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## Role of vocal distraction analgesia on pain management in the office hysteroscopy procedure: a randomized controlled study

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**ABSTRACT**

**Objective.** Hysteroscopy is a minimally invasive endoscopic surgical procedure recognized as a "gold standard" for the evaluation of the uterine cavity, for both diagnostic and therapeutic purposes. The possibility of performing hysteroscopy on an outpatient basis strictly depends on the patient's good compliance, which is a key prerequisite.

**Materials and Methods.** Various methods of analgesia are reported in the Literature, one of them is vocal distraction. Occupying the mind with a distracting activity reduces pain sensations, not just by psychological conditioning.

**Results.** Among patients who experienced verbal distraction analgesia, only 16% of them reported a high level of pain perception (VAS score > 4), while among untreated patients the percentage was 70%, 16% of which presented values within tolerable limits.

**Conclusions.** Vocal distraction is thus an effective and easy-to-use analgesic method.

## INTRODUCTION

Hysteroscopy is a minimally invasive endoscopic surgical procedure recognized as a "gold standard" for the evaluation of the uterine cavity, for both diagnostic and therapeutic purposes [1-3].

Technical advances have focused mainly on miniaturizing the instruments to perform operative procedures and to reduce classic patient discomfort resulting from cervical canal dilatation and anaesthesia [2]. During office hysteroscopy, for example, it is now possible to enucleate submucosal

myomas without a significant worsening of the patients' pain perception [4]. The same applies to the diode laser metroplasty for the treatment of septate uteri [5].

The spread of office hysteroscopy has been made possible thanks to various innovations that have marked fundamental moments in the evolution of the method: the technological improvement of instruments, the use of the physiological solution as a means of relaxation, the spread of the "no-touch" technique (vaginoscopy approach), the diffusion of bipolar technology, the introduction on the market of a dedicated electrosurgical system for hysteroscopy (Versapoint) and the spread of the "see & treat" philosophy (union of the diagnostic phase with the operational one) [6, 7].

The office hysteroscopy showed diagnostic accuracy comparable to that of hysteroscopy performed under general and/or loco-regional anaesthesia. At the same time, it has undoubted advantages: absence of anaesthetic risk, immediate return of patients to daily and working activities, improvement of the cost-benefit ratio.

However, the possibility of performing hysteroscopy on an outpatient basis strictly depends on the patient's good compliance, which is a key prerequisite. Currently, modern hysteroscopy aims to make a correct diagnosis causing the minimum possible discomfort. Pain represents the main limitation to the outpatient execution of this investigation.

The sensory innervation of the uterus starts from the myometrium, while the endometrium and any other fibrous tissue are not sensitive, so that working on them does not generate pain. In these anatomical characteristics of the uterus lies the rationale for performing operative procedures on an outpatient basis without the use of analgesia or anaesthesia. Pain during hysteroscopy is primarily due to the introduction and passage of the hysteroscope through the cervical canal, contractile activity of the myometrium caused by distension of the uterine cavity and direct stimulation of the uterine walls when they come into contact with the instrument.

Furthermore, numerous studies show that a fundamental role in the level of pain perceived by patients is determined by their state of anxiety [8-11]. Distraction Analgesia is based on this assumption: deviation of attention is commonly used to control pain. It is characterized by a redirection of attention away from the negative/adverse experience in progress and by committing cognitive faculties to other activities. Occupying the mind with a distracting activity reduces pain sensations, not just on a psychological level. Distraction inhibits the response to painful signals by altering the production of endorphins [12]. Various methods of distraction are reported in the literature, both passive and active: deep breathing, listening to relaxing music and/or environmental sounds that evoke pleasant sensations, visual distraction, hypnosis, cognitive distraction (performing mathematical calculations and/or mnemonic efforts, *etc.*), "therapeutic touch", vocal analgesia, *etc.* [13-18]. Several factors can, in fact, affect the perception of pain. Even waiting room time has been shown to play a role in this regard [19]. Acting on these elements, therefore, makes the diagnostic examination more tolerable.

The study aimed to investigate whether Vocal Distraction Analgesia may have an impact on the pain perceived by patients undergoing hysteroscopy.

## MATERIALS AND METHODS

This was a randomized controlled study approved by Local Ethics Committee (N. 4702013) on patients that consecutively underwent office hysteroscopy at the Obstetrics and Gynaecology Unit of the San Salvatore Hospital of L'Aquila, Italy. The patients included in the study group entered the hysteroscopy clinic because they had to undergo hysteroscopy due to clinical indications, in accordance with valid and current scientific guidelines and in compliance with medical ethics.

