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Music and oral premedication for pain management during outpatient hysteroscopy: results from a randomised controlled trial

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ABSTRACT

Background: Outpatient hysteroscopy is a common procedure, but pain can lead to failure and poor patient experience, especially in women without previous vaginal delivery and postmenopausal women.

Objectives: To compare the use of music during outpatient hysteroscopy with oral pre-procedural analgesia or no pain control intervention on perioperative and postoperative pain.

Methods: A randomised controlled trial was conducted at the outpatient hysteroscopy service of the University of Cagliari between December 2024 and June 2025. Women undergoing outpatient hysteroscopy were allocated to a music group (pre-defined instrumental relaxing music without lyrics, delivered through a Bluetooth speaker throughout the procedure), an oral premedication analgesia group (ibuprofen 200 mg + paracetamol 1000 mg, 90 min pre-procedure), or a control group (no pre-pharmacological or music-based analgesic support). A 5-mm hysteroscope and standardised vaginoscopic "no-touch" technique were used.

Main Outcome Measures: The primary outcome was maximum pain on a 0–10 visual analogue scale (VAS) intraoperatively (T0) and 30 minutes post-procedure (T1). Secondary outcomes included operative time, successful procedural completion, and complications. A pre-specified subgroup analysis was performed to explore potential treatment-by-previous vaginal delivery status (no previous vaginal delivery vs. women with a previous vaginal delivery) and menopausal status (reproductive age vs. menopause) interactions.

Results: Two hundred sixty-four women were randomised; 88 to intraprocedural music, 89 to pre-operative analgesia, and 87 to no pain control intervention. Peak intraoperative pain did not differ across groups (VAS mean ± standard deviation: 3.4±1.0 in the music group, 3.5±1.45 in the oral premedication group, and 3.6±0.9 in the control group; *P*=0.35). Post-procedural pain at 30 minutes was also similar across groups (1.5±1.4, 1.5±1.5, and 1.7±1.1, respectively; *P*=0.24). Operative time was comparable across groups (mean: 3.2, 3.1, and 3.2 minutes; *P*=0.13). Procedure completion rates did not differ between groups (*P*=0.62), and no complication rates or drug-related adverse events were observed. In exploratory analyses across the overall cohort, women with no previous vaginal delivery (n=82) reported higher intra-procedural pain scores than women with a previous vaginal delivery (n=182) (VAS 4.1±0.9 vs 3.2±0.9; *P*=0.032). Similarly, postmenopausal women (n=76) reported higher pain scores than women of reproductive age (n=188) (VAS 4.0±0.9 vs. 3.4±0.9; *P*=0.023).

Conclusions: The use of intraoperative music or pre-procedural analgesia with oral ibuprofen-paracetamol does not reduce pain compared with standard outpatient hysteroscopy.

What is New? Intraoperative music and oral analgesia during outpatient hysteroscopy are not more effective than standard hysteroscopy for reducing pain associated with outpatient hysteroscopy.

Keywords: Hysteroscopy, outpatient, pain, music therapy, patient experience, premedication

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Introduction

Outpatient hysteroscopy is the gold standard for diagnosing and treating intracavitary uterine pathology, combining feasibility and reproducibility, with a low complication rate.[1-3] Avoiding general anaesthesia enables faster recovery, earlier return to daily activities, improved patient satisfaction, and is cost-effective.[4] Nevertheless, pain during and after the procedure remains a barrier and is associated with incomplete procedures.[5]

Pain perception during outpatient hysteroscopy is multifactorial. The most relevant risk factors include lack of previous vaginal delivery, menopause, cervical synechiae, and prolonged operative time, whereas women with at least one prior vaginal delivery generally tolerate the procedure better.[6] From a pathophysiological standpoint, intraoperative pain is attributed to uterine contractions triggered by distension of the uterine cavity with saline, while postoperative pain is thought to be related to increased prostaglandin production.[7]

Beyond these biological contributors, psychological factors are clinically relevant: anxiety can reduce pain thresholds and amplify pain perception, which is not purely sensory but also shaped by emotional and cognitive components. Thus, anxiety represents a meaningful patient-related variable that may adversely affect tolerance and overall procedural success.[8,9]

