

A prospective trial comparing the effect of preoperative information given verbally with the use of an explanatory animated video before outpatient hysteroscopy on patients' anxiety and pain

 Neta Eisenberg-Kogan,  Maayan Gal-Kochav,  Maya Naor-Dovev,  Hilla Segal,  Matan Mor,  Noam Smorgick

Department of Obstetrics and Gynecology, Shamir Medical Center (Assaf Harofeh), Zerifin, Israel; affiliated with the Gray Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

ABSTRACT

Background: Hysteroscopy without anaesthesia is a routine gynaecological procedure but is commonly associated with patient anxiety and pain.

Objectives: To compare preoperative information provision using usual verbal interaction with the use of an animated video on patients' anxiety and pain associated with outpatient hysteroscopy.

Methods: Patients were allocated to receive verbal explanations immediately prior to the outpatient hysteroscopy or via an informative short, animated video.

Main Outcome Measures: Proportion of patients with moderate-high preoperative anxiety levels as assessed by the State-Trait Anxiety Inventory questionnaire. Secondary outcomes included maximal intraoperative pain levels recorded on a 10 cm visual analogue scale (VAS) completed directly after the procedure.

Results: One hundred patients undergoing 78 diagnostic hysteroscopies and 22 operative hysteroscopies were included in the study, with 50 patients allocated to each intervention group. Preoperative moderate or high anxiety levels were reported by 28 participants who also had higher VAS pain scores (3.6 ± 3.2 cm vs. 2.0 ± 2.5 cm in the lower anxiety group, $P=0.02$). The rates of preoperative moderate/high anxiety levels were significantly higher in the standard verbal education group compared with the animated video group [19 (38.0%) vs. 9 (18.0%), respectively, $P=0.04$], although their VAS pain scores were not significantly different. The logistic regression analysis confirmed that a low level of anxiety was associated with education by an animated video (odds ratio: 2.9, 95% confidence interval: 1.1-7.6).

Conclusions: Preoperative education by an animated video prior to hysteroscopy is associated with lower rates of moderate/high anxiety levels compared to the standard verbal education preparation.

What is New? Animated videos are an effective and easy-to-implement tool that may reduce anxiety before office hysteroscopy.

Keywords: Hysteroscopy, anxiety, State-Trait Anxiety Inventory (STAI)

Corresponding Author: Noam Smorgick, MD, Department of Obstetrics and Gynecology, Shamir Medical Center (Assaf Harofeh), Zerifin, Israel; affiliated with the Gray Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

E-mail: drnoasmorgick@gmail.com **ORCID ID:** orcid.org/0000-0002-4561-7659

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Introduction

Diagnostic and operative hysteroscopy without anaesthesia (level 1 analgesia according to the international consensus classification) are common gynaecologic procedure indicated for various gynaecologic problems, including abnormal uterine bleeding, infertility, habitual abortions, retained intrauterine device, and investigation of endometrial ultrasound findings.¹ Although hysteroscopy without anaesthesia is usually well tolerated and associated with high patient satisfaction, this awake procedure could cause considerable preoperative anxiety in up to 80% of patients.² Subsequently, high anxiety levels may adversely impact pain perception, procedural success rates, and overall satisfaction.³ Non-pharmacologic interventions, such as preoperative patient education, may reportedly alleviate excessive anxiety.³ Several strategies for patient education may be offered, including verbal explanation, use of pictorial charts, and the use of animated videos.^{4,5} Animated videos have emerged as a powerful tool for patient education, particularly for medical procedures which can be visually depicted. This strategy may reduce anxiety by providing clear representations of the procedure in a way that is easy to understand and remember.⁵ However, the most effective preoperative educational approach for reducing patient anxiety is undetermined.³

In the current study, we aimed to compare the standard preoperative verbal education with the education delivered via an animated video prior to diagnostic or operative hysteroscopy in the office setting. We specifically measured and compared preoperative anxiety levels and maximal intraoperative visual analogue scales (VAS) for pain.

Methods

This prospective non-blinded study included patients referred for diagnostic and/or operative hysteroscopy without anaesthesia (level 1) in an outpatient hysteroscopy clinic of Shamir Medical Centre, department of obstetrics and gynaecology.¹ Upon arrival at the hysteroscopy clinic, all patients aged 18 years or older who had not previously undergone the procedure were invited to participate in the study by the senior gynaecologist performing the hysteroscopy. The participants' demographic characteristics, gynaecological and obstetrical history, history of depression and/or anxiety, clinical presentation and hysteroscopic findings, and procedure time were prospectively recorded.

