ORIGINAL ARTICLE

DOI: 10.52054/FVVO.2025.40
Facts Views Vis Obgyn 2025;17(3):232-236

Menopausal symptoms after hysterectomy with opportunistic salpingectomy: a pilot study

Anne-Sophie Maryns[1], Tjalina Hamerlynck[2], Bart De Vree[1], Anne-Sophie Verboven[2], Amin P. Makar[2], Philippe Tummers[2], Wiebren Tjalma[3]

[1]Clinic of Gynaecology and Obstetrics, ZAS Middelheim Hospital Antwerp, Antwerp, Belgium
[2]Department of Gynaecology and Obstetrics, Ghent University Hospital, Ghent, Belgium
[3]Department of Obstetrics and Gynecology, Clinic of Multidisciplinary Breast, Gynecological Oncology Unit, Antwerp University Hospital, University of Antwerp, Edegem, Belgium

ABSTRACT

Background: Opportunistic salpingectomy during hysterectomy with ovarian preservation may reduce the risk of ovarian cancer, but concerns remain that adding salpingectomy to hysterectomy could affect ovarian vascularisation and subsequent function.

Objectives: To assess the feasibility of a full-scale trial to evaluate changes in menopausal symptoms based on the menopause rating scale (MRS) six months following hysterectomy, with and without opportunistic salpingectomy.

Methods: A prospective observational pilot study of premenopausal women age 40 to 55 years scheduled for hysterectomy with ovarian preservation was conducted, where participants were counselled and given the option of concomitant salpingectomy or not.

Main Outcome Measures: Forty-six out of 50 women chose opportunistic salpingectomy. It took 17 months to recruit 50 patients. Complete follow-up data was achieved in 43 of the 50 participants.

Results: The median MRS score remained unchanged in the opportunistic salpingectomy group at 9 [interquartile range (IQR): 3–14], both before surgery and six months afterwards (n=39). In contrast, the group of women who did not undergo opportunistic salpingectomy had a median MRS score of 11 (IQR: 3–16) preoperatively, which increased to 25 (IQR: 6–32) six months postoperatively (n=4).

Conclusions: The majority of patients in our cohort opted for opportunistic salpingectomy. However, no deterioration in menopausal symptoms was observed in this group after six months. A randomised controlled trial comparing hysterectomy with and without opportunistic salpingectomy in this patient population may not be feasible, given the strong patient preference for salpingectomy and slow recruitment.

What is New? The development of subjective menopausal symptoms is evaluated after hysterectomy with opportunistic salpingectomy.

Keywords: Hysterectomy, opportunistic salpingectomy, menopause, menopause rating scale, MRS

Corresponding Author: Anne-Sophie Maryns, MD, Clinic of Gynaecology and Obstetrics, ZAS Middelheim Hospital Antwerp, Antwerp, Belgium
E-mail: annesophiemaryns@hotmail.com **ORCID ID:** orcid.org/0000-0001-6471-8116
Received: 19.03.2025 **Accepted:** 05.07.2025 **Epub:** 23.09.2025 **Publication Date:** 30.09.2025

Cite this article as: Maryns AS, Hamerlynck T, De Vree B, Verboven AS, Makar AP, Tummers P, et al. Menopausal symptoms after hysterectomy with opportunistic salpingectomy: a pilot study. Facts Views Vis Obgyn. 2025;17(3):232-236

Introduction

High-grade serous carcinoma is now understood to originate from serous tubal intraepithelial carcinoma, a precursor lesion found in the fimbriae of the fallopian tube.[1,2] Opportunistic salpingectomy in post-reproductive women (removal of the salpinges bilaterally in women that are scheduled for surgery in the pelvis) has been associated with a 49%-65% reduction in ovarian cancer risk.[3,4] Given its apparent cost-effectiveness, the International Federation of Gynaecology and Obstetrics' position statement supports opportunistic salpingectomy as a preventive strategy for ovarian cancer.[5,6]

Hysterectomy alone may accelerate ovarian failure [hazard ratio (HR): 1.92], possibly due to the disruption of uterine artery branches supplying the ovary.[7] There is concern that adding bilateral salpingectomy could further compromise ovarian vascularisation, potentially exerting a greater impact on ovarian function.