With the adoption of the vaginoscopic "no touch" technique and the introduction of smaller-caliber hysteroscopes, multiple pharmacological and non-pharmacological interventions have been investigated to mitigate pain during outpatient hysteroscopy. Pharmacological strategies have included opioids (e.g., tramadol), local anaesthetics (e.g., ropivacaine or intrauterine lidocaine), antispasmodics, cervical priming agents (misoprostol or dinoprostone), and non-steroidal anti-inflammatory drugs (NSAIDs).[10,11] However, a recent Cochrane meta-analysis of 32 randomised controlled trials (RCTs) did not identify a clearly superior pharmacological approach.[12] Non-pharmacological methods have also gained attention, including the vocal–local approach, grounded in empathetic communication and continuous support, as well as stretching, hypnosis, heat application, music, and transcutaneous electrical nerve stimulation.[13] Nevertheless, the most commonly used approach is vocal local. During the procedure, a nurse, midwife, or resident doctor should provide emotional support to the woman to further reduce the level of anxiety and distract them from the procedure.[14] In parallel, interest in music as an adjunct has increased, based on its potential to reduce anxiety and modulate pain; its routine use is encouraged in several gynaecological and obstetric settings.[15,16]

Eventually, evidence remains conflicting, and there is currently no consensus on an optimal pain management strategy for office hysteroscopy (OH). Given the limited comparative literature, we conducted this study to evaluate whether music or oral pre-procedural analgesia provides superior pain control compared with standard care during OH.

Methods

Study Design

A prospective, triple-arm, RCT was conducted at the Hysteroscopy Unit of the University Hospital in Cagliari between December 2024 and June 2025. The study was approved by the Regional Ethics Committee on 25.11.2024 (protocol number: 31891) and conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained for each participant. Women referred for outpatient diagnostic or operative hysteroscopy during the study period were consecutively enrolled in this series and were allocated after baseline data collection. Participants were randomly allocated to the three study groups using a computer-generated randomisation list in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). The randomisation sequence was generated before patient enrolment and maintained by the study investigators. No block randomisation or stratification was applied. The research coordinators regularly performed data quality control, management, and verification of protocol compliance. Due to the nature of the intervention, blinding participants, care providers, and outcome assessors was not possible.

The patients were randomly allocated to three groups based on the pain-relief method used: the music group, the oral premedication group, and the control group. Oral premedication consisted of ibuprofen 200 mg + paracetamol 1000 mg administered 90 minutes before hysteroscopy. In contrast, women allocated to the music group listened to the same pre-defined instrumental relaxing playlist, without lyrics, delivered through a Bluetooth speaker (JBL GO 3, Harman International Industries, Stamford, CT, USA) placed approximately 1 metre from the examination table, with the volume adjusted to a comfortable level, allowing communication

with the operator during the procedure performed. Patients in the control group did not receive any pharmacological or music-based analgesic support.

All procedures were performed in an outpatient setting using a vaginoscopic "no-touch" technique.[3] The same expert gynaecologist performed all hysteroscopies in a dedicated room. A Bettocchi hysteroscope (Karl Storz, Tuttlingen, Germany) with a 30-degree lens and a 5-mm external diameter, featuring an oval profile, was used following the "no touch" approach via vaginoscopy, without the use of a speculum or cervical hook. This system is routinely adopted in our unit because it allows both diagnostic evaluation and minor operative procedures during the same outpatient session while maintaining good optical quality. In reproductive-age patients, procedures were scheduled in the early proliferative phase. Standard saline solution was used as the distension medium, maintaining intrauterine pressure below 80 mmHg and a flow rate of 150 mL/min via a mechanical irrigation system (Endomat, Karl Storz, Tuttlingen, Germany). Before starting the procedure, the following data were recorded and entered into our electronic database: age, body mass index, previous vaginal delivery, menopausal status, past medical and surgical history, ongoing medical treatments, allergies, indication for outpatient hysteroscopy, and ultrasound findings. Diagnostic hysteroscopy was defined as a visual assessment alone without additional intervention. For data analysis, procedures requiring an endometrial biopsy for diagnostic indications were classified as operative hysteroscopies.

