# Effectiveness of paracervical block for pain relief in women undergoing hysterosalpingography

# ABSTRACT

# **OBJECTIVES:** To evaluate the potential benefit, in terms of pain relief, of the paracervical block with 2% lignocaine in women undergoing hysterosalpingography (HSG). **STUDY DESIGN:** This study was a prospective randomized controlled study. **SETTINGS:** This study was conducted in infertility clinic of a tertiary care center. **MATERIALS AND METHODS:** Four hundred and six patients undergoing HSG as a part of infertility evaluation were included in the study. These women were randomized into two groups: Group I received paracervical block with 2% lignocaine at the time of HSG (n = 53) and Group II (n = 53) served as control. Hyoscine (10 mg) oral tablet was given to all the patients 30 min before the procedure. Pain perception during the procedure was analyzed by the patient between 0 and 10 on a numeric rating scale, immediately after HSG. **RESULTS:** The baseline demographic characteristics of participants in two groups were similar. Mean pain score immediately after HSG in the study group and control group was $4.84 \pm 2.56$ and $5.21 \pm 1.89$ , respectively (P = 0.21). **CONCLUSIONS:** There is no benefit of paracervical block with 2% lignocaine, in terms of pain relief, in women undergoing HSG.

**KEY WORDS:** Hysterosalpingography, lignocaine, pain score, paracervical block

# **INTRODUCTION**

Infertility is defined as the failure to achieve a pregnancy after ≥12 months of regular unprotected sexual intercourse.<sup>[1]</sup> In developing countries, the prevalence of infertility is approximately between 10% and 15%.<sup>[2]</sup> Tubal diseases account for 25%-35% of female factor infertility<sup>[3]</sup> and include tubal obstruction, peritubal adhesions secondary to infection, endometriosis, and previous surgery. There are various modalities for evaluation of tubal patency such as hysterosalpingography (HSG), sonosalpingography, hysterosalpingocontrast sonography, and laparoscopy with chromopertubation. Of all the available procedures to test tubal patency, HSG remains the first choice due to its reliability and cost-effectiveness. The National Institute for Health and Care Excellence guidelines recommend HSG to screen for tubal occlusion in the absence of comorbidities.<sup>[4]</sup> HSG is performed between 7th and 10th days of a menstrual cycle in outdoor settings without anesthesia.<sup>[5]</sup> While it is an integral part of

the infertility workup, it is considered to be very painful by about 70%–80% of women undergoing it.<sup>[6]</sup> The pain is due to several factors including cervical instrumentation, uterine distension, and peritoneal irritation from contrast spill into the peritoneal cavity. Furthermore, grasping the cervix with a tenaculum, as well as distending the uterus, may release local prostaglandins which can initiate uterine cramps resulting in delayed pain after HSG. Pain from the cervix and lower portion of the uterus is carried out by the pelvic splanchnic nerves, whereas pain sensation from the fundus and body of the uterus is conducted through the hypogastric

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How to cite this article: Jain S, Inamdar DB, Majumdar A, Jain DK. Effectiveness of paracervical block for pain relief in women undergoing hysterosalpingography. J Hum Reprod Sci 2016;9:230-5.

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Received: 23.05.2016 Review completed: 04.09.2016 Accepted: 30.09.2016



**DOI:** 10.4103/0974-1208.197643

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nerves to the lower thoracic segments.<sup>[7]</sup> This pain peaks at the time of instillation of contrast media until 5 min after the procedure and then starts to decrease rapidly between 5 and 10 min after the procedure so that at 30 min, most women classify it as a discomfort.<sup>[8]</sup> The pain experienced during and after HSG can have a negative impact on the woman's ability to cooperate with the procedure, thus limiting the usefulness of this investigation, as well as negatively influencing the woman's willingness to undertake similar diagnostic studies.<sup>[9]</sup> Different techniques have been used in attempts to make the procedure less painful including the use of balloon catheters rather than metal cannulas.<sup>[10]</sup> Furthermore, there are so many studies comparing different analgesics for pain relief during HSG, but so far there appears to be no consensus in terms of type, route, and timing of analgesia to be administered. Therefore, establishing the most effective analgesia to offer during this procedure is important to minimize these factors.

