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Original Research

Impact of a Multisensory Clinical Environment on Pain and Patient Experience During Office Hysteroscopy: The VISION-HYST Randomized Controlled Pilot Trial

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Abstract

Background: Pain and anxiety remain major barriers to the tolerability and widespread adoption of office hysteroscopy, despite advances in minimally invasive techniques and the use of nitrous oxide (N_2O) analgesia. Non-pharmacological interventions targeting the clinical environment may offer a complementary strategy to improve patient experience. To evaluate the preliminary effect of a multisensory clinical setting, incorporating visual environmental distraction, on pain perception during operative office hysteroscopy. **Methods:** This randomized, parallel-group pilot trial enrolled 50 women undergoing operative office hysteroscopy in an outpatient setting. Participants were allocated to standard care with N_2O (control group) or N_2O combined with a multisensory intervention consisting of a wall-mounted virtual window displaying relaxing visual content (intervention group). The primary outcome was procedural pain assessed on a 10-point scale. Secondary outcomes included referral to the operating room and procedural feasibility. Between-group differences were analyzed using Welch's *t*-test. **Results:** 50 patients were randomized (25 per group), and all completed the study. Mean pain scores were significantly lower in the intervention group than in the control group (3.1 ± 1.5 vs. 5.8 ± 1.9; $p < 0.001$). The reduction in pain was observed across different hysteroscopic techniques and appeared more pronounced among multiparous women. No significant between-group differences were observed in secondary outcomes, including referral to the operating room (20% vs. 12%; $p = 0.702$). No adverse events related to the intervention or N_2O were reported. **Conclusions:** In this pilot randomized trial, the addition of a simple visual environmental distraction to standard N_2O analgesia was associated with reduced pain during operative office hysteroscopy. These findings suggest that non-pharmacological, environment-based strategies may complement existing analgesic approaches to enhance patient experience. Larger, adequately powered studies are needed to confirm these preliminary findings. **Clinical Trial Registration:** This study is registered on the ClinicalTrials.gov (registration number: NCT07473206).

Keywords: office hysteroscopy; multisensory environment; pain management; visual distraction

1. Introduction

Office hysteroscopy has become a cornerstone of modern gynecological practice and represents the gold standard for the diagnosis and management of intrauterine pathology. Advances in endoscopic technology, particularly the miniaturization of instruments and the adoption of the vaginoscopic approach, have enabled a progressive shift from operating room-based procedures to outpatient settings. This transition has yielded significant clinical and organizational benefits, including reduced reliance on general anesthesia, shorter recovery times, lower healthcare costs, and improved patient throughput. Current guidelines from major scientific societies, including the Italian Society of Gynecological Endoscopy (SEGI) and the Royal College of Obstetricians and Gynaecologists, support the use of office hysteroscopy as a first-line diagnostic and therapeutic tool whenever feasible [1,2,3].

Despite these advances, pain and anxiety remain major barriers to the widespread adoption and patient acceptability of office hysteroscopy. A considerable proportion of patients report moderate to severe discomfort during the procedure, which may result in incomplete procedures or referral to the operating room. Pain perception during hysteroscopy is multifactorial, encompassing procedural factors such as cervical manipulation, uterine distension, and instrument size, as well as patient-related factors including parity and cervical anatomy. Notably, psychological variables, particularly anticipatory anxiety, play a crucial role in determining pain perception and procedural tolerance [4,5]. The interaction between anxiety and pain is mediated by central mechanisms that amplify nociceptive pro-

cessing through increased attentional focus and stress responses [6].

Nitrous oxide (N_2O) has emerged as a valuable option for pain management in outpatient hysteroscopy due to its rapid onset, favorable safety profile, and combined analgesic and anxiolytic properties [7,8,9]. However, pharmacological approaches alone may not fully address the multidimensional nature of pain experienced during these procedures. Growing attention has therefore been directed toward non-pharmacological strategies, particularly those targeting the clinical environment and overall patient experience.

The concept of a healing environment emphasizes the role of sensory stimuli in modulating stress and emotional responses. Environmental factors such as lighting, sound, and visual input can influence patient perception and physiological stress responses, thereby affecting the overall procedural experience [10]. In this context, music therapy has been shown to reduce anxiety and improve pain tolerance through modulation of autonomic and neuroendocrine pathways [11]. Similarly, visual distraction techniques aim to redirect attentional focus away from nociceptive stimuli toward engaging sensory inputs.

Among these, virtual reality (VR) has demonstrated effectiveness in reducing pain and anxiety during various medical procedures, including outpatient hysteroscopy [12,13,14]. However, its implementation may be limited by cost, technical requirements, and patient acceptance. Consequently, simpler and more accessible forms of visual distraction have been proposed. A wall-mounted virtual window displaying natural scenes represents a pragmatic alternative, leveraging biophilic design principles to promote relaxation without interfering with the procedure.