The impact of opportunistic salpingectomy on ovarian function has been studied using menopause markers such as oestradiol, anti-Müllerian hormone (AMH), follicle-stimulating hormone and luteinising hormone levels, as well as ultrasound changes in the ovary or antral follicle count. The 2019 Cochrane Review has concluded that there was no significant difference in postoperative hormonal status and no clinically relevant reduction in AMH. However, the review highlighted a notable lack of studies evaluating objective menopausal symptoms.[8]

A population-based Canadian cohort study of 40,000 women confirmed that women who underwent hysterectomy with opportunistic salpingectomy did not consult earlier with menopausal complaints than those without opportunistic salpingectomy [adjusted HR: 0.98; 95% confidence interval (CI): 0.88-1.09]. Similarly, there was no significant difference in the time from surgery to the prescription of hormone replacement therapy between the two groups (adjusted HR: 0.82; 95% CI: 0.72-0.92).[9]

Conversely, a retrospective observational cohort study of 23000 women reported an increase in menopausal symptoms one year after surgery [relative risk (RR): 1.29; CI: 1.04-1.60], particularly in the subgroup of women between the ages of 44 and 69 years (RR: 1.53; CI: 1.06-2.20).[10]

The Hysterectomy and Opportunistic Salpingectomy (HOPPSA) trial, a multicentre randomised clinical trial evaluating the safety and effectiveness of performing opportunistic salpingectomy at hysterectomy to reduce the risk of epithelial ovarian cancer, is in progress and is collecting data on menopausal symptoms using the menopause rating scale (MRS).[11] We had previously planned to conduct a pilot study to assess the feasibility of a full-scale trial to evaluate changes in menopausal symptoms using the MRS as a primary outcome, six months following hysterectomy, with and without opportunistic salpingectomy.

Methods

We conducted a multicentre prospective pilot cohort study across three centres: Ghent University Hospital, Antwerp University Hospital, and ZAS Middelheim Hospital in Antwerp, Belgium. This study was approved by the independent Medical Ethics Committee of all three participating clinics (permission of the Ethics Committee of the Middelheim Hospital was obtained on the 11th of March 2020, reference number: B009202043074. Permission of the Ethics Committee of the Ghent University Hospital was obtained on the 4th December 2020, decision no: BC-08426. Permission of the Ethics Committee of the Antwerp University Hospital was obtained on 18th November 2020, decision no: 5334).

As part of standard clinical care and shared decision making, patients were counselled by their gynaecologists on hysterectomy and the potential advantages and disadvantages of opting for or declining from opportunistic salpingectomy. Written informed consent was obtained from all study participants. The study information sheets contained information about the evidence of opportunistic salpingectomy in 2020, namely: "researchers showed that the risk of developing ovarian cancer could be reduced by removing the fallopian tubes. The fallopian tubes do not produce hormones and transport oocytes to the uterus to become pregnant. The salpinges can be taken away from the female pelvis when the desire to have children is complete. If the removal of the fallopian tubes is done during another procedure to prevent cancer, the procedure becomes opportunistic. Opportunistic salpingectomy could mean a 49%-65% risk reduction compared to developing ovarian cancer. To date, however, there are no long-term results (e.g. 30 years later) that have studied survival or reduction of the risk of ovarian cancer after surgery. In theory, removing the fallopian tubes could have a limited impact on the functioning of the ovary. On short-term (up to 1 year later) and long-term effects (3 to 5 years later), no difference was seen in hormonal production

after opportunistic salpingectomy. Yet, in September 2019, a renowned research team (Cochrane) concluded that menopause could develop up to 20 months earlier after opportunistic salpingectomy with hysterectomy. Few studies have been conducted on menopausal symptoms after opportunistic salpingectomy."

Inclusion criteria included premenopausal women aged 40 to 55 years scheduled for hysterectomy for benign disease without oophorectomy. Exclusion criteria included a prior period of amenorrhea lasting six months, use of hormonal replacement therapy or any oral contraceptive method within one month before surgery, previous unilateral or bilateral oophorectomy, a history of a malignancy requiring pelvic radiation or systemic chemotherapy, or a history of acute or chronic pelvic inflammatory disorder.

Menopausal symptoms were assessed using the MRS, a validated health-related quality of life scale for evaluating menopausal complaints. The MRS includes eleven questions about different menopausal subdomains, with a total score ranging from 0 to 44; a higher score indicates more severe subjective menopausal symptoms.[12] The scale is widely recognised for its applicability and reliability in evaluating menopausal symptoms. MRS scores were calculated preoperatively and six months postoperatively.

