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## Effectiveness of warm saline for pain relief in office hysteroscopy: A prospective randomized control trial

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### Abstract

**Background:** Office Hysteroscopy is often considered the gold standard in diagnosing intrauterine pathology. Pain during the procedure usually is the cause of failure in Office Hysteroscopy. Various techniques have been developed and employed for making the patient more comfortable during the procedure. The main objective of this study was to compare pain intensity and degree of satisfaction reported by patients undergoing Office Hysteroscopy using saline solution kept at room temperature (control group) and saline solution warmed up to 41°C (test group).

**Methods:** 110 patients were recruited for the study, 55 in test group and 55 in control group as per inclusion criteria. A computer generated randomization sequence was used for allocation of group. Ambient temperature was set at 26°C and an automated fluid warmer was used for heating the saline medium to 41°C for test group. Office Hysteroscopy was performed by vaginoscopic technique using a 3.2mm Compact Hysteroscope. VAS (Visual Analogue Scale) score was assessed during the procedure and 15 minutes later.

**Results:** VAS score during the procedure was found to be significantly lower in warm saline group (2.64±1.62) as compared to placebo (4.90±1.90);  $p = 0.001$ . Moreover, the VAS score at 15 minutes post-procedure was found to be significantly lower in the warm saline group (1.82±0.39) as compared to room temperature saline (2.94±0.96);  $p = 0.001$ . Warm saline as distension medium had a significant positive effect on satisfaction level of patients; 78% (n=39) women in warm saline group expressed their willingness to undergo the procedure again, if required, versus 23.5% (n=12) in room temperature saline;  $p = 0.001$ . Also, 74% (n=37) women in warm saline group would recommend the procedure to their friends and relatives versus 31.3% (n=16) in room temperature saline;  $p = 0.001$ .

**Conclusions:** Using warm saline (41°C) as distension medium for Office Hysteroscopy significantly reduces pain during and after the procedure. Moreover, patient satisfaction is better with warm saline as distension medium.

**Keywords:** Office Hysteroscopy, pain, warm saline, VAS score, patient satisfaction

### Introduction

In this 'see and treat' era of modern Gynaecology, Hysteroscopy has become the gold standard for diagnosis of intrauterine pathology and at times for operative intervention in the same sitting [1]. Office Hysteroscopy is performed in the out-patient or day-care setting using a miniature hysteroscope with either carbon dioxide or normal saline as distension medium. There have been various advancements in the field of hysteroscopy over the last few years with introduction of newer surgical instruments, smaller hysteroscopes as well as amelioration of operative techniques [2]. These upgrades have facilitated hysteroscopy becoming even more popular and hence, migrating from the operating room to the more accessible and cheaper office setting [3-5]. Hysteroscopy is, largely, a well-tolerated procedure. However, pain, discomfort, vaso-vagal syndrome and syncopal attacks are sometimes witnessed in patients subject to the procedure. Pain along with the inability to negotiate the cervical os is cited as the main reason for failed office hysteroscopy [6-8]. Nagele *et al.* noted that 84% of failed hysteroscopies were due to excessive discomfort [7]. De Iaco *et al.* stated that 34.8% of patients undergoing anaesthesia free hysteroscopy reported severe pain while Carvalho *et al.* reported moderate to severe pain immediately after anaesthesia free hysteroscopy in 64.8% of patients [8-9]. There have been various techniques such as vaginoscopic technique of doing hysteroscopy, preoperative cervical preparation with Misoprostol etc. which have been studied and frequently employed to alleviate pain during the procedure [9-13]. Although it is believed that warming the distension fluid to near physiological temperature of 37.5°C decreases perceived pain, the evidences are inconclusive [14].

The objective of this study was to compare the degree of pain perceived by patients while undergoing hysteroscopy without anaesthesia using normal saline as distension medium at room temperature with that performed using normal saline warmed up to 41°C.

### Methods

Our study was a prospective randomized control trial which was conducted at a tertiary care centre with a well-established minimally invasive surgical division. The study was approved by Institute Ethics Committee. Any patient in the age group of 18 to 70 years undergoing office hysteroscopy for any indication as deemed necessary upon clinical evaluation was included in the study. Those who were having active genital infection, ongoing vaginal bleeding, previous cervical surgery were excluded from the study.

In an earlier similar type of study, Tawfek *et al.* (2019) had shown that the mean VAS score for warm saline group was  $1.64 \pm 0.82$  and corresponding room temperature saline group  $3.05 \pm 1.17$  [1]. Assuming similar results could be obtained in our study, a minimum number of 50 patients in each arm was considered sufficient enough to deduct statistically significant difference at 5% level of significance with 90% power. However, considering some dropouts and 2-3% failure rate of the procedure, 55 patients were recruited in each arm.