Patients were assigned to either the control group (verbal explanation) or the study group (animated video) by arbitrarily designating specific clinic days for each group (i.e., one type of preoperative education was delivered to all patients participating in the study on a given date). There was no stratification for patient characteristics or hysteroscopy indications.

The patients in the control group received the standard preoperative verbal education from the attending gynaecologist who performed the hysteroscopy. The patients in the study group viewed a 4-minute animated video developed by the study investigators (Supplementary video 1), which provided step-by-step information on the hysteroscopy process and recovery. The animated video also explained the indications for hysteroscopy, exam room setup, and the roles of the medical and nursing staff present during the procedure.

Immediately following the preoperative education by either the verbal explanation or the educational video, preoperative anxiety was measured using a validated questionnaire: the State-Trait Anxiety Inventory (STAI) (licensed for use in this study by Mind Garden, Inc.).⁶ The STAI questionnaire is a validated psychological assessment tool designed to assess two types of anxiety: "state anxiety", which reflects a temporary condition or emotional state in response to specific situations, and "trait anxiety", which indicates a more general and long-standing tendency to experience anxiety across various circumstances. The questionnaire includes 20 questions, each assigned a score from 1 to 4. According to the recommended classifications of anxiety levels, a total score of less than 30 is considered indicative of low anxiety, scores between 30 and 45 represent moderate anxiety, and scores of 46 or higher denote high anxiety.⁶

The hysteroscopy procedure was then performed by means of the vaginoscopy approach. The diagnostic hysteroscopies were performed with the use of a diagnostic sheath fitted on a 2.9 mm 30° rigid hysteroscope (Karl Storz, Tuttlingen, Germany). The operative procedures included visually directed endometrial biopsy, removal of endometrial polyps, removal of retained products of conception, adhesiolysis, and removal of an intrauterine device. A 5 mm 30° rigid Bettocchi hysteroscope equipped with a working channel and miniaturised non-electrical hysteroscopic instruments, including a grasper and scissors (Karl Storz, Tuttlingen, Germany), was utilised for the operative procedures. Normal saline 0.9% delivered by a manual pressure pump was used as the distention

medium. All procedures were performed without any anaesthesia or analgesia (level 1), by three experienced minimally invasive gynaecology surgeons.

Directly after completion of the hysteroscopy, all patients were asked to record the maximal intraoperative pain by means of a 10 cm VAS anchored at 0 (designated as "no pain") and 10 (designated as the "worst pain imaginable").

The study's primary outcome was the proportion of patients reporting preoperative moderate or high anxiety levels (as assessed by the STAI score) in the study group vs. the control group. The secondary outcome was the mean maximal intraoperative VAS pain level scores in each group.

The study was approved by the Shamir Medical Centre Institutional Review Board (0011-23-ASF) on January 30th, 2023, and registered in the Clinicaltrials.gov registry (NCT06625567). All participants signed an informed consent upon enrolment, as well as the standard written informed consent for undergoing the hysteroscopy.

Sample Size and Statistical Analysis

The sample size was calculated to detect a 30% difference in the rates of moderate/high anxiety between groups, using a 80% power and 5% significance. This calculation

yielded a minimum cohort of 90 patients, which was inflated to 100 to allow for loss to follow-up. All statistical analyses were performed using the SPSS software (Version 29, IBM Corp). The Student t-test, analysis of variance, Fisher's exact test, and chi-square test were employed as appropriate. A binary logistic regression model was used to predict whether participants had low anxiety or moderate/high anxiety, considering factors such as group allocation (control or study), the type of hysteroscopy performed, and other demographic and gynaecologic variables. The results are shown as odds ratios (ORs) with 95% confidence intervals (CIs). A two-sided *P* value of <0.05 was considered statistically significant.

Results

The study included 100 women, 50 in the study group (standard verbal education) and 50 in the control group (education by animated video). Comparisons of demographic and gynaecologic characteristics between groups are shown in Table 1. Groups were comparable apart from the clinical indications for hysteroscopy (Table 1). The flow chart of the study is shown in Figure 1.