The primary outcome was to estimate the change in MRS scores from preoperatively to six months postoperatively in both groups using descriptive statistics to compare medians and interquartile ranges (IQR). We also intended to test the feasibility of designing a randomised clinical trial.

Results

Over 17 months (Dec 2020 and Jan 2022), 50 patients were enrolled in the study. Of the 52 patients approached, 50 consented to participate after reviewing the patient information leaflet. Demographic data are presented in Table 1. The mean age at the time of hysterectomy was 45 years (± 4.02). The majority of participants (46 out of 50, or 92%) chose to undergo opportunistic salpingectomy at the time of hysterectomy. Seven patients were lost to follow-up six months post-surgery. All the missing data belonged to patients who underwent hysterectomy with opportunistic salpingectomy.

In the opportunistic salpingectomy group, the median MRS score remained stable at 9 (IQR: 3-14) both before surgery and six months after surgery (n=39). In contrast, the group without opportunistic salpingectomy had a median MRS score of 11 (IQR: 3-16) preoperatively, which increased to 25 (IQR: 6-32) six months postoperatively (n=4).

Discussion

Main Findings

Our study was not powered for statistical analysis between the two groups; however, we observed no

Table 1. Demographics of the study population.

	Overall study population (n=50)	**Patients with opportunistic salpingectomy (n=46)**	**Patients without opportunistic salpingectomy (n=4)**
Age at time of surgery in years Median (IQR)	44.0 (42.0-49.0)	44.0 (41.8-49.0)	47.5 (44.8-49.5)
BMI at the time of surgery Median (IQR)	26.1 (22.7-30.7)	26.1 (22.7-29.5)	27.3 (19.2-36.9)
Family history of breast cancer	9 (18%)	9 (19.6%)	0
Family history of ovarian cancer	1 (2%)	1 (2%)	0
Type of hysterectomy			
• Laparoscopic • Laparotomic • Vaginal • v-NOTES	37 (74%) 10 (20%) 2 (4%) 1 (2%)	35 (76%) 9 (20%) 1 (2%) 1 (2%)	2 (50%) 1 (25%) 1 (25%) 0
Menopause rating scale* pre-surgery Median (IQR)	9.50 (2.9-13.5)	9.0 (2.9-13.5)	11 (2.8-16.35)

*Menopause rating scale is a validated health-related quality of life scale for menopausal complaints with values ranging from 0 to 44. A higher score means that the patient experiences more subjective symptoms. IQR: Interquartile range, BMI: Body mass index, v-NOTES: Vaginally-assisted natural orifice transluminal endoscopic surgery.

deterioration in menopausal symptoms, six months after surgery, in the opportunistic salpingectomy group. Additionally, our results clearly demonstrated a strong patient preference for opportunistic salpingectomy when combined with hysterectomy. As our study employed a non-randomised design, patients were free to choose their preferred treatment. A roundtable discussion among the study team explored possible reasons for the patient' preference for salpingectomy. The investigators felt that most patients prioritised the oncological risk reduction while potentially underestimating the relationship between salpingectomy and premature menopause. Despite thorough counselling, patients do not always fully comprehend that menopause is not solely defined by the cessation of menstrual bleeding and the end of fertility, but also by hormonal and systemic changes.

We speculated that the four women, opting to keep the salpinges, may have already experienced more menopausal complaints from the start and attempted to delay further progression by avoiding salpingectomy. However, this strategy appeared unsuccessful, as their mean MRS scores doubled within six months postoperatively.

When salpingectomy involves resecting a large part of the broad ligament, there may theoretically be an increased risk of damaging smaller vessels between the fallopian tube and ovary. We propose to operate as closely as possible to the fallopian surface to minimise potential additional impact on ovarian vascularisation.

Strengths and Limitations

The MRS was chosen as an outcome parameter because it is a validated instrument that offers a reliable assessment of subjective menopausal symptoms. In the literature, there are limited data on MRS scores following hysterectomy with or without opportunistic salpingectomy. The key advantage of the MRS score is that it relies on patient-reported outcomes rather than requiring hospital visits and blood sampling. Biochemical markers of ovarian reserve are not always a good predictor of subjective complaints.