Primary outcomes were intraoperative pain (T0) and post-procedural pain (T1), measured using a 0–10 visual analogue scale (VAS). Intraoperative pain (T0) was recorded immediately after completion of the hysteroscopic procedure, while post-procedural pain (T1) was assessed 30 minutes after completion. VAS scores were collected in the presence of the investigators, who provided standardised instructions without influencing patient responses. Secondary outcomes included operative time, procedure completion rate, and complication rate. We considered the operative time from the entry of the hysteroscope into the external cervical orifice till its exit from the cervix. The procedure was recorded as "failed" when it was impossible to complete because of the pain due to severe cervical canal stenosis requiring mechanical dilatation under general anaesthesia. These patients were excluded from statistical analysis.

Inclusion and Exclusion Criteria

We considered the following inclusion criteria: patients over 18 years old; traditional indications for outpatient hysteroscopy (abnormal uterine bleeding, infertility, suspected intrauterine pathologies, endometrial thickness over 4 mm on sonographic evaluation in postmenopausal women); ability to make a voluntary decision to participate; and ability to sign consent after being properly informed. The patient's exclusion criteria were allergy or other contraindications to administering analgesic drugs used in the study, any contraceptive (oral, vaginal, intrauterine, dermal, or subcutaneous) because they would confound the study, the use of any analgesic for other pathologies and presenting any disease or disability that may intervene in the aim of this study (any auditory or sensory deficits, diseases or mental syndromes that could make the study difficult or impossible to complete). Before the procedure, all participants were specifically asked whether they had taken any analgesic medication prior to attending the appointment.

Subgroup Analysis

A prespecified subgroup analysis was performed to explore differences in pain by previous vaginal delivery status (women without previous vaginal delivery vs. women with a previous vaginal delivery) and menopausal status (reproductive age vs. menopause). Previous vaginal delivery was defined as at least one previous vaginal birth of a viable pregnancy, while menopausal status was determined clinically and by medical history. Intra-procedural pain scores (VAS at T0) were compared between subgroups across the overall cohort. Because no formal sample size calculation was performed and the trial was not powered for subgroup comparisons, these analyses are exploratory and are reported as mean ± standard deviation with unadjusted *P* values.

Statistical Analysis

The independent-samples t-test was used to assess statistical significance, along with Fisher's exact test and the chi-square test when appropriate. A Kruskal-Wallis test was performed to compare the three groups. $P<0.05$ was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics (version 29.0; IBM Corp., Armonk, NY, USA). This exploratory randomised trial was conducted on a convenience sample of consecutive eligible women during the study period; no formal sample size calculation was performed.

Results

During the study period, 293 women of Caucasian ethnicity underwent hysteroscopy at our outpatient hysteroscopy service of the University of Cagliari and were considered eligible for enrollment. After applying exclusion criteria, only 264 patients were included in the analysis. They were divided as follows: control group (n=87), oral premedication group (n=89), and music group (n=88), as shown in Figure 1. None reported the use of additional analgesics on the day of the procedure.

Demographic characteristics were comparable among the three groups, and no differences were observed for the type of surgery (diagnostic or operative) (P>0.05) (Table 1).

The most common hysteroscopy indication was the suspicion of intrauterine lesions at ultrasound examination (143/264; 54%), followed by evaluation for abnormal uterine bleeding (70/264; 27%), infertility work-up (48/264; 18%), and intrauterine device displacement (3/264; 1%).

Endometrial polyps were treated in 18 patients (music n=8, oral premedication n=5, control n=5), with a mean polyp size of 19±5.1 mm. Endometrial biopsies were performed in 56 patients (music n=17, oral premedication n=20, control n=19). The remaining 10 operative procedures consisted of minor targeted interventions (removal of small intracavitary lesions and adhesiolysis) and were similarly distributed among the groups. The distribution of operative procedures was comparable across groups. None of the women enrolled in the study suffered intraoperative complications or experienced vasovagal reactions, and no women in the oral premedication group suffered from medication-related side effects (nausea, rash, tachycardia, or hypotension). The overall mean operative time was 3.2 minutes, with no differences among groups (*P*>0.05). No statistically significant differences were found in the procedure success rate by pain-relieving method (*P*=0.62), with pain being the most common cause of failure, followed by severe stenosis of the cervical canal requiring mechanical dilation under general anaesthesia. Primary and secondary outcomes by treatment group are summarised in Table 2. There were no between-group differences in operative time, complication rate, or mean pain scores at either time point (T0 and T1), consistent with the overall analyses (T0 *P*=0.35; T1 *P*=0.24). The three groups showed similar results for the primary outcome of the study, with no statistically significant differences in mean pain scores during the

Table 1. Baseline characteristics of participants.

