

Original Research Article

Effectiveness of paracervical block for pain relief in women undergoing hysterosalpingography in Bayelsa State, South-South Nigeria: a randomized control trial

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ABSTRACT

Background: One of the major short comings of hysterosalpingography is discomfort and/or pain for the patient during or after the investigative modality; and this is a major cause of anxiety for many patients. Objectives were to compare the effectiveness of paracervical block with 2% lignocaine and placebo in pain reduction when undergoing hysterosalpingography.

Methods: This randomised control trial was conducted at the radiology departments and infertility clinics of the Federal Medical Centre, Yenagoa and Niger Delta University Teaching Hospital, Okolobiri, both in Bayelsa State, Nigeria, from July 2021-February 2022. Three hundred and eighty infertile women undergoing hysterosalpingography were assigned into two groups. Women in group I received paracervical block, while the women in group II received placebo. Data were analysed using statistical product and service solutions for windows® version 25. Results were presented in frequencies and percentages for categorical variables; mean and standard deviation for continuous variables. Student's t-test was used to compare sample means; and Chi-square for associations.

Results: The mean pain score±SD for group I was 3.8±2.6, while that in group II was 6.2±2.2. The difference between the means was statistically significant ($t=9.77$; $p=0.001$). While 140 (73.7%) women experienced moderate pain in group II, 70 (36.8%) women in Group I experienced moderate pain.

Conclusions: Our study revealed that paracervical block improved the overall pain score of women undergoing hysterosalpingography, although a significant proportion of the women expressed some pain during instillation of contrast media.

Keywords: Hysterosalpingography, Pain, Paracervical block, Lignocaine, Placebo

INTRODUCTION

Infertility is the inability of a couple to conceive after 12 months of regular unprotected sexual intercourse. It is primary if a couple is unable to achieve pregnancy, while secondary infertility is the failure to achieve pregnancy

after a previous pregnancy, irrespective of the outcome of that pregnancy. About 6%-15.7% of couples are affected by infertility, globally.¹⁻⁴ The prevalence of infertility varies widely in Sub-Saharan Africa. It is 14.3% in the Gambia, 10.4% in Sudan and 32% in South-South Nigeria.^{1,2,5} Infertility is estimated to be 6% and 10% in

the United Kingdom and the United States of America, respectively.⁴

Hysterosalpingography is an investigative modality used in the evaluation of the uterine cavity, fallopian tubes, and adjacent peritoneal cavity following the injection of contrast material through the cervical canal.⁶ Hysterosalpingography is the most common method of evaluating for tubal patency in our environment, and the most common form of uterine instrumentation in infertile women.⁷ This is so because it is cheap, readily available and reliable. However, one of the major shortcomings of hysterosalpingography is discomfort and/or pain for the patient during or after the investigative modality; and this is a major cause of anxiety for many patients.⁸

Patients feel pain at various points during hysterosalpingography. In our practice, individual patients may feel pain during the insertion of speculum, grasping the lip of the cervix with a tenaculum, insertion of the canula or injection of contrast media into the uterine cavity. Apart from hysterosalpingography, other investigative modalities that can be used for the evaluation of infertile women are transvaginal ultrasound scan, hysteroscopy, sonohysterosalpingography, laparoscopy and dye test, and magnetic resonance hysterosalpingography. Different methods of controlling pain during hysterosalpingography have been researched upon with varying outcomes. Therefore, the objective of this randomised control trial was to compare the effectiveness of paracervical block with 2% lignocaine and placebo in pain reduction when undergoing hysterosalpingography in Bayelsa State, South-South Nigeria..

METHODS

This randomised control trial was conducted at the radiology departments and infertility clinics of the Federal Medical Centre, Yenagoa and Niger Delta University Teaching Hospital, Okolobiri, both in Bayelsa State, Nigeria. It was conducted over an eight-month period, from July, 2021 - February, 2022. These two tertiary health institutions in Bayelsa State, provide specialised gynaecological services to women in the State, and serve as referral centres for other hospitals in Bayelsa State and surrounding Rivers and Delta States. Ethical approval was obtained from the hospitals' research and ethics committee, and was sregistered with the Pan African Clinical Trial Registry (PACTR202203697292254).