A diagnostic hysteroscopy was performed in 76 cases and an operative hysteroscopy in the remaining 24 cases. The operative procedures included visually

Table 1. Comparison of the demographic, gynaecologic, and clinical characteristics between the study group (educational video) and the control group (standard education).

| Characteristic | Control group (n=50) | Study group (n=50) |
|---|----------------------|--------------------|
| Age (years) | 41.5±12.6 | 38.4±11.3 |
| Body mass index (kg/m ²) | 26.2±5.2 | 25.8±5.6 |
| History of anxiety/depression | 8 (16.0) | 3 (6.0) |
| Parity | 2 (0-5) | 2 (0-4) |
| Nulliparity | 11 (22.0) | 8 (16.0) |
| History of caesarean section | 14 (28.0) | 12 (24.0) |
| Menopausal status | | |
| Premenopausal | 41 (82.0) | 46 (92.0) |
| Postmenopausal | 9 (18.0) | 4 (8.0) |
| Indication for hysteroscopy referral | | |
| Abnormal uterine bleeding | 11 (22.0) | 25 (50.0) |
| Suspected uterine polyp | 15 (30.0) | 14 (28.0) |
| Infertility workup | 9 (18.0) | 7 (14.0) |
| Suspected retained products of conception | 11 (22.0) | 0 (0) |
| Other* | 4 (8.0) | 4 (8.0) |

*Including intrauterine device removal and assessment of caesarean section defect. Data are presented as mean ± standard deviation, median (range) or number (%).

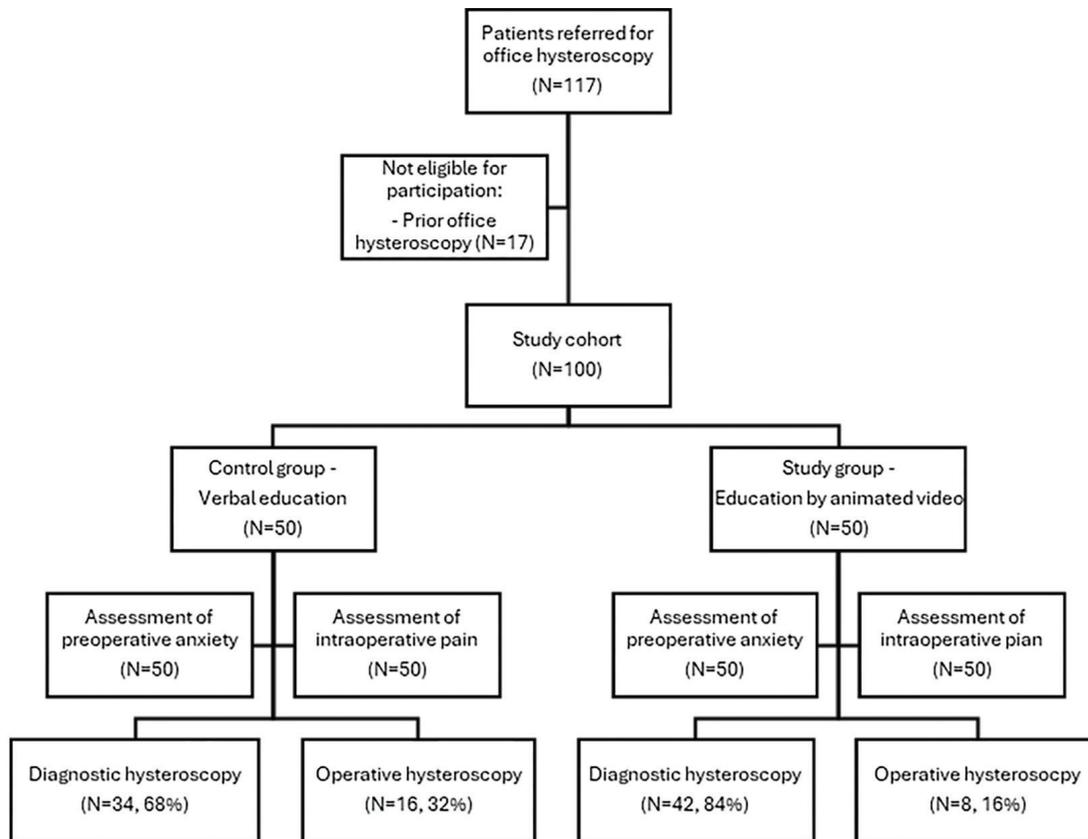


Figure 1. Flow chart of the study.

Table 2. Comparison of hysteroscopic characteristics between the study group (educational video) and the control group (standard education).

| Characteristic | Control group (n=50) | Study group (n=50) |
|---|----------------------|--------------------|
| Successful completion of the hysteroscopy procedure | 48 (96.0) | 50 (100.0) |
| Hysteroscopic diagnosis of cervical stenosis | 6 (12.0) | 6 (12.0) |
| Hysteroscopy operative time (seconds) | 52.5±35.3 | 60.6±25.7 |
| Type of hysteroscopy procedure | | |
| Diagnostic | 34 (68.0) | 42 (84.0) |
| Operative | 16 (32.0) | 8 (16.0) |

Data are presented as mean ± standard deviation or number (%).

directed endometrial biopsy in 8 cases, removal of retained intrauterine device in 7 cases, removal of retained products of conception in 6 cases, uterine adhesiolysis in 2 cases, and resection of endometrial polyp in one case. Hysteroscopy was successfully completed in 98 cases. Two patients were diagnosed as having complete cervical stenosis and failed to complete the hysteroscopy. Comparisons of the hysteroscopic characteristics between the two groups are given in Table 2. There were no significant group differences in operative time, rates

of diagnostic versus operative procedures, or rates of failed hysteroscopy due to cervical stenosis (Table 2).