	Music group (n=88)	**Oral premedication group (n=89)**	**Control group (n=87)**	***P*-value**
Age (years)	45.21±7.5	42.96±7.1	43.38±7.6	*P*=0.10
BMI	26.3±1.1	26.5±1.3	26.6±1.3	*P*=0.26
Reproductive status				*P*=0.61
Premenopausal	62/88 (70%)	67/89 (75%)	59/87 (68%)	
Postmenopausal	26/88 (30%)	22/89 (25%)	28/87 (32%)	
Previous vaginal delivery status				*P*=0.69
No previous vaginal delivery	30/88 (34%)	25/89 (28%)	27/87 (31%)	
Previous vaginal delivery	58/88 (66%)	64/89 (72%)	60/87 (69%)	
Indication for outpatient hysteroscopy (%)				*P*=0.76
Intrauterine lesion	52%	57%	55%	
AUB	29%	24%	30%	
Infertility	18%	17%	15%	
IUD displacement	1%	2%	0%	
Type of procedure (%)				*P*=0.65
Diagnostic	57/88 (65%)	61/89 (69%)	62/87 (71%)	
Operative	31/88 (35%)	28/89 (31%)	25/87 (29%)	

AUB: Abnormal uterine bleeding, BMI: body mass index, IUD: Intrauterine device.

procedure and 30 minutes after completion (T0 *P*=0.35; T1 *P*=0.24, respectively), despite the mean pain score being consistently slightly higher in the control group. The VAS score was also comparable between the three groups at stratification for both diagnostic and operative procedures (*P*=0.31 and *P*=0.43, respectively).

Among the 264 women included, the proportion of premenopausal participants did not differ across arms: 70% in the music group arm (62/88), 75% in the oral premedication group arm (67/89), and 68% in the control group arm (59/87). Accordingly, postmenopausal women represented 30%, 25%, and 32% of each group, respectively.