The sample size for this study was calculated using the formula⁹

$$N = \frac{(Z\alpha + Z\beta)^2 \times 2 \times P(1 - P)}{d^2}$$

Where N=minimum sample size

$Z\alpha$ =95% confidence level=1.96

$Z\beta$ =20% β error (at 80% power)=0.84

p=prevalence of infertility which was 12.1% (0.121) from a previous study.¹⁰

d=expected margin of error=10%=0.1

Calculation

$N = (1.96 + 0.84)^2 \times 2 \times 0.121(1 - 0.121) / (0.1)^2$

$N = 7.84 \times 0.242 \times 0.879 / 0.01$

$N = 1.667 / 0.01$

$N = 166.7$ (minimum sample size per group)

Putting into consideration an attrition rate of 10% (16.7);
 $N = 183.4$

'N' was adjusted to 190

The sample size is calculated to be 190 per group, making a total of 380 participants in the study.

Three hundred and eighty infertile women undergoing hysterosalpingography were enrolled in the study. They were assigned into two groups by computer-generated randomisation. Women in group I will have paracervical block with 10 ml (200 mg) 2% lignocaine hydrochloride manufactured by Pfizer, while the women in group II will have placebo with 10 ml of water for injection manufactured by Medlab pharmaceuticals, India. Following adequate counselling, written informed consent was obtained from all the women. The allocating team and the team performing the hysterosalpingography were different, to help prevent selection bias.

Infertile women referred for hysterosalpingography, and women that gave consent and completely filled the consent/questionnaire form were included in the study.

Exclusion criteria included abnormal uterine/vaginal bleeding before the procedure, on-going menstruation, pregnancy, discharge on inspection of the cervix, cervical stenosis/cervical pathology, evidence of pelvic inflammatory disease, previous history of contrast hypersensitivity, history of allergy to lignocaine, and all patients that declined consent or incompletely filled the consent form and questionnaire. The nature of the study, the procedure and the likely benefits to the patients were explained to them. Their age, level of education, occupation, parity, body mass index and other patients' information were obtained and documented. Afterwards, they were referred to the radiology department for hysterosalpingography.

Procedure

Hysterosalpingography for the women was performed within the proliferative phase of the menstrual cycle (7th

- 10th day). Lead apron for body protection and eye shield were worn. After passing urine to empty her urinary bladder, the patient was initially placed in the supine position on the X-ray table. The scout radiograph of the antero-posterior view of the pelvis was taken. She was then placed in the lithotomy position, and draped to ensure privacy. The visual analogue scale (VAS) was used to document the level of pain expressed by the patients at different stages of the investigation, by an assistant who was blinded to the randomisation (Figure 1).¹¹

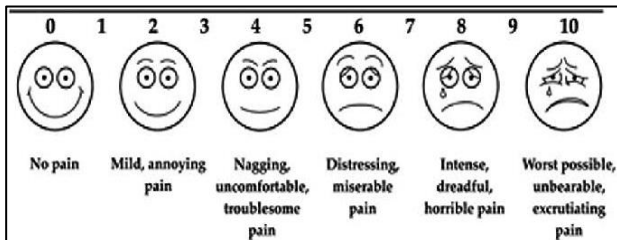


Figure 1: Visual analogue scale.

After hand-washing and putting on sterile gloves, under a good light source, a sterile Cusco's speculum was inserted into the vagina to expose the cervix. The ectocervix was cleaned with savlon solution. Paracervical block (with 2% lignocaine for women in group I and with placebo for women in group II) was injected at 5 o'clock and 7 o'clock positions to avoid the blood vessels that run at the 3 o'clock and 9 o'clock positions of the cervix. After 5 minutes of administering paracervical block, the cervical lip of the cervix was grasped with the use of a tenaculum. A self-retaining cannula was inserted into the cervix, and the speculum was removed for the patient's comfort. Urographin, a water-soluble, high osmolar contrast media (10-20 ml) was warmed to body temperature, and injected slowly into the endometrial cavity. To outline the endometrial cavity, fallopian tubes and intraperitoneal spillage, 3 radiographs were taken respectively. The instruments were removed, the vulva was cleaned, and she subsequently dressed up.