A paracervical block is routinely used to decrease pain (though of questionable benefit) with therapeutic abortions, endometrial biopsy, intrauterine device insertion, office hysteroscopy, and oocyte retrieval in *in vitro* fertilization.<sup>[11]</sup> Paracervical anesthetics block transmission of pain through sympathetic, parasympathetic, and sensory fibers before they enter the uterus at the level of the internal os. Thus, we hypothesized that a paracervical block would also decrease pain during a HSG.

### Aims and objectives

To assess the effectiveness of paracervical block with 2% lignocaine for pain relief in women undergoing HSG for evaluation of infertility.

# MATERIALS AND METHODS

This was a prospective randomized controlled study conducted at the tertiary care infertility clinic from February 2011 to August 2011. One hundred and six women undergoing HSG as a part of infertility evaluation were enrolled in the study. Patients were assigned to two groups by computer-generated randomization. After proper counseling, written informed consent was obtained from all participants. The allocating team and the team performing HSG were different, so there was no risk of selection bias. The approval of Ethics Committee of the institution was taken.

### **Inclusion criteria**

- Married women with age 21–39 years
- Infertility: Primary/secondary.

### **Exclusion criteria**

Allergic to radiopaque dye

- Past history of allergy to lignocaine
- Pelvic inflammatory disease
  - Chronic pelvic pain
  - Cyst or mass on ultrasonography
  - Refusal to participate in the study.

### Intervention

All HSGs were carried out in the outpatient setting. Participants were explained about the procedure beforehand to allay anxiety. All women were instructed to take oral antispasmodic tablet hyoscine butylbromide 10 mg, 30 min before the procedure. Women were laid in dorsal position. Five percent of povidone-iodine solution was used for antisepsis. Sims speculum was inserted. The paracervical block with 2% lignocaine was injected at 4 o'clock and 8 o'clock position [Figure 1]. Five minutes were allowed to elapse before proceeding to HSG. The cervix was then grasped at anterior aspect with single-toothed tenaculum, and a Leech-Wilkinson cannula was advanced into the external cervical os. The cannula and tenaculum were secured together, and the speculum was removed. Twenty milliliters nonionic water-soluble radiopaque contrast solution (Omnipaque, GE Healthcare, USA) was instilled through the cannula while the traction on the tenaculum was maintained. The placement of cannula, alignment of uterocervical canal, and the flow of dye through uterus and fallopian tubes were assured on image intensifier fluoroscopy screen. Four X ray films were taken at predefined stages. The cannula and tenaculum were then removed. The study group received a total of 213.5 mg (10 ml) of 2% lignocaine as paracervical block. The second group did not receive anything except oral tablet hyoscine 10 mg and served as control. The patients were kept under observation for 30 min after the procedure and then discharged on oral antibiotics and nonsteroidal anti-inflammatory drugs (NSAIDs) for following 3 days. If at any point, the patient was unable to continue with HSG or any difficulty in performing

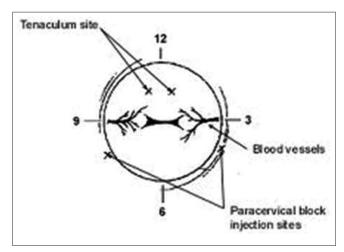


Figure 1: Paracervical block

it, the procedure was abandoned. To account for any operator-related discrepancy, the same team carried out the procedure in all the women.

Immediately after HSG (between 0 and 5 min), each patient was asked by a technician to score her pain in writing using numerical rating scale (NRS) from 0 to 10 where 0 was no pain and 10 was unbearable pain. The primary endpoint was a difference among the two groups in pain scores using NRS [Figure 2].<sup>[12]</sup> In addition, results of HSG were also collected to record patency of fallopian tubes, hydrosalpinx, intracavitary filling defect, or any other abnormal finding. This allowed for a subgroup analysis to evaluate whether any particular pathology had an effect on pain scores.

### **Outcome measures**

### Primary outcomes

• Pain score immediately after the procedure (validated pain scale).

### Secondary outcomes

- Subgroup analysis: Difference in pain scores as per the result of HSG
- Any adverse effect in either group.