Written informed consent was obtained from all subjects. All participants fulfilled the following inclusion criteria:

- 18-50 years old.
- Regular menses.
- Multiparous women.
- $19 \leq BMI \leq 24$.
- Waiting time for exam < 90 minutes.

Patients with the following criteria were excluded:

- Nulliparous women.
- Postmenopausal women.
- Previous caesarean section.
- Previous abortions.
- Women who had delivery in the past 6 months.
- Women on drug therapy for anxiety and/or depressive states.
- Women who had taken an analgesic in the 24 hours before hysteroscopy.

- Women who were on drugs and/or abused alcohol.
- Women with a positive gynaecological history of Chronic Pelvic Pain, vaginismus or dyspareunia.

Women who had given birth less than 6 months were also excluded to avoid the possible undiagnosed presence of post-partum depression, which would have amplified the sensation of pain [20].

The patients' demographic information and clinical histories were collected using data collection forms designed for the study. As an example, the information recorded included age and starting anxiety state.

Patients were randomized into two groups: the experimental group treated with vocal distraction analgesia and the control group. The same medical practitioner performed all hysteroscopies through a vaginal approach using a Storz Bettocchi hysteroscope (5 mm): 2.9 mm Hamou rod lens, forward-oblique telescope 30°, continuous flow sheath and working channel. The hysteroscopies were performed in a dedicated ambulatory room.

Before starting the hysteroscopy and during its execution, a properly trained nurse performed Vocal Analgesia on all patients: an uninterrupted verbal communication on topics of interest to the patient.

At the end of the examination, the patients were given a VAS (Visual Analog Scale) for pain assessment during hysteroscopy. The primary aim of our study was to compare pain between patients undergoing office hysteroscopy, those treated with vocal distraction analgesia being part of the experimental group and those treated without vocal distraction analgesia belonging to the control group.

The secondary aim was to assess if age, starting anxiety and distraction analgesia were factors associated to pain (VAS score > 4). The study was designed to have 80% power to detect an effect size d = 0.6 for pain on the visual analog scale, with 2-sided alpha levels of 0.05. Considering a sample size calculation for independent groups, we estimated a sample size of 45 participants in each group. Considering a drop out of 10%, we enrolled 50 subjects in each group.

The Shapiro test was used to investigate normality for the continuous variables, while the Student's t-test was used to compare pain scores between groups controlling for the equality of standard deviations (Levene's test statistic). When appropriate, the Chi-square test or the Fisher exact test were used to compare proportions.

The VAS score was dichotomized in the pain variable (yes if VAS score > 4/no if VAS score ≤ 4).

Univariable and multivariable logistic regression analyses were run to evaluate the association between pain (yes/no) as dependent variable and distraction analgesia (yes/no), spontaneous delivery > 1 (yes/no) as independent factors. Unadjusted (OR) and adjusted odds ratio ($OR_{adj}$) were reported with 95% Confidence Interval (95%CI).

All statistical analyses were performed using STATA MP/14 software, setting alpha level to 0.05 and including all randomized patients, in accordance with the Consolidated Standards of Reporting Trials Statement (**Figure 1**).