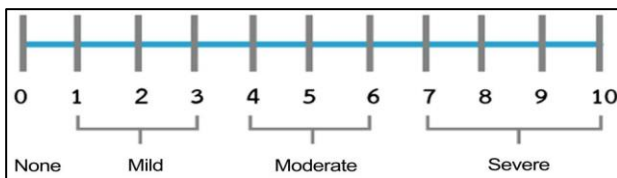


Figure 2: Numerical rating scale (NRS).¹²

The hysterosalpingography films were reported by the consultant radiologist. The outcome of the procedure was discussed with the women. Thirty minutes after the procedure, the level of pain that the women felt were recorded with the use of the numerical rating scale (Figure 2).¹² This is the commonest scale used in the grading of pain. The patient rates the level of pain on a scale of 0-10. A score of 0 indicates no pain, 1-3 suggests

mild pain, 4-6 suggests moderate pain, 7-10 suggests severe pain.¹²

Outcome measures

The primary outcomes included pain score immediately after the procedure. The secondary outcomes included difference in pain scores, and presence of any adverse effect in any group.

Data analysis

Data were entered into a pre-designed proforma, and were analysed using statistical product and service solutions for windows® version 25 (SPSS Inc.; Chicago, USA). Results of categorical variables were presented in frequencies and percentages; that of continuous variables were presented in mean and standard deviation. Student's t-test was used to compare sample means; and Chi-square for associations. P value less than 0.05 was taken as being statistically significant.

RESULTS

Sociodemographic characteristics and anthropometric measurements

Three hundred and eighty women who gave written informed consent completed the study, and were included in data analysis. The mean age of the women was 35.8 years with a standard deviation of 4.5 years (Table 1). Although women in the paracervical block (PCB) group had a slightly higher mean age (36.2±5.5 years) than the women who had placebo (35.5±3.2 years), this difference was not statistically significant ($t=1.59$; $p=0.114$). Table 1 also shows that majority of the women were aged between 30-34 years (36.8%), educated to the tertiary level of education (55.5%), employed as civil servants (43.7%), and resided in Bayelsa State (86.1%). Distribution of participants in the 2 study groups in relation to age group, educational level, occupation, and residential location was not significantly different ($p>0.05$).

The mean weight, height and body mass index of participants were 71.8±13.5 kg, 1.59±0.05 m, and 28.6±4.4 kg/m² respectively (Table 1). Furthermore, Table 1 showed that there was no significant difference between the groups with respect to weight ($t=1.68$; $p=0.093$), height ($t=0.57$; $p=0.560$), and body mass index ($t=1.28$; $p=0.199$).

Gynaecological features and infertility related factors

As shown in Table 2, 64 (33.7%) participants in the PCB group were nulliparous while 78 (41.1%) participants were nulliparous in the placebo group. More women in the PCB group (28; 14.7%) compared to the placebo group (20; 10.5%) were grand-multiparous women. This difference in parity was, however, not statistically significant ($\chi^2=3.40$; $p=0.334$). About two-third of

women in PCB group (64.2%) and placebo group (65.8%) had hysterosalpingography for secondary infertility. While 113 (59.5%), 61 (32.1%) and 16 (8.4%) women in the PCB group, and 126 (66.3%), 50 (26.3%) and 14 (7.4%) women in the placebo group had infertility for <5 years, 6-10 years and 11-15 years respectively. This observed difference was not statistically significant ($\chi^2=1.93$; $p=0.381$).

Past gynaecological history

Dysmenorrhoea was the most common (50%) presenting symptom, and there was no statistical difference ($\chi^2=0.38$; $p=0.538$) in its distribution between the two groups (Table 3). Chronic pelvic pain was the presenting symptom in the 72 (37.9%) women in the PCB group, while only 33 (17.4%) women in the placebo group reported chronic pelvic pain (Table 3). The distribution of chronic pelvic pain was significantly different between the 2 groups of women ($\chi^2=20.02$; $p=0.001$).

Pain perception following hysterosalpingography

The mean pain score of women in the PCB group was 3.8 with a standard deviation of 2.6, while that in the placebo group was 6.2 with a standard deviation of 2.2 (Table 4 and Figure 3). The difference between the means was statistically significant ($t=9.77$; $p=0.001$). While 140 (73.7%) women experienced moderate pain in the

placebo group, 70 (36.8%) women in the PCB group experienced moderate pain (Table 4).

Pain perception was significantly ($\chi^2=62.14$; $p=0.001$) reduced in women in PCB group when compared to women in the placebo group (Table 4). None of women had any form of side/ adverse effects arising from hysterosalpingography.