The STAI questionnaire revealed low levels of preoperative anxiety in 72 cases, moderate levels in 25 cases, and high levels in 3 cases. Nulliparous women exhibited higher incidences of moderate to high anxiety than parous patients; however, there were no statistically significant differences observed among other demographic, gynaecologic, or hysteroscopic characteristics (Tables 3 and 4). The mean maximal

intraoperative pain scores as measured by VAS and the proportion of women who reported a VAS ≥ 5 cm were significantly higher among women with moderate/high preoperative anxiety (Table 4).

On comparisons of anxiety and pain scores between the study and control group, the rates of moderate/high anxiety were significantly lower in the study group compared with the control group (9/50 vs. 19/50), respectively, $P=0.04$), while the mean anxiety scores were not significantly different (22.2 ± 9.9 vs. 25.9 ± 10.4 , respectively, $P=0.07$). The mean maximal intraoperative

pain scores were similar between groups (VAS of 2.3 ± 2.5 cm vs. 2.6 ± 3.0 cm, respectively, $P=0.6$).

A logistic regression analysis was performed to assess the association between the study group allocation and moderate/high vs. low levels of anxiety. Education by the animated video was significantly associated with low anxiety levels (OR: 2.93, 95% CI: 1.12-7.66), while none of the other demographic, gynaecologic, and hysteroscopic parameters was independently associated with low versus moderate/high anxiety levels (data not shown).

Table 3. Comparison of demographic and clinical characteristics between patients with low versus moderate/high preoperative anxiety scores.

| Characteristic | Low anxiety* (n=72) | Moderate/high anxiety* (n=28) | P value |
|---|---------------------|-------------------------------|---------|
| Age (years) | 39.6 \pm 11.6 | 42.1 \pm 12.9 | 0.3 |
| Body mass index (kg/m ²) | 26.7 \pm 5.4 | 24.4 \pm 5.2 | 0.06 |
| History of anxiety/depression | 7 (9.7) | 4 (14.3) | 0.5 |
| Parity | 2 (0-5) | 2 (0-4) | 0.8 |
| Nulliparity | 10 (13.9) | 9 (32.1) | 0.04 |
| History of caesarean section | 20 (27.8) | 6 (21.4) | 0.6 |
| Premenopausal | 64 (88.9) | 23 (82.1) | 0.5 |
| Indication for hysteroscopy referral | | | |
| Abnormal uterine bleeding | 25 (34.7) | 11 (39.3) | 0.5 |
| Suspected uterine polyp | 22 (30.6) | 7 (25.0) | |
| Infertility workup | 12 (16.7) | 4 (14.3) | |
| Suspected retained products of conception | 9 (12.5) | 2 (7.1) | |
| Other** | 4 (5.6) | 4 (14.3) | |

*Assessment of preoperative anxiety was conducted using the State-Trait Anxiety Inventory (STAI) questionnaire, with participants categorised as having low anxiety (score <30), moderate anxiety (scores between 30 and 45), or high anxiety (scores of 46 or above).
 **Including: Intrauterine device removal and assessment of caesarean section defect.
 Data are presented as mean \pm standard deviation, median (range) or number (%).

Table 4. Comparison of hysteroscopic characteristics between patients with low versus moderate/high preoperative anxiety scores.

| Characteristic | Low anxiety** (n=72) | Moderate/high anxiety** (n=28) | P value |
|--|----------------------|--------------------------------|-------------|
| Hysteroscopy successfully completed | 71 (98.6) | 27 (96.4) | 0.4 |
| Hysteroscopic diagnosis of cervical stenosis | 7 (9.7) | 5 (17.9) | 0.2 |
| Hysteroscopy operative time (seconds) | 56.7 \pm 32.2 | 56.3 \pm 28.2 | 0.9 |
| Hysteroscopy procedure | | | |
| Diagnostic hysteroscopy | 56 (77.8) | 20 (71.4) | 0.6 |
| Operative hysteroscopy | 16 (22.2) | 8 (28.6) | |
| VAS* pain score (cm) | 2.0 \pm 2.5 | 3.6 \pm 3.2 | 0.02 |
| VAS** ≥ 5 cm | 10 (13.9) | 9 (32.1) | 0.04 |

*VAS: Visual analogue scale, recorded on a 10 cm line anchored at 0 (designated as "no pain") and 10 (designated as the "worst pain imaginable").
 **Assessment was conducted using the State-Trait Anxiety Inventory (STAI) questionnaire, with participants categorized as having low anxiety (score <30), moderate anxiety (scores between 30 and 45), or high anxiety (scores of 46 or above).
 Data are presented as mean \pm standard deviation or number (%).