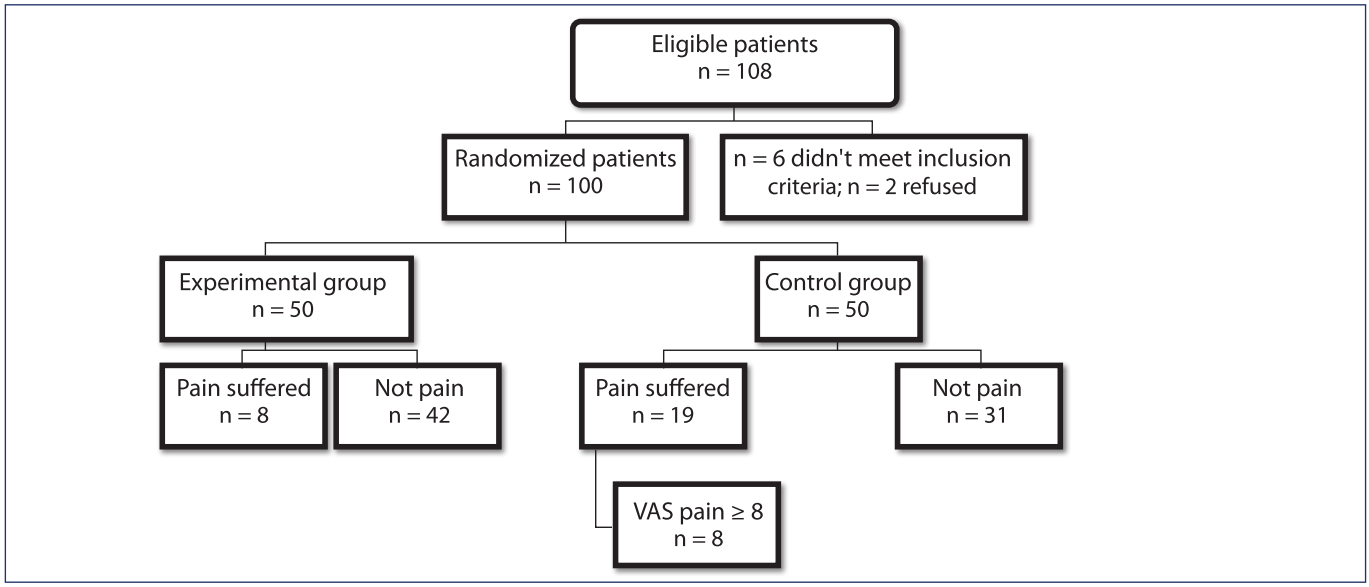


**Figure 1.** *Flow chart diagram, study population.*

## RESULTS

One hundred patients were recruited, fifty were treated with vocal distraction analgesia and fifty were allocated in the control group.
The mean age was 46 years (± 5.5), the mean STAY score was 42.72 (± 4.5) and 85 patients reported more than 1 spontaneous delivery: 42 (49%) of them were treated with vocal distraction analgesia.
The mean pain score perceived by women from the experimental group was 2.6 (± 1.8), significantly different from that perceived by patients from the control group, that reported an approximately double VAS value (4.1 (± 2.5), t-test = t = 3.231, p = 0.0017) (**Figure 2**).
The analysis of dichotomized pain (yes/no) if VAS score > 4 showed that only the vocal distraction analgesia was associated with pain and it was a significant protective factor for pain (OR = 0.33; 95%CI: 0.12-0.80). Among patients who experienced verbal distraction analgesia, 8/50 patients (16%) reported a high level of pain perception (VAS score > 4), while among patients not treated, the percentage was 70% (19/50) and 8 patients (16%) presented values at the limits of tolerability (7 patients with VAS score = 8 and one with VAS score = 9).
Only 3 women who experienced more than 1 spontaneous delivery reported pain and it seemed to be a protective factor by pain (OR = 0.41), but it was not as significant as the other investigated factors (**Table 1**).
Multivariable analysis confirmed this result, and the vocal distraction analgesia controlling for all other investigated factors was a protective factor for the perception of pain in women undergoing office hysteroscopy ($OR_{adj}$ = 0.30; 95%CI: 0.11-0.78).