Patients were enrolled into the study as per the inclusion criteria. Written informed consent was taken from each patient. Each patient was assigned to either of the groups by using a computer generated randomization sequence. All office hysteroscopies were done by a single surgeon using 3.2mm Compact Hysteroscope, employing vaginoscopic technique. No preoperative cervical preparation was done in any of the groups. Anaesthesia or analgesia was not used in any of the groups. Ambient temperature of the room was kept at 26°C and normal saline bottles kept in the room itself were used for room temperature arm. Warm saline group had continuously warmed fluid by an automated fluid-management system with a function that warms the distension medium to 41°C continuously.

Pain during the procedure was recorded as per Visual Analogue Scale (VAS) of 0 to 10, where a VAS score of 4 or less was considered as comfortable, 5 to 7 was considered as moderately painful and 8 to 10 was considered as intolerable pain. The procedure was considered as 'failed' if uterine cavity could not be entered, if assistance with speculum and tenaculum was found necessary or if additional cervical dilatation was required. Any requirement of additional analgesia during the procedure was noted. Intraoperative complications such as laceration of cervix, creation of false passage, uterine perforation and vasovagal syncope were recorded. Patient was reassessed after 15

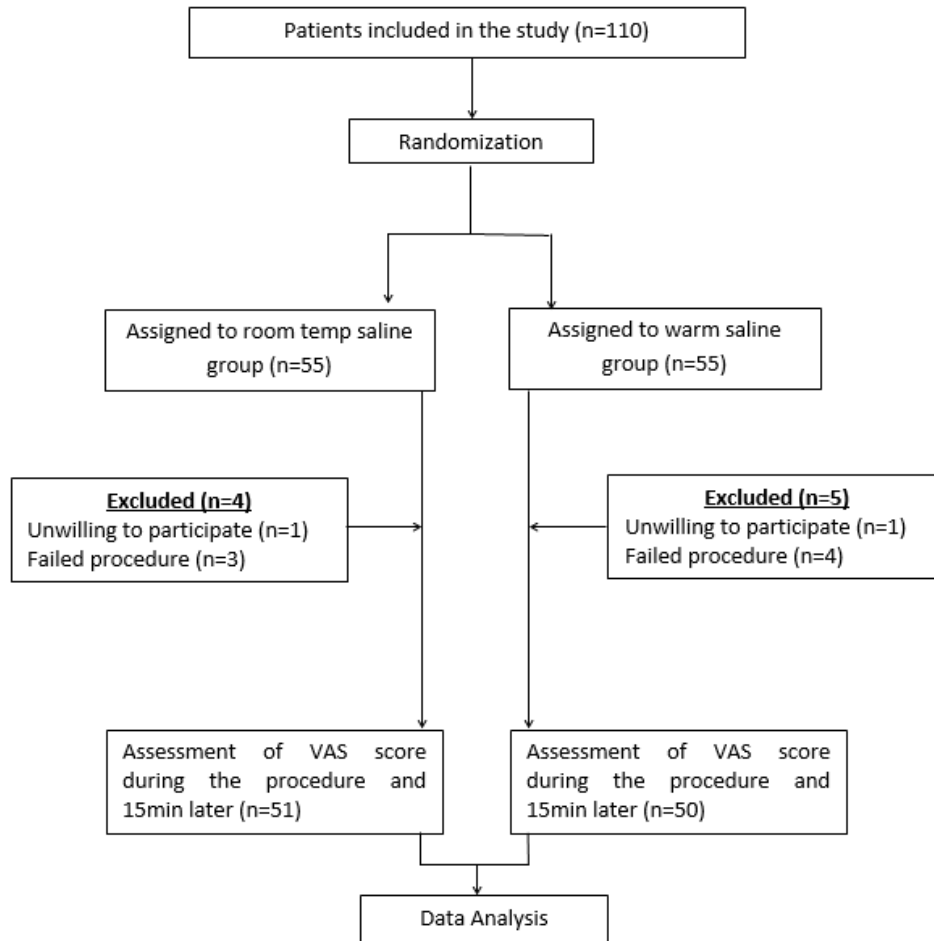
minutes and pain (VAS score) was noted. In order to assess the patient's satisfaction level, she was asked whether she would undergo the same procedure again if needed and whether she would recommend this procedure to any of her friends or relatives. Answers to this questionnaire were noted down in the proforma for data collection.

Data analysis was carried out using statistical software STATA ver 12.0. Continuous variables were tested for normality assumption using Kolmogorov - Smirnov's test. Descriptive statistics such as mean, standard deviation and range values were calculated for normally distributed data and comparison of mean values were done using Student's 't' independent test. For non-normal data, median values and inter-quartile range values were computed and compared using non-parametric Mann-Whitney test. Categorical variables were presented as frequency and percentage values. Comparison of categorical variables was carried out using Chi-square or Fisher's exact test as appropriate. For all statistical tests, a two tailed probability of less than 0.05 was considered statistically significant.