### Statistical analysis

### Statistical tests

Statistical analysis was performed by the SPSS version 17.0 program for Windows (SPSS Inc., Chicago, IL,USA). Continuous variables are presented as mean  $\pm$  standard deviation if the data were unevenly distributed, and categorical variables are presented as absolute numbers and percentage. Data were checked for normality before statistical analysis. Normally distributed continuous variables were compared using unpaired *t*-test, whereas Mann–Whitney U-test was used for those variables that were not normally distributed. Categorical variables were analyzed using Fisher's exact test. For all statistical tests, *P* < 0.05 was considered statistically significant.

### RESULTS

In our study, 110 eligible patients were recruited and randomized into study group and control group. The participant flow through the trial is displayed in Figure 3.

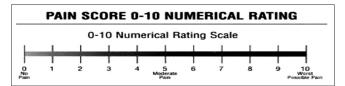


Figure 2: Numerical rating scale

All participants who were randomized and underwent HSG and who recorded any pain scores were included as intention to treat for purposes of statistical analysis of the data points that were available. The baseline demographic characteristics of patients in two groups were similar and are shown in Table 1. The results of the study are shown in Table 2. There is no difference in the mean pain scores between the two groups. Approximately, 90% patients reported instillation of dye as the most painful step during HSG. There was no improvement in pain perception during instillation of contrast in the study group compared with the control group. The results of the HSG are presented in Table 3. In a subgroup analysis according to results of HSG, a subgroup of patients having intracavitary filling defects had significant relief of pain with paracervical block.

There were no adverse outcomes during the study, and no patient had an allergic reaction to the dye media or injected medications. There were no cases of cervicitis, endometritis, or pelvic inflammatory disease in the study participants.

### DISCUSSION

This prospective randomized controlled study aims to

### Table 1: Demographic variables

Variables	Study group	Control group	Р
	( <i>n</i> =51)	( <i>n</i> =53)	
Age (years), mean±SD	28.20±3.62	29.57±5.08	0.12
Primary infertility (n)	33	35	1.00
Secondary	18	18	1.00
infertility (n)			
Dysmenorrhea (n)	11	12	1.00
Past gynecological	4	10	0.15
operative procedure ( <i>n</i> )			
Past abortion ( <i>n</i> )	13	12	0.82
Difficult	2	1	0.61
cannulation $(n)$			

Data are presented as mean±SD or absolute numbers as applicable. SD=Standard deviation

## Table 2: Primary outcome

	Study group ( <i>n</i> =51)	Control group ( <i>n</i> =5	3) <i>P</i>
Mean pain score	4.84±2.56	5.21±1.89	0.41
Data are presented as	mean±SD. SD=Standard devia	ation	

### Table 3: Subgroup analyses: Hysterosalpingography findings and mean pain scores

	Study group (n=51)	Control group (n=53)	Р
No tubal obstruction	4.68±2.55 ( <i>n</i> =41)	4.98±1.94 ( <i>n</i> =41)	0.56
Unilateral tubal obstruction	4.57±1.90 ( <i>n</i> =7)	6.17±1.47 ( <i>n</i> =6)	0.12
Bilateral tubal obstruction	7.67±3.21 ( <i>n</i> =3)	5.83±1.72 ( <i>n</i> =6)	0.29
Intracavitary filling defect	3.67±0.58 ( <i>n</i> =3)	6.33±1.15 ( <i>n</i> =3)	0.02

Data are presented as mean±SD. SD=Standard deviation

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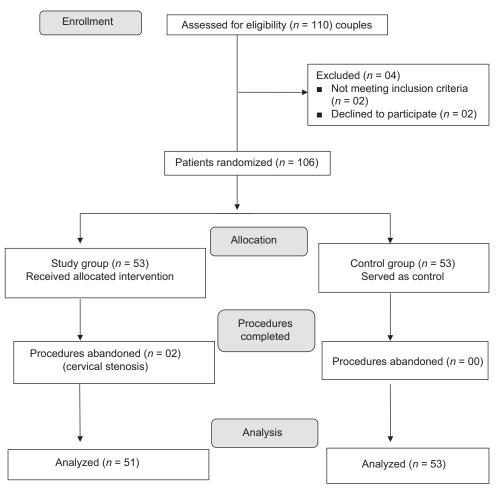


Figure 3: CONSORT flow diagram

evaluate the potential benefit of the paracervical block with 2% lignocaine in terms of pain relief; in women undergoing HSG as a part of workup during infertility evaluation. In our study, paracervical block did not decrease pain perception during the most painful component of the HSG, which is the instillation of contrast into the uterus. Although a subgroup of patients having intracavitary filling defects had significant relief of pain with paracervical block, definite recommendation cannot be made on this sole observation as the number of patients in the subgroup was low.