It remains uncertain whether AMH levels, which are being used most frequently as a marker for ovarian reserve, are an accurate measure to assess the effects of opportunistic salpingectomy. AMH values first show a steep decline postoperatively, to make a recovery several months afterwards.[8] There are no cut-off levels formulated to predict the onset of menopause, and AMH levels are of a fluctuating nature. Furthermore, its predictive utility decreases with advancing age.[13]

Seventeen months were needed to obtain fifty inclusions across three different hospitals. The slow recruitment rate was likely influenced by the coronavirus disease-2019 pandemic. Additionally, the exclusion of patients using hormonal contraception, in order to minimise bias in preoperative MRS score, limited enrollment. Many premenopausal patients were on hormonal therapy for irregular bleeding and/or heavy menstrual bleeding, making them ineligible for inclusion. The number of women excluded for this reason was not recorded. In hindsight, this exclusion may have been unnecessary, as contraception is discontinued immediately after hysterectomy.

A key limitation of this study is the short follow-up period. Six months of follow-up may be insufficient to draw conclusions about menopausal symptoms, given that the average age of menopause in Belgium is approximately 51 years, while the mean age of participants was 45 years.

Due to the small sample size, no statistical comparison between surgical subtypes was performed. It is also worth noting that the surgical approach may influence ovarian vascularisation, with laparotomy potentially having a greater impact than laparoscopic hysterectomy.[14] However, no conclusive data currently exist comparing the impact of different surgical techniques on ovarian vascularisation and function.[15]

Clinical and Policy Implications

Given the limited evidence regarding both the cancer preventive potential of opportunistic salpingectomy and its possible effects on ovarian vascularisation, we recommend providing uniform, standardised information during the counselling process for premenopausal patients scheduled for hysterectomy. Such standardised counselling is crucial, as current recommendations emphasise the importance of discussing the benefits and risks of opportunistic salpingectomy but offer no guidance on their implementation in daily practice, leading to wide variations in current practice among gynaecologists. Ideally, opportunistic salpingectomy should be linked to enable systematic follow-up of patients.

Unanswered Questions and Future Research

Conducting a randomised controlled trial (RCT) comparing hysterectomy with and without opportunistic salpingectomy in our patient population appears less

feasible due to a strong patient preference for concurrent salpingectomy and a slow rate of recruitment. However, an interim analysis conducted during 2021 of the HOPPSA RCT comparing the safety and effectiveness of performing opportunistic salpingectomy at hysterectomy, recommended that the study should continue until the target sample size is reached, suggesting recruitment was feasible.[16] The subject enrollment is estimated to be completed in March 2026, and the menopausal symptoms will be evaluated one year following surgery. The results of this trial are eagerly awaited.

Conclusion

The majority of patients in our cohort opted for opportunistic salpingectomy. However, no deterioration in menopausal symptoms was observed in this group after six months. An RCT comparing hysterectomy with and without opportunistic salpingectomy in this patient population may not be feasible, given the strong patient preference for salpingectomy and the slow rate of recruitment. In the meantime we propose conducting prospective observational studies with longer follow-up, integrating MRS scores with serial hormonal assessments to better understand the long-term impact on menopausal symptoms and ovarian function.

Acknowledgements: We thank all patients who participated in the study.

Contributors: Surgical and Medical Practices: A-S.M., T.H., B.D.V., A-S.V., A.M.P., P.T., W.T., Concept: A-S.M., Design: A-S.M., T.H., A.M.P., P.T., W.T., Data Collection or Processing: A-S.M., A-S.V., Analysis or Interpretation: A-S.M., A-S.V., Literature Search: A-S.M., A-S.V., Writing: A-S.M., T.H., B.D.V., A-S.V., A.M.P., P.T., W.T.

Funding: The authors declared that this study received no financial support.

Competing interests: No conflict of interest was declared by the authors.

Ethical approval: This study was approved by the independent Medical Ethics Committee of all three participating clinics (permission of the Ethics Committee of the Middelheim Hospital was obtained on the 11th of March 2020, reference number: B009202043074. Permission of the Ethics Committee of the Ghent University Hospital was obtained on the 4th December 2020, decision no: BC-08426. Permission of the Ethics Committee of the Antwerp University Hospital was obtained on 18th November 2020, decision no: 5334).

Informed consent: Written informed consent was obtained from all study participants.

Data sharing: Data is available on request from the authors.

Transparency: Dr Anne-Sophie Maryns affirms 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 (and, if relevant, registered) have been explained.

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