The integration of multiple sensory modalities into a multisensory clinical setting represents a holistic approach to improving patient experience, addressing both the physical and psychological components of pain. Within this framework, the outpatient hysteroscopy unit of Azienda Sanitaria Locale (ASL) Biella implemented a model combining standard N_2O analgesia with environmental interventions, including visual environmental distraction. Other environmental elements (e.g., music and lighting) were part of the standard clinical setting and did not differ between groups. The present randomized pilot study was designed to evaluate the preliminary impact of this multisensory setting on pain perception and procedural experience during operative office hysteroscopy. Specifically, the study aimed to assess whether the addition of visual environmental distraction to standard N_2O analgesia could significantly reduce procedural pain, as measured by the 10-point numerical rating scale (NRS), and improve procedural outcomes.

2. Materials and Methods

This study was designed as a randomized, parallel-group pilot clinical trial aimed at evaluating the preliminary effect of a multisensory environmental intervention on pain perception during operative office hysteroscopy. Given its exploratory nature, the study was not intended to provide definitive evidence of efficacy, but rather to assess feasibility, estimate the magnitude of the intervention effect, and generate hypotheses for future large-scale trials. The study was conducted at the outpatient hysteroscopy unit of ASL Biella, Italy, a tertiary referral center organized according to a patient-centered care model that integrates clinical practice with environmental design and patient-centered care principles.

Women aged 25 to 60 years who were referred to the outpatient hysteroscopy clinic for diagnostic or operative evaluation of intrauterine pathology were eligible for inclusion. Indications included suspected endometrial polyps, submucosal fibroids, endometrial thickening, intrauterine adhesions, or uterine malformations. Inclusion criteria required clinical eligibility for office hysteroscopy and suitability for N_2O analgesia per routine practice. Exclusion criteria encompassed known or suspected contraindications to N_2O administration, such as pneumothorax or severe obstructive pulmonary disease, altered consciousness, pregnancy, prior major cervical surgery (e.g., conization), or inability to provide informed consent.

Participants were recruited consecutively from the outpatient clinic over a predefined study period (January 2026 to April 2026), following a pragmatic approach aligned with routine clinical activity. Following verification of eligibility criteria, patients were invited to participate and underwent a standardized pre-procedural counseling session conducted by the hysteroscopist. This session included an explanation of the procedure, expected duration, type of assistance provided, analgesia modality, and post-procedural care instructions. Upon agreement to participate and signature of the informed consent form, patients were enrolled and assigned to one of the two study groups.

The allocation sequence was generated before patient enrollment using a simple random sequence. Participants were assigned in a 1:1 ratio to the intervention or control group through a sealed-envelope system. Identical opaque envelopes containing the group assignments were prepared by an independent member of the research team who was not involved in patient care or data analysis. The envelopes were mixed, securely stored, and opened only after enrollment and informed consent. No restrictions, including block randomization or stratification, were applied. No formal sample size calculation for hypothesis testing was performed. This was an exploratory pilot trial; therefore, the sample size of 50 participants (25 per group) was selected pragmatically to assess feasibility and to provide preliminary estimates of the intervention effect and outcome variability, rather than to achieve predefined statistical power. Accordingly, no assumptions regarding effect size, α level, statistical power, or anticipated dropout rate were used to determine the sample size. This method minimized selec-

tion bias and preserved the integrity of the randomization process.

All participants underwent operative office hysteroscopy using a vaginoscopic approach without speculum or tenaculum whenever feasible, consistent with current best practices. Procedures were performed using either a Bettocchi hysteroscope (Karl Storz, Tuttlingen, Germany) or a bipolar mini-resectoscope (15 Fr, Karl Storz, Tuttlingen, Germany; 16 Fr, Tontarra Medizintechnik, Tuttlingen, Germany), selected according to the clinical indication and operator preference. Medical-grade N_2O, supplied by the hospital pharmacy, was administered in both groups as standard analgesic care via a self-administered buccal-nasal mask, starting approximately five minutes prior to the procedure and maintained throughout its duration. The administration protocol was consistent with routine clinical