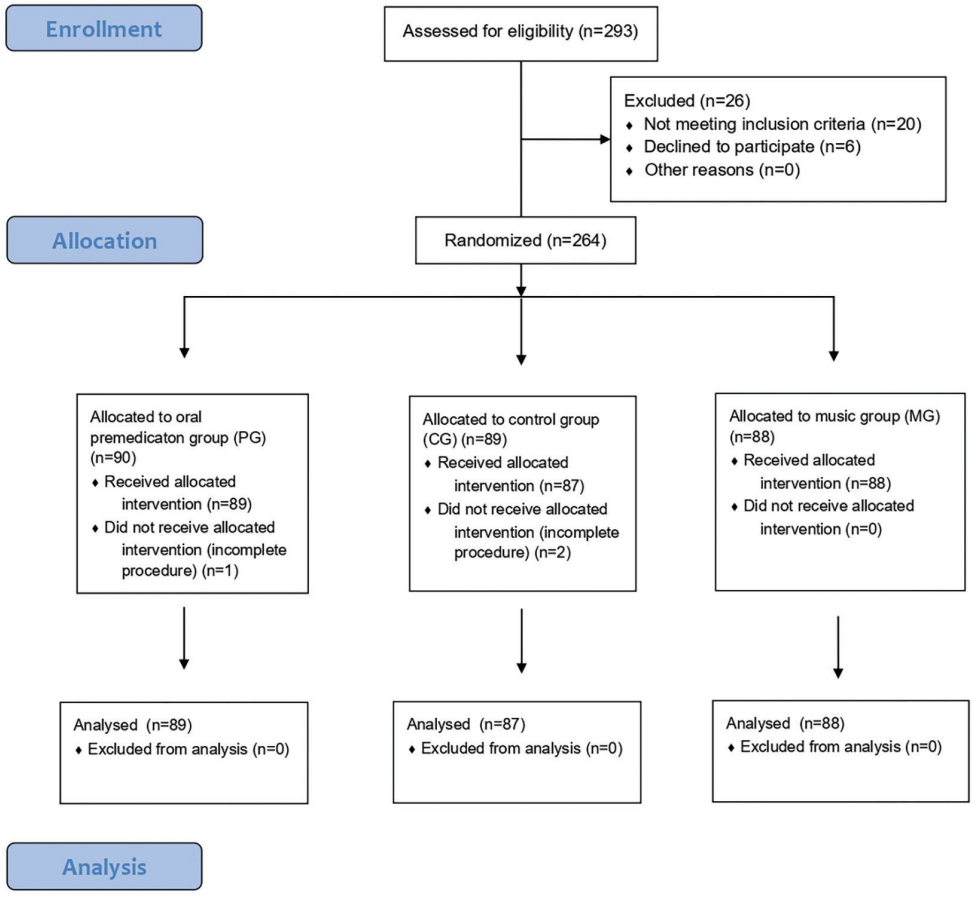

Figure 1. Patient study enrollment, allocation, and analysis.

Table 2. Primary and secondary outcomes.

	Music group (n=88)	**Oral premedication group (n=89)**	**Control group (n=87)**	***P*-value**
Operative time (min)	3.2±0.3	3.1±0.5	3.2±0.3	*P*=0.13
Complication rate	0/88 (0%)	0/89 (0%)	0/87 (0%)	*P*=1.0
Mean pain score (VAS)				
T0	3.4±1.0	3.5±1.45	3.6±0.9	*P*=0.35
T1	1.5±1.4	1.5±1.5	1.7±1.1	*P*=0.24
Mean pain score (VAS)				
diagnostic	3.3±1.4	3.4±1.3	3.2±1.3	*P*=0.31
operative	3.6±1.6	3.6±1.6	3.8±1.5	*P*=0.43

VAS: Visual analogue scale, min: Minute.

Women without previous vaginal delivery ranged from 28% to 34% across groups, while the majority had a previous vaginal delivery (66-72%). No statistically significant differences were observed in these baseline characteristics among the three study arms. Across the overall cohort, women without previous vaginal delivery experienced significantly more pain during outpatient hysteroscopy than women with a previous vaginal delivery (VAS score 4.1±0.9 vs. 3.2±0.9, respectively; *P*=0.032), as illustrated in Figure 2A. This difference was not observed 30 minutes after the procedure, when pain scores were comparable between the two groups (VAS score 1.5±1.2 vs. 1.4±1.1; *P*>0.05; Figure 2B). Regarding reproductive status, Figure 2C shows that postmenopausal women reported moderately higher intra-procedural pain scores than those of reproductive age (VAS score 4.0±0.9 vs. 3.4±0.9, respectively; *P*=0.023), while Figure 2D shows a similar trend at 30 minutes post-procedure, although the difference was not statistically significant.