Studies evaluating pain are greatly biased by the large number of variables influencing pain. These include local and systemic sensitizing and desensitizing factors, differences in individual physical susceptibility, and the subjective nature of pain. Comparison of potential pelvic and systemic sensitizing factors (history of dysmenorrhea, past gynecological operative procedures, tubal ligation, labors, and abortions or previous experience of HSG) revealed that both the groups had similar characteristics [Table 1].

In the literature, most studies observed pain to vary at different steps of the HSG procedure. According to Liberty

*et al.*, insertion of cervical instruments was the most painful step during the HSG procedure,<sup>[13]</sup> whereas Robinson *et al.*, Hacivelioglu *et al.*, Unlu *et al.*, and our study reported instillation of contrast media as the most painful step.<sup>[14-16]</sup> The knowledge of the most painful phase during the HSG is very important for psychological preparation of the patient as stress and anxiety can play a negative role during the procedure. We have considered this point in our study as we did preprocedure counseling of all women by a skilled operator before going through HSG.

All of the studies using paracervical block for pain relief during HSG have used a specific premedication 30 min to 1 h before the procedure. This could be a potential bias in relation to the outcome as we know administration of systemic analgesics can be a confounding factor. Robinson *et al.*, Hacivelioglu *et al.*, and Unlu *et al.* used NSAID,<sup>[14-16]</sup> Chauhan *et al.* gave intramuscular atropine and promethazine hydrochloride<sup>[17]</sup> whereas de Mello *et al.* used oral hyoscine butylbromide with an analgesic dipyrone.<sup>[18]</sup> We have not used any analgesic to eliminate this bias; instead, we gave an oral antispasmodic hyoscine butylbromide to all participants 30 min before going through HSG. The studies were not consistent in the time points; they measured pain scores during the procedure. In most of the studies, pain score was taken from the beginning parts of the procedure, which involve the period of cervical manipulation mostly. Therefore, it would follow that topical application of the anesthesia to the cervix would have more of an effect than topical application of the anesthesia to the uterus, which is less involved in mediating pain during the early steps of the procedure. Therefore, the variation seen may in part be due to variations in the application site of the anesthesia and does highlight one of the potential biases. Certain analgesics may have shown benefit at specific time points. de Mello et al. and Robinson et al. both found a significant reduction in the pain associated with cervical grasping by prior paracervical block, but no benefit during instillation of contrast through uterus and fallopian tubes.<sup>[14,18]</sup> Similarly, Unlu et al. found a beneficial effect for topical anesthetic only during dye instillation, despite the fact that earlier pain scores during the procedure did not show any benefit.<sup>[16]</sup> In our study, we measured a single pain score immediately after the completion of HSG which eliminates any variation in the pain perception of the patient due to a particular step, be it injecting paracervical block, cervical manipulation, or instillation of contrast.

In previous studies, there is a significant variation in relation to concentration, dose, and number of points where lignocaine was injected as paracervical block. In the present study, a total of 10 ml (213 mg) 2% lignocaine was injected at two points only as paracervical block. The rationale behind was adequate analgesia with minimum discomfort to the patient during injection of paracervical block itself.

Out of total five studies done with paracervical block, three shows a significant difference in pain score with paracervical block, but when we look at a number of participants, two of them are underpowered [Table 4]. Only study with an adequate number of participants was by Chauhan *et al.* which seem to be biased by the effect of systemic analgesics used before the procedure.<sup>[17]</sup> According to Hacivelioglu *et al.*, adding a paracervical block to systemic or intracavitary analgesics had no significant beneficial effect on pain relief.<sup>[15]</sup>Our results suggest HSG is a moderately painful procedure which is well tolerated by most of the women (average pain score 5). Recent Cochrane Review on pain relief in HSG by Hindocha *et al.* concluded that locally injected anesthetic was not associated with any benefit, both during the procedure and within the first 30 min following the procedure though the quality of the evidence was low.<sup>[19]</sup>