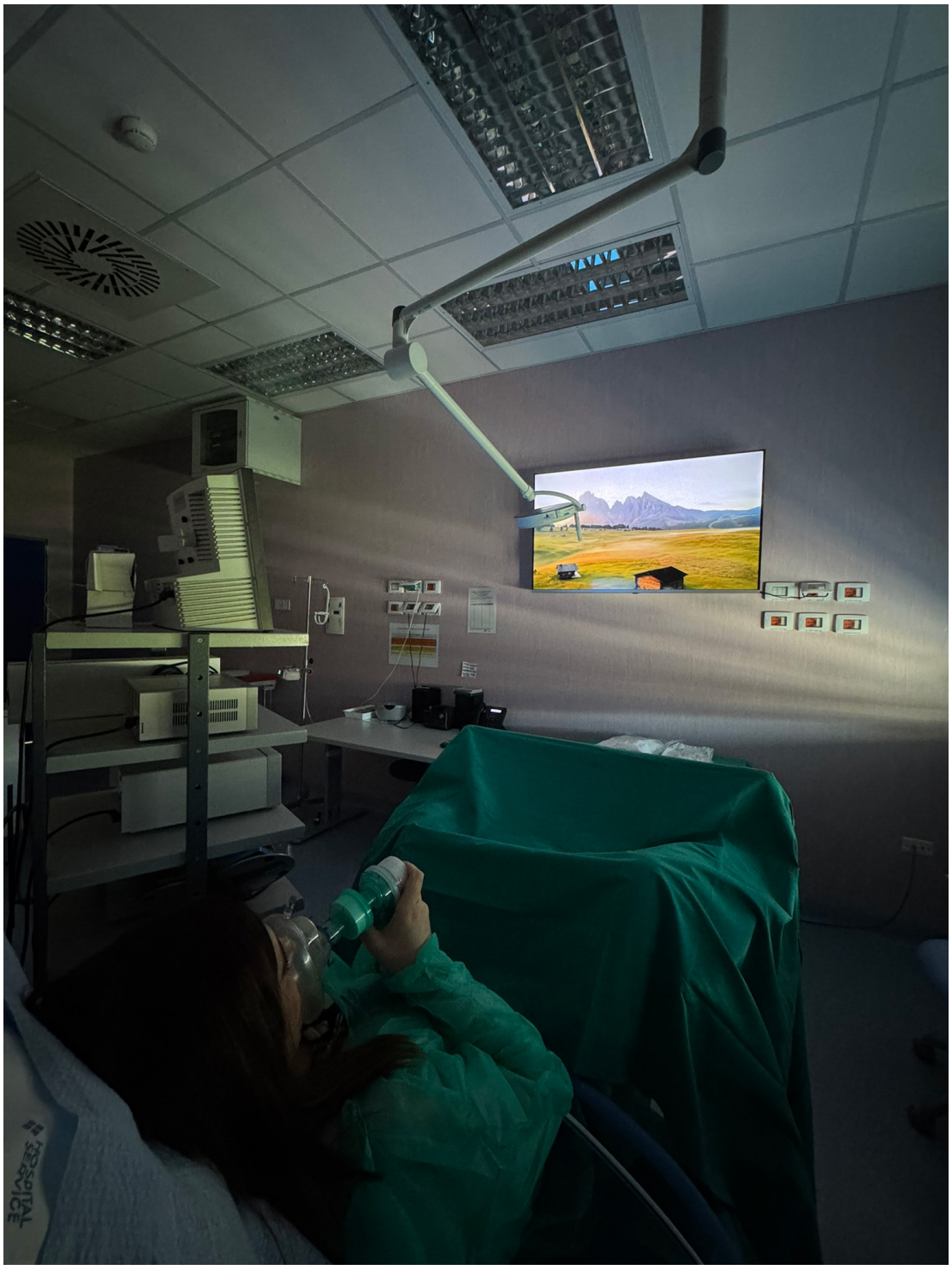

Fig. 1. Multisensory outpatient hysteroscopy setting.

practice and did not constitute an experimental intervention within the study.

The distinguishing feature between the two study groups was the presence or absence of a visual environmental distraction. In the intervention group, patients were exposed to a wall-mounted screen functioning as a virtual window, displaying relaxing visual content, such as natural landscapes, marine environments, or other calming scenes selected by the patient. This visual stimulus was activated prior to the beginning of the procedure and maintained continuously until its completion. The system was not classified as a medical device but was considered an environmental support tool aimed at enhancing patient comfort and reducing anxiety. In the control group, patients underwent the procedure under standard conditions with N_2O analgesia alone, without additional visual distraction. No additional environmental modifications differed between groups.

The clinical setting is illustrated in Fig. 1, and a video demonstrating the multisensory setting and procedural workflow is available as **Supplementary Video 1**.

Data were collected prospectively using a dedicated database. Baseline variables included age, parity, comorbidities, previous uterine surgeries, date of last menstrual period, and indication for hysteroscopy. Procedural variables included the type of hysteroscopic instrument used and procedure duration. At the end of the procedure, all patients were asked to rate the pain experienced during hysteroscopy using a 10-point NRS, where 0 corresponded to no pain and 10 to the worst imaginable pain. This measure was selected as the primary outcome given its widespread use and validated reliability in assessing acute procedural pain.

Secondary outcomes included the need for procedure interruption, inability to complete the hysteroscopy, and referral to the operating room for completion under general anesthesia. These outcomes were recorded to evaluate the potential impact of the intervention on procedural feasibility and clinical workflow.