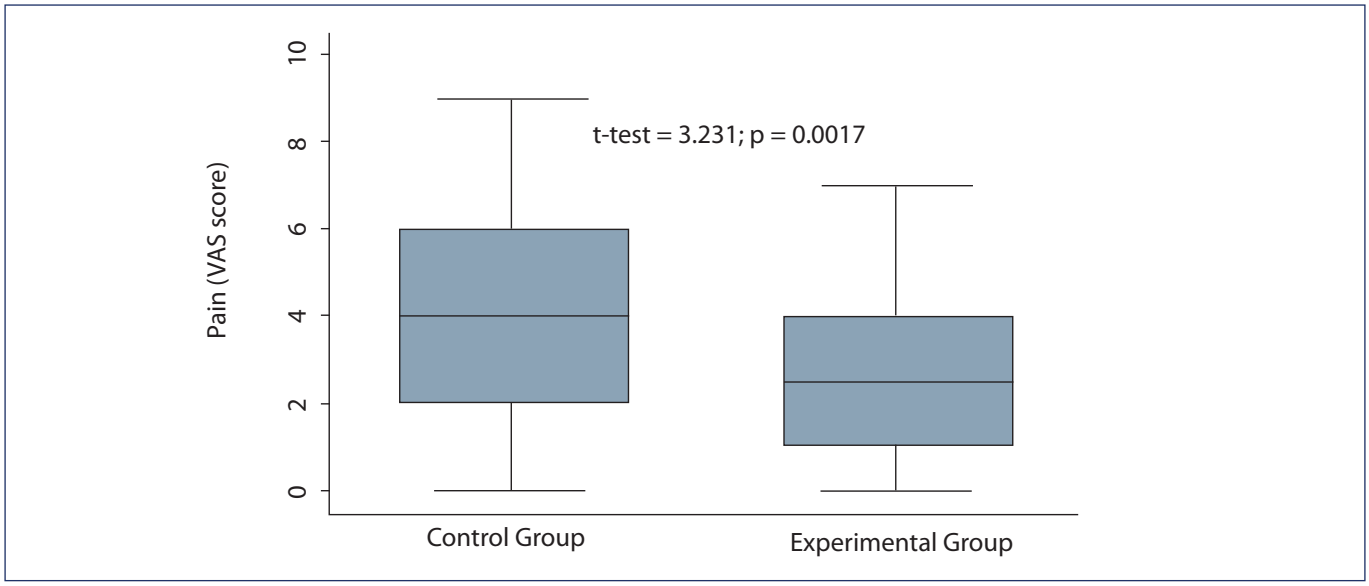


**Figure 2.** *Pain comparison between experimental group vs control group.*

**Table 1.** *Univariate logistic regression analysis. The population analyzed was homogeneous in its initial characteristics. Instead, the two groups differed in vocal distraction result. Among patients who experienced verbal distraction analgesia, 8/50 patients (16%) reported a high level of pain perception (VAS score > 4) while among patients not treated, the percentage was 70% (19/50).*

| | | Pain | | | | |
|---|---|---|---|---|---|---|
| | | No (VAS ≤ 4) N = 73 (95%CI: 63%-81%) | Yes (VAS > 4) N = 27 (95%CI: 19%-37%) | | | |
| **Variables** | | **Mean (ds) or n (%)** | **Mean (ds) or n (%)** | **p*** | **OR** | **95%CI** |
| Age | | 46.4 (5.8) | 46.6 (4.2) | 0.643 | 1.0 | 0.93-1.09 |
| Anxiety (STAY- score) | | 42.64 (4.6) | 42.8 (4.46) | 0.8605 | 1.0 | 0.94-1.14 |
| Vocal distraction analgesia | no | 31 (42%) | 19 (70%) | 0.013** | 1 | |
| | yes | 42 (58%) | 8 (30%) | | 0.33 | 0.12-0.80 |
| Spontaneous delivery > 1 | no | 61 (84%) | 24 (89%) | 0.753** | 1 | |
| | yes | 12 (16%) | 3 (11%) | | 0.41 | 0.16- -1.03 |

*t-student test; **chi-square test.

## DISCUSSION

The study aimed to investigate the pain perceived by women undergoing office hysteroscopy by comparing those treated with vocal distraction analgesia with the untreated ones (control group). With respect to the primary outcome, we found that the women treated with vocal distraction analgesia reported a mean score of pain (VAS score) statistically lower than the control group that reported an approximately double VAS score (2.6 *vs* 4.1; p = 0.0017).

BMI and waiting time were considered among inclusion criteria and their possible impact on the outcome of the study could be excluded [19, 21, 22]. In selecting the study population, it was decided to evaluate multiparous women for the lower incidence of cervical canal stenosis. Furthermore, nulliparous women have a greater perception of pain, and this would have distorted the statistical evaluation [23, 24]. We excluded menopausal women for the same reason [25-27], although some studies do not consider this state as a predisposing condition for increased pain perception [28]. Considering the results of Cicinelli's review, we also excluded women with a previous caesarean section [27]. These choices resulted in a narrow selection of the study population, but ensured the exclusion of confounding anamnestic factors, ultimately strengthening the reliability of our conclusions.

A study in Kenya of 1000 women has demonstrated the effectiveness of vocal distraction as a method for reducing the perception of pain in the inability to use anaesthetic drugs [29]. In this study, women were divided into two groups: in one they were subjected to local anaesthesia and vocal distraction during the tying of the salpinges with a mini-laparotomy technique without the use of opioid analgesics, while in the control group the latter was administered.

The processing of the data showed a statistically significant difference in the perception of postoperative pain between the two groups, with a greater state of well-being among the women who had not obtained opioid analgesics. In the end, there were no significant intraoperative differences between the two groups in pain perception. Our univariate analysis revealed that the vocal distraction analgesia was significantly associated with pain (VAS score > 4): women treated with the vocal distraction analgesia had a low risk of pain perception OR = 0.33; 95%CI: 0.12-0.80.