### Results

A total of 110 patients were enrolled into the study as per inclusion criteria. After randomization, patients were allotted to either room temperature saline group (n=55) or warm saline group (n=55) as depicted in flow chart [Fig-1]. One patient from each arm expressed unwillingness to participate in the study. There were 3 procedure failures in room temperature saline group and 4 in warm saline group. Data from 51 patients were evaluated in room temperature saline group and data from 50 patients were evaluated in warm saline group. Baseline characteristics of patients and indications for hysteroscopy were similar in both arms of the study as depicted in Table-2.

VAS score during the procedure was significantly lower in warm saline group ( $2.64 \pm 1.62$ ) as compared to room temperature saline group ( $4.90 \pm 1.90$ );  $p = 0.001$ . VAS score at 15 minutes post procedure also was significantly lower in warm saline group ( $1.82 \pm 0.39$ ) as compared to room temperature saline group ( $2.94 \pm 0.96$ );  $p = 0.001$ . Warm saline had a significant positive effect on satisfaction level of patients. Majority of women in warm saline group, 78% (n=39), expressed their willingness to undergo the procedure again, if required, versus 23.5% (n=12) in room temperature saline group;  $p = 0.001$ . Also, 74% (n=37) women in warm saline group would recommend the procedure to their friends and relatives versus 31.3% (n=16) in room temperature saline group;  $p = 0.001$ . There was no significant complication in either of the groups. Two patients in room temperature saline group and one patient in warm saline group complained of abdominal cramps in the immediate post-operative period.



**Fig 1:** Flowchart depicting patient enrolment.

**Table 1:** Baseline characteristics of patients and indications for hysteroscopy.

Characteristic	Warm Saline (n=50)	Room Temp Saline (n=51)
Age [Mean(SD)]	34.26(4.6)	33.34(4.3)
BMI [Mean(SD)]	23.02(1.8)	23.6(2.0)
<b>Indication for Hysteroscopy</b>		
Infertility	23(46%)	22(43.1%)
Recurrent Pregnancy Loss	7(14%)	8(15.7%)
Abnormal Uterine Bleeding	20(40%)	21(41.2%)

**Table 2:** Outcome measures comparison in both groups; expressed as Mean (SD) unless specified

Evaluation Criteria	Warm saline (n=50)	Room Temp Saline(n=51)	'p' value
VAS during the procedure	2.64(1.62)	4.90(1.90)	0.001
VAS at 15 minutes post procedure	1.82(0.39)	2.94(0.96)	0.001
Complications	Nil	Nil	Insignificant
Would undergo the procedure again if required	39(78%)	12(23.5%)	0.001
Would recommend the procedure to friend or relative	37(74%)	16(31.3%)	0.001

## Discussion

The main aim of our study was to compare the degree of comfort and pain relief during office hysteroscopy by using normal saline warmed up to 41°C as the distension medium as compared with saline solution at room temperature. It was hypothesized that warmed saline solution would cause less discomfort to patients since its temperature would be close to body temperature, thereby diminishing the uterine contractile responsiveness and therefore, the colic. There is a scarcity of literature available on the same subject. Accordingly, there is no specific guideline for using warm saline for office hysteroscopy. On evaluation of available studies, most of the studies have used saline warmed up to 37.5°C. However, in our study, we used saline warmed up to a slightly higher temperature of 41°C.

Evangelista *et al.* in their study (2010) concluded that there is no significant difference in pain during office hysteroscopy done with room temperature saline or warm saline [14]. However, they agree with the fact that patients gave an agreeable sensation of contact while using warm saline as distension medium as compared with room temperature saline. This points to the fact that patients' comfort level would be definitely higher if warm saline is used as distension medium.

In another study by Salazar *et al.* (2019), 48 patients were randomized into three arms: Arm 1- at room temperature (22°C), Arm 2- bags pulled from a warming cabinet set at 40°C and left to hang in ambient temperature during the case and Arm 3- using a fluid management system that can maintain the warmed fluid distension medium continuously at 40°C. No significant

differences were found between the 3 groups regarding post operative pain scores, contradicting our study results <sup>[15]</sup>. However, Salazar *et al.* in their study had recruited patients undergoing operative hysteroscopy under intravenous sedation, whereas, in our study no operative intervention was performed and no additional analgesia or sedation was administered.

### Conclusion

There is a definite decrease in perception of pain during office hysteroscopy if saline solution warmed up to 41°C (slightly above physiological body temperature) is used as distension medium. An automated fluid management system which ensures a constant flow of warm saline at a constant preset temperature is recommended. Patients' comfort level during office hysteroscopy is higher with warm saline as distension medium. However, we suggest further studies on larger cohorts to gather concrete evidence on the subject matter.

### Declarations

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**Conflict of interest:** Authors have no conflict of interest.

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