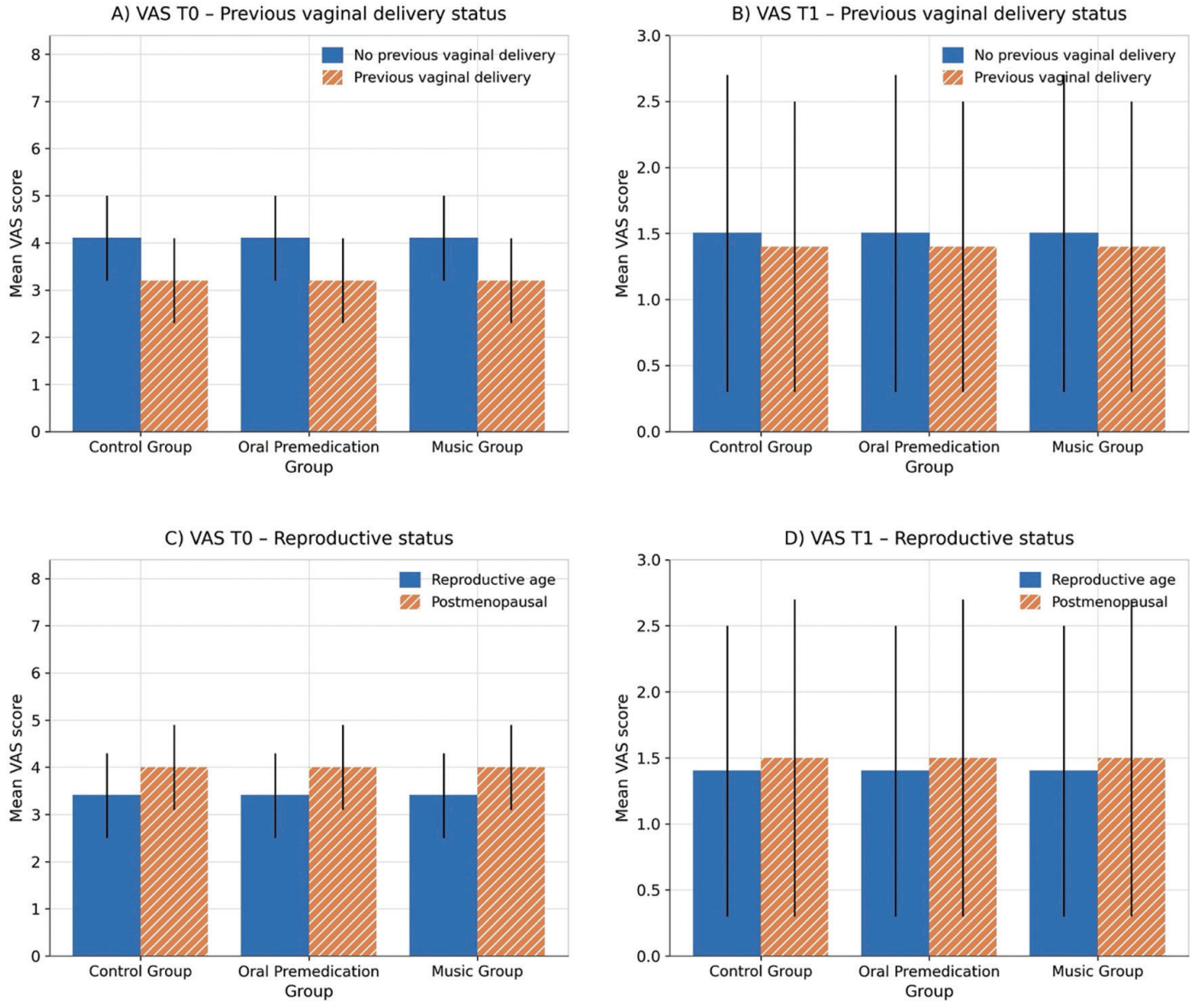

Figure 2. Pain scores (VAS) at T0 (intra-procedural) and T1 (30 minutes post-procedure) by subgroup, across the overall cohort, and independently of treatment allocation. A, B) Women without previous vaginal delivery reported higher pain scores than women with a previous vaginal delivery during the procedure (T0), with no difference 30 minutes after the procedure (T1). C, D) Postmenopausal women reported moderately higher intra-procedural pain scores than women of reproductive age (T0), with a comparable, non-significant trend at 30 minutes (T1). Error bars represent standard deviation.

VAS: Visual analog scale.

Discussion

Main Findings

In this RCT, neither intraoperative music nor oral pre-procedural ibuprofen–paracetamol premedication reduced pain during or after outpatient hysteroscopy when compared with standard care performed using a vaginoscopic technique. Pain scores were low across all groups, and no differences were observed in operative time, complication rates, or procedure completion. Independently of treatment allocation, patient-related factors such as absence of previous vaginal delivery and postmenopausal status were associated with higher intra-procedural pain scores, but no difference in pain scores was observed between purely diagnostic and operative hysteroscopic procedures. The diagnostic and operative approach to the most common intrauterine anomalies has undergone significant changes since the widespread adoption of outpatient hysteroscopy in general gynaecological practice, leading to less invasive procedures. The outpatient setting allows for the management of up to 60–65% of hysteroscopies, with consequent advantages for both clinicians and patients.[17] Despite this technique being considered well tolerated by most women, the pain is still responsible for variable completion rates ranging from 77% to 97%, with conflicting results about the most effective pain-relieving method.[18]

For prior oral analgesic medication, we chose ibuprofen and paracetamol because their use, particularly NSAIDs, is recommended by the Royal College of Obstetricians and Gynaecologists.[19] In addition, when compared to other pharmacological drugs such as opioids or local anaesthetics, these molecules are less associated with adverse events, do not require anaesthetic supervision, and are a cheap, non-invasive, and readily available measure. The combined use (or co-administration) of NSAIDs and paracetamol is also reported in the literature, as the latter can exert a synergistic effect in preventing prostaglandin production through a different mechanism of action.[20] On the other hand, the effectiveness of music in reducing pain perception has been demonstrated in both postoperative and chronic pain management.[21,22] More recently, the same results have been observed and proven during outpatient hysteroscopy.[16,23]