Spontaneous delivery > 1 could be a protective factor, but it was not significant (OR = 0.41; 95%CI: 0.16-1.0.3).

The multivariable analysis confirmed that the vocal distraction analgesia was a protective factor for pain (VAS > 4) ($OR_{adj}$ = 0.30; 95%CI: 0.11-0.78) and the other investigated factors resulted not significantly related to pain.

This result agrees with the study carried out in Kenya [29], in which the majority of respondents were over 30 (78%), married (96%) with 3 or more children (99%).

We can define the reported results as reliable and non-operator dependent, because the hysteroscopy was always performed by the same physician of the team, minimizing evaluation errors for different procedural approaches.

In evaluating the perception of pain, we could have considered the size of the lesions found, that may affect the success and perception of the exam. Previous studies have shown, however, that the volume of the lesions is not influential [2].

It would be interesting to evaluate other secondary aims in future studies, such as whether or not executing a biopsy and the perception of pain related to any diagnostic suspicion reported by the doctor to the patient at the end of the hysteroscopy.

By investigating the effectiveness of vocal distraction, it might be interesting to evaluate its effects in operative hysteroscopy with respect to the instrumentation used (hysteroscope diameter) and the procedures performed during the examination (biopsy, polypectomy, *etc.*). Instruments such as the intrauterine morcellator, in fact, could deflect the patient's attention from the distracting operator.

This study highlighted the irrefutable effectiveness of the vocal distraction by selecting patients without confounding anamnestic elements (*e.g.*, nulliparous or menopausal women). From this base, a future goal will be to extend the study to a more varied sample of patients.

## CONCLUSIONS

Healthcare professionals are often confronted with pain, and they can be a source of pain or relief themselves. Proper pain management is essential for establishing a good relationship of trust between operator and patient and therefore good patient compliance in the diagnostic-therapeutic process. The office hysteroscopy can cause anxiety

in patients by significantly reducing the tolerance to the exam. By acting on the factors that generate anxiety, it is possible to obtain better compliance by increasing the diagnostic and therapeutic potential of the procedure. Clear pre-exam explanations may predispose the patient to a less traumatizing experience. From the study, Vocal Distraction proves to be a powerful weapon against fear and pain in women.

It is important that doctors make an effort to talk to their patients and spend time with them. A greater relationship of trust is considered the prime gateway to more effective and satisfying clinical and diagnostic results [30]. The ever more evident introduction of telemedicine in clinical practice leads to new ways in which doctor and patient relate to one another. Moreover, it is important to find evidence of how this relationship affects the quality of health care [31].

There is a risk of identifying the patient with their illness or symptom, thus neglecting the individual as a person. It is not only important to know how to speak, but it is also essential to have the ability to listen to create empathy and acceptance. We could talk about "narrative Medicine", considering the complexity of the doctor-patient interaction and the background associated with it. Dialogue, as in our scientific study, even becomes an instrument of treatment.

Our study accurately highlights this aspect, enhancing the importance of the empathic relationship between doctors and patients.

The execution of an office hysteroscopy avoids the risks associated with anaesthesia and allows a reduction in healthcare costs.

When the gynaecologist is able to establish a dialogue with the patient by diverting her attention from the procedure in progress through active distraction, it will be plausible to wait for a reduction in anxiety and the possibility of completing the endoscopic examination, causing minimal discomfort and therefore greater patient satisfaction.

## COMPLIANCE WITH ETHICAL STANDARDS

### *Authors contribution*

P.P.: study design, clinical participation, supervision of study and manuscript. A.S.: collection of data, clinical participation, writing the manuscript. A.D'A.: supervision of the study. I.C.: study design, clinical participation, collection of data. S.N.: statistical evaluation. V.C.: statistical evaluation and supervision of the manuscript. N.P.: clinical participation. M.G.: study design, clinical participation, supervision of study.

### *Funding*

None.

### *Study registration*

N/A.

### *Disclosure of interests*

The authors declare that they have no conflict of interests.

### *Ethical approval*

IRB approval number is 4702013 (IRB of University of L'Aquila). The Institutional Review Board approved the study (number 05/2019) on February 11, 2019.

### *Informed consent*

An informed written consent was obtained from all patients before the enrolment in the study.

### *Data sharing*

Data are available under reasonable request to the corresponding author.

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