Discussion

Main Findings

Office hysteroscopy is a common procedure indicated for a wide range of gynaecologic problems, but could be associated with significant anxiety, which may adversely affect patients' satisfaction and pain.² Non-pharmacologic interventions designed to decrease patients' anxiety (such as detailed preoperative education, use of virtual reality headset, listening to music, and "vocal local") may offer significant benefits with low potential side effects.³ In the current study, we have found that preoperative education using an animated video successfully reduced rates of moderate/high anxiety when compared to the standard preoperative communication. However, the mean anxiety score and the mean intraoperative pain score did not differ between the study and control groups.

Strengths and Limitations

Our study has several limitations. First, it was conducted in a single centre, and all procedures were performed by experienced surgeons, which may limit the generalisability of our findings. Assignment to the study and control groups was determined arbitrarily based on the day of the procedure, without randomisation or stratification for patients' characteristics and types of hysteroscopy, which may have led to selection bias. Although the assessment of the study outcomes was self-reported by the participants, the non-blinded study design may have also introduced investigator bias. The results may have been influenced by differences in the indications for hysteroscopy between groups, although the hysteroscopic procedures performed—diagnostic versus operative—were comparable. Lastly, while rates of moderate/high anxiety were lower in the animated video group, there were no statistical differences in the mean anxiety score or in the mean intraoperative pain, possibly due to insufficient power.

Strengths and Limitations Compared to Other Studies

Several studies have investigated the effectiveness of non-pharmacologic approaches in reducing anxiety before office hysteroscopy.⁷⁻¹¹ Among those, decreasing waiting time, listening to music during the procedure, continuous interaction and support, and the use of a virtual reality headset during hysteroscopy have been shown to be effective. Akca et al.⁵ investigated the effectiveness of preoperative education using an animated video to reduce anxiety and pain during office hysteroscopy,

compared with providing written information. Like our results, they observed decreased anxiety levels but found no impact on pain.

Several patient characteristics have also been investigated in association with anxiety levels prior to hysteroscopy, including age, menopausal status, parity, previous caesarean section, history of depression or anxiety, and the type of hysteroscopic procedure (diagnostic vs. operative). Similar to previous studies, we did not find any significant association between these parameters and moderate/high levels of anxiety.^{5,7}

Importantly, increased anxiety has been associated with higher pain levels due to the physiological interconnection between anxiety and pain perception.^{3,12} Similar to previous studies, we found higher mean VAS pain scores and higher rates of VAS >5 among patients with moderate/high levels of anxiety compared to those with low levels of anxiety.^{8,9,12} These findings highlight the importance of reducing anxiety prior to the performance of office hysteroscopy in the effort to concomitantly address patients' pain perception.

Clinical and Policy Implications

Preoperative education is key to reducing patients' anxiety before office hysteroscopy. Among the available strategies for patient education, the use of an animated video is a simple and effective tool which may be superior to standard verbal education. It is recommended that all clinics offering office hysteroscopy adopt protocols aimed at addressing patient anxiety.

Unanswered Questions and Future Research

As office-based hysteroscopy procedures—particularly those with an operative component—become increasingly prevalent, addressing preoperative patient anxiety is of growing importance. The optimal strategy for managing this anxiety has not yet been established, and further studies are necessary to determine the most effective approach.

Conclusion

Animated preoperative videos before office hysteroscopy without anesthesia can lower moderate/high anxiety rates compared to standard verbal education, and may help reduce anxiety commonly experienced during office procedures.

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Ethical approval: The study was approved by the Shamir Medical Centre Institutional Review Board (0011-23-ASF) on January 30th, 2023 and registered in the Clinicaltrials.gov registry (NCT06625567).

Informed consent: All participants signed an informed consent upon enrolment, as well as the standard written informed consent for undergoing the hysteroscopy.

Data sharing: Data will be available upon 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 (and, if relevant, registered) have been explained.

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Supplementary Video 1. <https://precare.ca/healthcare-guides/diagnostic-hysteroscopy/>