To reduce bias in outcome assessment, data analysis was conducted in a blinded manner. Patients were coded as group A or B within the database, and the investigators responsible for statistical analysis remained unaware of the actual group allocation until the analysis was completed. Blinding of participants and healthcare providers was not feasible due to the nature of the intervention, which involved a visible environmental modification. This lack of blinding may have introduced performance bias; however, a standardized procedural protocol was applied across both groups, and outcome assessment was conducted in a blinded manner to mitigate its potential impact.

Statistical analysis was performed using standard statistical software. Continuous variables are expressed as means with standard deviation, while categorical variables are reported as frequencies and percentages. Between-group differences were evaluated using appropriate statistical tests, including Welch's *t*-test for comparison of means. Additional stratified analyses were conducted according to parity (nulliparous vs. multiparous) and type of hysteroscopic instrument, in order to explore potential confounding factors and subgroup effects. All data were handled in accordance with current European data protection regulations (GDPR), ensuring confidentiality, pseudonymization, and secure storage. Only authorized members of the research team had access to the dataset, and results were reported in aggregate form to prevent identification of individual participants.

All 50 randomized participants completed the study, and no dropouts or missing primary-outcome data were recorded. Therefore, no missing-data method, including imputation, was required. The manuscript does not specify a formal intention-to-treat or per-protocol analysis framework; however, because all randomized participants completed the protocol and were included in the analysis, the final analysis included all randomized participants.

Participant enrollment and allocation are shown in Fig. 2.

3. Results

A total of 50 women meeting the inclusion criteria were enrolled in the study and randomized in a 1:1 ratio to either the intervention group (multisensory setting with visual distraction) or the control group (standard setting), with 25 patients allocated to each arm. All participants completed the study protocol and no dropouts were recorded during the recruitment period, confirming the feasibility of the study design and the acceptability of both conditions within routine clinical practice.

Baseline demographic and clinical characteristics were generally comparable between the two groups, although some differences were observed in parity distribution and type of hysteroscopic instrument used, likely reflecting the limited sample size. Baseline characteristics are summarized in Table 1. The age range of participants was consistent with the inclusion criteria (25–60 years), and the distribution of key variables, such as parity, indication for hysteroscopy, and previous gynecological history, showed no clinically relevant imbalances. The study population comprised both nulliparous and multiparous women, as well as a heterogeneous spectrum of intrauterine pathologies typically managed in the outpatient hysteroscopy setting, including suspected endometrial polyps, submucosal fibroids, endometrial thickening, and intrauterine adhesions. Procedures were performed using either a Bettocchi hysteroscope or a bipolar mini-resectoscope, selected according to clinical indication and operator preference, ensuring a pragmatic representation of real-world clinical practice. Mean procedure duration was comparable between groups, averaging approximately 7 minutes in both the control and intervention groups.

