ultrasound showed no evidence of endometrial thickening and office hysteroscopic endometrial biopsy was negative, confirming the effectiveness of the treatment. Moreover, the patient reported no further abnormal uterine bleeding and overall satisfaction with the minimally invasive procedure.

Discussion

Endometrial cancer is the most common gynaecological malignancy in developed countries with endometrioid

adenocarcinoma being the predominant histological type. While surgery remains the gold standard treatment for early stage endometrioid adenocarcinoma, obese patients with multiple comorbidities present with a significant surgical risk. Therefore, research on conservative treatments of endometrial cancer is considered a global priority.[9] The use of LNG-IUS for endometrial cancer treatment has gained increasing recognition in recent years. LNG-IUS acts primarily by releasing levonorgestrel, a progestin that promotes endometrial atrophy and reduces estrogen levels. This hormonal therapy has shown effectiveness in treating early-stage disease, particularly for patients who wish to preserve fertility or are not suitable surgical candidates.[10] Regarding fertility-sparing treatment, recent guidelines described conservative approach for atypical endometrial hyperplasia (AEH) or grade 1 endometrioid endometrial adenocarcinoma (EAC), without myometrial invasion.[11] For non-surgical candidates, there are only few clinical trials which investigated the efficacy and oncologic safety of LNG-IUS for AEH or EAC in high-risk patients. These studies reported pathological response rates ranging from 37% to 66%.[12-16]

In this video article, we presented a novel technique for total endoscopic LNG-IUS placement in an obese patient with early-stage endometrioid adenocarcinoma who was deemed high-risk for surgery. To our knowledge, this is the first time that this technique has been described. The technique, performed by an expert surgeon, successfully delivered the LNG-IUS into the uterine cavity without the need for vaginal speculum or cervical grasping, allowing for a minimally invasive and patient-friendly procedure, without the need of any kind of anaesthesia. The total endoscopic LNG-IUS placement technique offers several advantages over traditional methods, particularly for obese patients with anatomical challenges like those presented in this case.

By eliminating the need for vaginal speculum and cervical grasping, the procedure minimizes discomfort and potential trauma to the cervix and vagina. Additionally, the use of a hysteroscope allows for direct visualization of the uterine cavity, ensuring accurate placement of the LNG-IUS. This advantage is particularly significant for obese patients, as the hysteroscope overcomes anatomical challenges that might otherwise hinder precise placement.

However, this technique does present some limitations. The use of grasping forceps can partially obscure the endoscopic view, making the visualization of the cervical os and canal challenging. Additionally, the presence of grasping forceps within the working channel reduces the inflow of distension media, potentially compromising visualization. Thus, a preliminary hysteroscopy is essential to map the cervical canal and assess its axis and direction.

Proper alignment of the scope is particularly important, as the grasping forceps, when loaded with the IUS, increase the overall bulk, which may cause resistance when advancing through the cervical canal. Therefore, operators must be cautious not to apply excessive force and should ensure that the hysteroscope remains properly aligned to minimize the risk of perforation.

For these reasons, this technique should not be considered a routine procedure and should be performed only by experienced hysteroscopists, as it requires advanced endoscopic skills.

In the present case, the patient experienced no complications related to the LNG-IUS placement procedure and reported significant improvement in her symptoms of abnormal uterine bleeding. After six months of treatment, follow-up imaging and clinical assessment confirmed stable disease without evidence of recurrence.

Conclusion

The total endoscopic LNG-IUS placement technique presented in this case report offers a promising alternative management strategy for obese patients with early-stage endometrioid adenocarcinoma who are not suitable for conventional surgery. The endoscopic technique provides a minimally invasive, patient-friendly approach that can be performed in an office setting, without any kind of anaesthesia, avoiding major surgery risks. Further research is warranted to evaluate the long-term efficacy and safety of this technique in a larger cohort of patients.

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Video 1. https://youtu.be/2doj6ihaX9U