A drawback of paracervical block is that the administration of a lignocaine block does require knowledge of cervical anatomy and proper injection technique. It takes approximately 5-10 min extra to inject and to allow the block to be effective, and this would increase the time required to perform the procedure. Finally, the addition of paracervical block would slightly increase the cost of the HSG because of the use of an additional syringe, spinal needle, and local anesthetic. The adverse effects due to paracervical block can be nausea, vomiting, constipation, drowsiness, respiratory depression, hypotension, allergic reaction, and infection, despite the fact that none of the participants in our study experienced any of them. In Robinson et al.'s study, none of the 38 participants who received intracervical lignocaine experienced any adverse effects.<sup>[14]</sup> However, Chauhan et al. reported that one participant experienced light-headedness, two experienced head numbness, and two experienced tinnitus with intracervical block.[17] In Hacivelioglu et al.'s study, two participants experienced vomiting with paracervical block.[15]

A recent Cochrane Review by Tangsiriwatthana *et al.* concluded that available evidence fails to show whether paracervical block is inferior, equivalent, or superior to alternative analgesic techniques in terms of efficacy and safety for women undergoing cervical dilatation and uterine interventions.<sup>[11]</sup>

In this study, NRS is used as a validated pain scale to score the pain perception of patients during HSG as it was easily understood by most of the patients as they had to give a score at the time of experience of pain. Using complicated pain scores might have given inaccurate or biased results. Significant heterogeneity is recorded by various authors in this respect as visual analog scale from 0 to 10 mm, 0–10 cm,

### **Table 4: Review of literature**

Study	Pain score in paracervical block group (number of participants)	Pain score in control group (number of participants)	Р
de Mello et al. <sup>[18]</sup>	3.9 ( <i>n</i> =29)	6.8 ( <i>n</i> =30)	< 0.05
Robinson <i>et al</i> . <sup>[14]</sup>	2.8 ( <i>n</i> =38)	3.3 ( <i>n</i> =43)	< 0.459
Chauhan <i>et al</i> . <sup>[17]</sup>	2.6 (95% CI 1.7-3.5) ( <i>n</i> =50)	5.1 (95% CI 4.3-6.0) ( <i>n</i> =50)	0.001
Hacivelioglu <i>et al</i> . <sup>[15]</sup>	6.8±2.0 ( <i>n</i> =31)	7.6±1.9 ( <i>n</i> =30)	0.20
	7.2±1.4 ( <i>n</i> =31)	8.0±1.7 ( <i>n</i> =28)	0.77
Unlu et al. <sup>[16]</sup>	4.7±2.5 ( <i>n</i> =19)	7.2±1.6 ( <i>n</i> =20)	<0.001
Our study	4.84±2.56 ( <i>n</i> =51)	5.21±1.89 ( <i>n</i> =53)	0.41

or 0–20 cm and verbal descriptive score has been considered in previous trials.

The only limitation of our study was that the participants were not blinded to the intervention used for each group recruited into the study.

# CONCLUSIONS

HSG is simple, reliable, and cost-effective procedure for evaluation of tubal patency in infertile women, but its only drawback is its painful nature. The results of our study and the latest Cochrane Review do not support the routine use of paracervical block for pain relief in women undergoing HSG. The most painful component of the HSG is the instillation of contrast into the uterus. A method that will significantly decrease pain for this part of the procedure is still needed. Women are unacceptable to pain during interventions when performed awake in the absence of neuraxial blockade, which is unaltered by paracervical block. Hence, there is a need to consider psychological factors also. Allaying anxiety before undergoing HSG can be of great help as we found in our study. Skilled personnel and gentle technique remain the most important factors in reducing pain during HSG.

Further high quality, well-powered trials are required to investigate the efficacy and timing of analgesia during HSG. Research is also needed in evaluating the effectiveness of combination of analgesia of different classes on HSG-related pain.

### Acknowledgment

The authors are thankful to Dr. Mohinder Kochar, Dr. Shweta Mittal, Dr. Neeti Tiwari, and Dr. Ruma Satwik, for providing subjects and inputs for the study. We are grateful to Dr. K. K. Saxena and Mr. Abhrahim Philip from Department of Radiodiagnosis, Sir Ganga Ram Hospital, for their co-operation. Dr. Ajay Jain is appreciated for his generous help and constant inspiration. We express gratitude to all the patients who participated in the study.

### **Financial support and sponsorship** Nil.

### **Conflicts of interest**

There are no conflicts of interest.

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