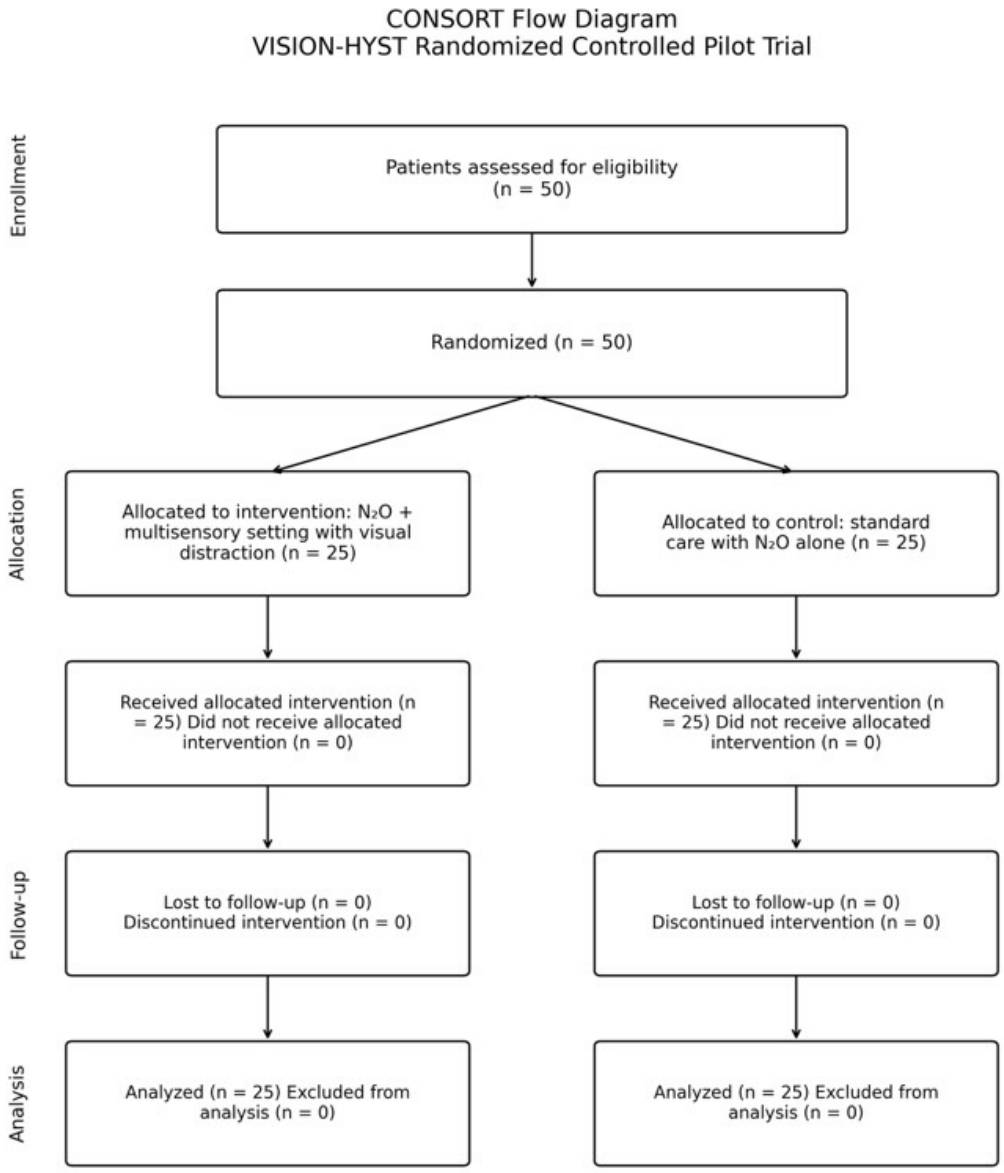

Fig. 2. CONSORT flow diagram illustrating patient enrollment, randomization, follow-up, and analysis in the VISION-HYST randomized controlled pilot trial. CONSORT, Consolidated Standards of Reporting Trials; VISION-HYST, Vision Hyst is a study name and not an acronym.

Table 1. Baseline characteristics of the study population.

Variable	Control (n = 25)	Intervention (n = 25)
Age (years), mean ± SD	49.5 ± 9.9	47.2 ± 10.1
Nulliparous, n (%)	8 (32%)	6 (24%)
Multiparous, n (%)	17 (68%)	19 (76%)
Comorbidities, n (%)	5 (20%)	7 (28%)
Bettocchi hysteroscope, n (%)	18 (72%)	22 (88%)
Bipolar mini-resectoscope, n (%)	7 (28%)	3 (12%)

SD, standard deviation.

Assessment of the primary outcome of the study, namely pain perception measured by the 10-point NRS, demonstrated a statistically significant difference between the two groups. Patients in the multisensory setting group reported significantly lower pain scores compared to those treated in the standard setting group receiving N_2O alone.