Strengths and Limitations

To our knowledge, this is the first randomised controlled study to directly compare the effects of music and oral premedication on reducing pain during outpatient hysteroscopy. The study design, a prospective, triple-arm, RCT, provides more data than previous research, which did not directly compare music with prior analgesic medication. Strengths include standardisation of diagnostic and operative procedural approaches across groups and completeness of follow-up. The main limitation of this study relates to the adequacy of the sample, as we did not perform a power calculation. This limits the strength of any clinical recommendations and raises the risk of type II errors, in which negative results are falsely declared. Another limitation is the trial's non-blinded design. This relates to the pain-relieving methods we tested, as they enable patients to identify which group they belong to, which may influence their pain evaluation. Another limitation of this study is that pain intensity measured by the VAS was the only patient-reported outcome collected. Although VAS remains the most widely used measure of procedural pain in outpatient hysteroscopy trials, it does not fully capture the overall patient experience.[24] Measures of acceptability, satisfaction, and willingness to undergo repeat hysteroscopy may provide a more comprehensive assessment of procedural tolerance. Future studies should incorporate broader patient-reported outcome measures to better evaluate the overall experience of women undergoing outpatient hysteroscopy. An additional potential limitation concerns the diameter of the hysteroscope used. All procedures were performed with a 5-mm Bettocchi hysteroscope, but smaller-diameter hysteroscopes are increasingly available and may be associated with lower pain perception, particularly in women without previous vaginal delivery and postmenopausal women. Finally, the generalisability of our findings is limited, as all procedures were performed by a single experienced surgeon.

Strengths and Limitations Compared to Other Studies

Our findings regarding the effectiveness of prior oral medication were similar to those reported by Teran-Alonso et al.,[25] who found that women who received prior oral analgesia experienced a significant reduction in the occurrence of non-painful hysteroscopic side effects, without any difference in intraoperative or postoperative pain. Regarding postoperative pain evaluation, we hypothesised that the T1-VAS score in the oral premedication group might have been statistically significantly lower, as prostaglandin release and its peak have been associated with delayed pain.

We found no difference among the three groups regarding postoperative pain, and the timing of drug administration could not explain this, as the same results also emerged for administration at 60 and 120 minutes before the procedure.[25,26]

Conversely, our results for the music group contrast with those reported in the literature. In the study by Law et al.,[23] listening to music during outpatient hysteroscopy was associated with significantly less pain than the standard procedure. The technique used during outpatient hysteroscopy could explain the discrepancies between these results. In the current study, the procedure was performed in all patients using standardised vaginoscopy, providing the least invasive approach possible. At the same time, in the other study, a speculum and tenaculum were used at the surgeon's preference, without stating whether there was any statistically significant difference between the two groups with respect to this variable.

On the contrary, the significantly higher VAS score in the women without a previous vaginal delivery and menopausal subgroup compared to women with a previous vaginal delivery and reproductive age women mirrored the results of several previous published studies.[27-29] Indeed, our subgroup analysis is consistent with the absence of previous vaginal delivery as a determinant of procedural pain during outpatient hysteroscopy, with women without previous vaginal delivery consistently reporting higher pain levels than women with a previous vaginal delivery. Importantly, these differences emerged across the overall cohort and independently of treatment allocation, since neither music nor premedication reduced pain in the primary analysis. These findings, although exploratory, may inform the design of future trials specifically powered to detect clinically relevant differences within these subgroups.

Clinical and Policy Implications

Our data do not suggest that investment in resources such as music systems or routine use of prior oral administration of ibuprofen and paracetamol is justified to reduce intra- and postoperative pain experienced during outpatient hysteroscopy. However, adoption of recommended approaches to conducting outpatient hysteroscopy, such as the routine use of small-diameter instruments and vaginoscopy, should be encouraged.

Unanswered Questions and Future Research

Further RCTs are needed to evaluate novel pain-controlling interventions to minimize the pain associated with outpatient hysteroscopy and improve patient experience, with particular attention to higher-risk subgroups such as women without previous vaginal delivery and postmenopausal women.

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Informed consent: Written informed consent was obtained for each participant.

Data sharing: The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

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

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