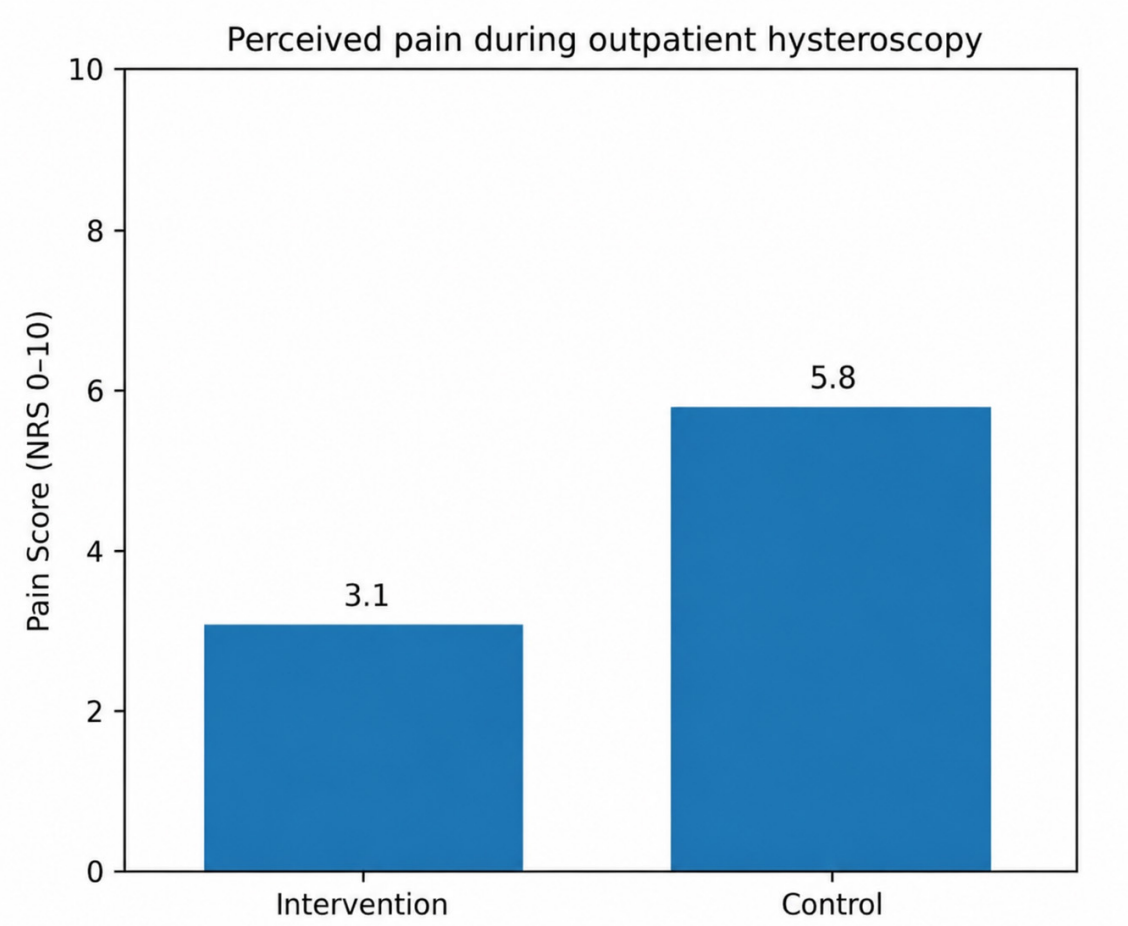

Fig. 3. Comparison of NRS pain scores between the intervention and control groups. A statistically significant reduction in pain was observed in the multisensory setting group ($p < 0.001$, Welch's *t*-test). NRS, numerical rating scale.

Mean NRS pain scores were 5.8 ± 1.9 in the control group and 3.1 ± 1.5 in the intervention group. The between-group difference in pain scores reached a high level of statistical significance ($p < 0.001$, Welch's *t*-test), indicating a robust effect of the intervention despite the limited sample size. The confidence intervals (CIs) further supported the consistency of this finding, suggesting that the observed pain reduction was not attributable to random variation but rather to the effect of the multisensory environment. The between-group difference in pain perception is illustrated in Fig. 3.

Additional exploratory analyses were conducted to examine whether the effect of the intervention was influenced by patient-related or procedural factors. Stratified analysis by parity revealed that the reduction in pain scores remained statistically significant, particularly among multiparous women, whereas the effect appeared less pronounced in nulliparous patients. This finding may reflect differences in cervical compliance, prior obstetric experience, or baseline anxiety levels, although the study was not powered to formally test these hypotheses.

Similarly, stratified analysis by hysteroscopic instrument demonstrated a statistically significant benefit of the multisensory setting across both procedural techniques. Patients undergoing procedures with either the Bettocchi hysteroscope or the bipolar mini-resectoscope reported reduced pain scores when exposed to the visual distraction intervention. This suggests that the beneficial effect of the multisensory environment is independent of procedural complexity and may be consistently applied across different operative modalities.

The stratified analyses by parity and hysteroscopic instrument are presented in Fig. 4.

Regarding secondary outcomes, no statistically significant differences were observed between the two groups. Referral to the operating room was required in 3/25 (12%) patients in the control group and 5/25 (20%) in the intervention group ($p = 0.702$). Although a trend toward improved procedural tolerance was observed in the intervention group, this did not reach statistical significance, likely due to the limited sample size and the relatively low incidence of such events in the study population. Nonetheless, the absence of increased adverse events or procedural failures in the intervention group supports the safety and feasibility of incorporating the multisensory setting into routine clinical practice.

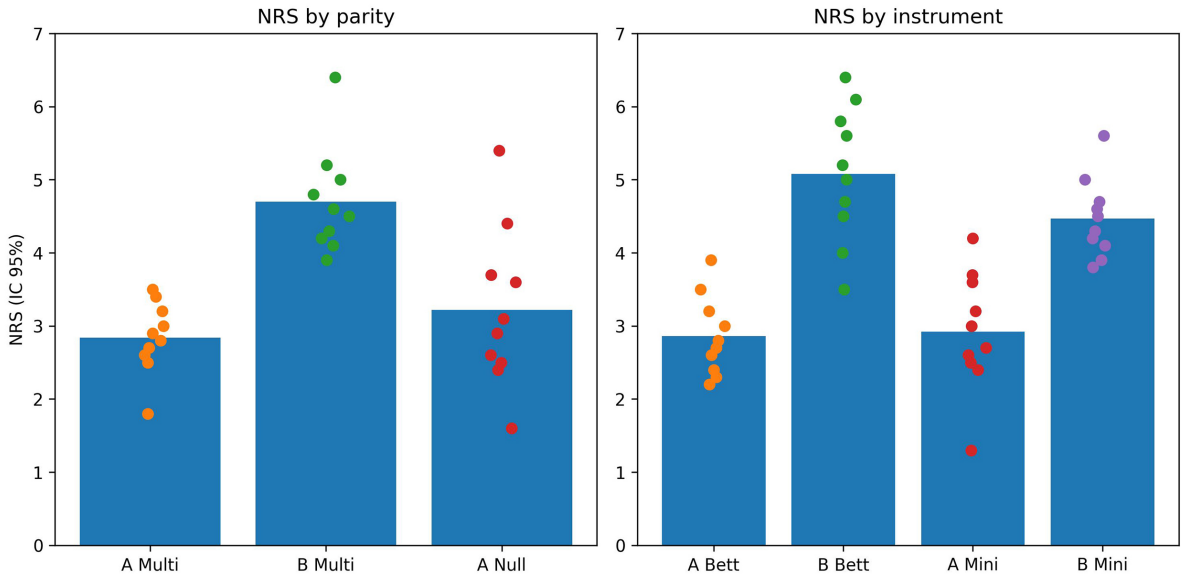

Fig. 4. Stratified analysis of NRS pain scores according to parity and hysteroscopic instrument (Bettocchi hysteroscope vs. bipolar mini-resectoscope). Pain reduction was observed across both techniques. Abbreviations: null, nulliparous; multi, multiparous; Bett, Bettocchi; Mini, mini-resectoscope; A, intervention group; B, control group.

Importantly, the intervention was well tolerated by all participants, and no adverse events related to either N_2O administration or the visual environmental intervention were observed during the study period. Patients in the intervention group demonstrated good compliance and appeared more relaxed and cooperative during hysteroscopy, as observed qualitatively by the clinical team. Although these observations were not formally quantified, they are consistent with the reduction in reported pain scores and support the hypothesis that environmental factors can positively influence the procedural experience.

Overall, the results of this pilot study indicate that implementation of a multisensory clinical setting incorporating visual environmental distraction is associated with a significant reduction in perceived pain during operative office hysteroscopy. These findings provide preliminary evidence supporting the integration of non-pharmacological interventions into standard outpatient gynecological care, while also highlighting the need for larger, adequately powered studies to confirm these results and further explore their clinical implications.

4. Discussion

This randomized pilot study suggests that implementation of a multisensory clinical setting incorporating visual environmental distraction is associated with a significant reduction in pain perception during operative office hysteroscopy performed under N_2O analgesia. Although the between-group difference was statistically significant, its clinical relevance should be interpreted with caution, given the absence of predefined minimal clinically important difference thresholds in this setting. Despite the limited sample size, the magnitude and consistency of the observed effect suggest that environmental factors play a clinically meaningful role in shaping patient experience during outpatient gynecological procedures.

Pain during office hysteroscopy is widely recognized as a multifactorial phenomenon, influenced not only by procedural variables but also by psychological components, particularly anxiety. Previous evidence has consistently demonstrated that pre-procedural anxiety is an independent predictor of increased pain perception and reduced procedural tolerance [4,5]. The interaction between anxiety and pain is mediated by central mechanisms involving attentional processes and stress-related neurophysiological pathways that amplify nociceptive perception [6]. In this context, interventions targeting the emotional and cognitive dimensions of the patient experience may represent an effective adjunct to pharmacological analgesia.

N_2O is increasingly used in outpatient hysteroscopy due to its rapid onset, favorable safety profile, and combined analgesic and anxiolytic properties [7,8,9]. However, although effective, it does not fully eliminate discomfort in all patients. The present findings suggest that the addition of a non-pharmacological intervention, such as visual environmental distraction, may enhance the overall analgesic effect, supporting a multimodal approach to pain management in this setting.

The concept of a “healing environment” has gained increasing attention in healthcare design, with growing emphasis on the role of sensory stimuli in modulating stress and patient perception [10]. Environmental factors such as lighting, sound, and visual input can influence both emotional responses and physiological stress markers, thereby

affecting pain perception. In the present study, the use of a wall-mounted virtual window displaying natural scenes represents a pragmatic application of this concept, providing a simple and scalable alternative to more complex immersive technologies.

Visual distraction techniques are based on the principle of attentional shift, whereby cognitive resources are redirected away from nociceptive stimuli toward engaging sensory inputs. This mechanism has been widely explored in the context of VR, which has demonstrated efficacy in reducing pain and anxiety during medical procedures, including outpatient hysteroscopy [4,12,13,14,15]. Although the present study did not employ immersive VR systems, the results suggest that even a non-immersive visual intervention can produce meaningful clinical benefits, likely through comparable cognitive mechanisms.

A further noteworthy finding is the consistency of the intervention effect across different procedural techniques, suggesting that the benefit of the multisensory setting is not contingent on procedural complexity. The more pronounced effect observed among multiparous women may reflect differences in baseline anxiety levels, cervical compliance, or prior procedural experience, although the study was not powered to explore these factors in detail. These subgroup findings should therefore be interpreted with caution and considered hypothesis-generating, given the limited sample size. Further research is warranted to clarify the association between patient characteristics and responsiveness to environmental interventions.

No significant differences were observed in secondary outcomes, including procedural completion rates or referral to the operating room. This finding should be interpreted with caution, as the study was not powered to detect differences in these outcomes. Nevertheless, the absence of adverse effects or increased procedural failure supports the safety and feasibility of integrating the multisensory setting into routine clinical practice.

From a clinical perspective, improving patient experience during office hysteroscopy carries important implications. Reduced pain and anxiety may enhance patient acceptance, facilitate procedural completion, and potentially expand the range of interventions performed in the outpatient setting. This aligns with current recommendations promoting minimally invasive, resource-efficient care pathways in gynecology [2,3].

Recent evidence has further highlighted the multifactorial determinants of pain perception during office hysteroscopy, encompassing cervical factors, procedural duration, and patient-related variables such as baseline anxiety and obstetric history [16,17,18]. In particular, emerging data suggest that anatomical characteristics, including cervical length and uterine access conditions, may significantly influence both procedural difficulty and perceived pain [16].

Additionally, recent studies have reinforced the role of non-pharmacological strategies in improving patient experience, confirming that visual distraction and immersive or semi-immersive techniques may reduce pain perception and enhance tolerability during outpatient procedures [19,20]. These findings support the rationale for integrating environmental and cognitive approaches into standard hysteroscopic practice, although further research is needed to better define their relative contributions and optimize their implementation.

Limitations

The present study has several limitations. First, its pilot design and relatively small sample size limit the generalizability of the findings and preclude definitive conclusions regarding efficacy. The limited sample size further restricts the overall statistical power of the study. Minor imbalances in baseline characteristics, including parity and type of hysteroscopic instrument, were observed between groups, which may have influenced the results and should be considered when interpreting these findings. Second, the lack of blinding of participants and operators may have introduced performance bias, although outcome assessment was conducted in a blinded manner. Third, pain was assessed immediately after the procedure using a single subjective measure, which may be susceptible to recall bias and influenced by the overall procedural experience, including environmental factors. Anxiety was not formally assessed using validated instruments, which represents an important limitation, and no objective physiological parameters were recorded. Finally, the study design does not allow for the isolation of the individual contribution of each component of the multisensory intervention.

Despite these limitations, the study provides preliminary evidence supporting the integration of environmental and non-pharmacological strategies into standard pain management protocols for office hysteroscopy. Future large-scale, multicenter randomized trials are warranted to confirm these findings, delineate the contribution of individual sensory modalities, and assess the impact on broader clinical outcomes.

5. Conclusions

This randomized pilot study suggests that integrating a multisensory environmental approach into office hysteroscopy may reduce perceived pain when combined with standard N_2O analgesia. The addition of a simple visual distraction system, such as a wall-mounted virtual window, appears to enhance the overall procedural experience without imposing substantial procedural burden.

These findings support the clinical relevance of addressing not only the technical and pharmacological aspects of hysteroscopy but also the environmental and psychological dimensions that influence patient perception. These findings suggest that optimizing the clinical setting can

meaningfully improve procedural tolerability, potentially facilitating the broader adoption of operative procedures in the outpatient context.

Given its feasibility, safety, and scalability, this approach may represent a practical strategy for enhancing patient-centered care in gynecological endoscopy. Further large-scale, multicenter studies are warranted to confirm these preliminary findings and to support the development of standardized recommendations for environmental optimization in office hysteroscopy.

Availability of Data and Materials

The complete dataset is available from the corresponding author upon reasonable request due to privacy restrictions.

Author Contributions

Conceptualization: AM and BM; methodology: AM, AL, and PA; data collection: GL, GP, CC, FV, TB, RT, LL, and SV; formal analysis: AM, RT, LL, and AL; writing—original draft preparation: AM; writing—review and editing: all authors; supervision: BM. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

The study protocol was developed in accordance with international ethical standards for biomedical research involving human subjects, including the principles outlined in the Declaration of Helsinki and Good Clinical Practice guidelines. Ethical approval was obtained from the Intercompany Ethics Committee of Novara (Comitato Etico Interaziendale di Novara, approval number CE342/2025), and the study was prospectively registered on ClinicalTrials.gov (Identifier: NCT07473206). All participants provided written informed consent prior to enrollment, after receiving detailed information regarding the study objectives, procedures, potential benefits, and data management.

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Conflicts of Interest

The authors declare no conflicts of interest.

Declaration of AI and AI-Assisted Technologies in the Writing Process

During the preparation of this work the authors used ChatGPT-3.5 in order to check spelling and grammar. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/CEOG53148.

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