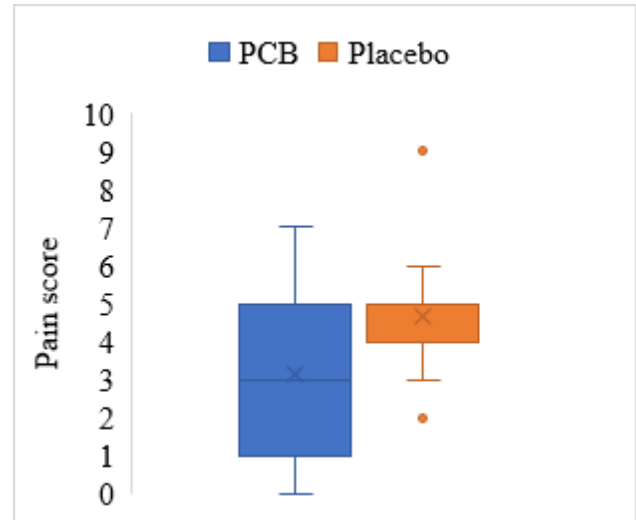


Figure 3: Box and whisker chart showing the pain scores in women in the PCB and the placebo group.

Table 1: Socio-demographic characteristics and anthropometric measurement.

Characteristics	Total, N=380 (%)	Study groups		Chi-square	P value
		PCB, N=190 (%)	Placebo, N=190 (%)		
Age group (years)					
<30	24 (6.3)	13 (6.8)	11 (5.8)	5.52	0.138
30-34	140 (36.8)	68 (35.8)	72 (37.9)		
35-39	135 (35.5)	60 (31.6)	75 (39.5)		
≥ 40	81 (21.3)	49 (25.8)	32 (16.8)		
Mean age±SD in years	35.8±4.5	36.2±5.5	35.5±3.2	1.59	0.114
Level of education					
Primary	30 (7.9)	13 (6.8)	17 (8.9)	0.63	0.728
Secondary	139 (36.6)	66 (34.7)	73 (38.4)		
Tertiary	211 (55.5)	111 (58.5)	100 (52.6)		
Occupation					
Civil servant	166 (43.7)	78 (41.1)	88 (46.3)	3.59	0.309
Professional	35 (9.2)	15 (7.9)	20 (10.5)		
Trader	131 (34.5)	68 (35.8)	65 (34.2)		
Unemployed	48 12.6)	29 (15.3)	19 (10.0)		
Residence					
Bayelsa	327 (86.1)	166 (87.4)	161 (84.7)	0.55	0.460
Outside Bayelsa	53 (13.9)	24 (12.6)	29 (15.3)		
Body mass index (kg/m²)					
Normal weight	86 (22.6)	42 (22.1)	44 (23.2)	1.68	0.640
Overweight	161 (42.4)	77 (40.5)	84 (44.2)		
Class I obesity	112 (29.5)	58 (30.5)	54 (28.4)		
Class II obesity	21 (5.5)	13 (6.8)	8 (4.2)		
Weight	71.8±13.5	73.4±14.2	71.2±11.1	1.68	0.093
Height	1.59±0.05	1.58±0.06	1.59±0.04	0.57	0.560
Body mass index	28.6±4.4	29.2±5.2	28.6±3.8	1.28	0.199

Note: PCB-Paracervical block.

Table 2: Gynaecological features and infertility related factors.

Characteristics	Total, N=380 (%)	Study groups		Chi-square	P value
		PCB, N=190 (%)	Placebo, N=190 (%)		
Parity					
Nulliparity	142 (37.4)	64 (33.7)	78 (41.1)	3.40	0.334
Primiparity	90 (23.7)	44 (23.2)	46 (24.2)		
Multiparity	100 (26.3)	54 (28.4)	46 (24.2)		
Grandmultiparity	48 (12.6)	28 (14.7)	20 (10.5)		
Duration of marriage (years)					
<5	121 (31.8)	63 (33.2)	58 (30.5)	3.57	0.312
6-10	162 (42.6)	86 (45.3)	76 (40.0)		
11-15	53 (13.9)	24 (12.6)	29 (15.3)		
>16	44 (11.6)	17 (8.9)	27 (14.2)		
Number of children					
None	267 (70.3)	130 (68.4)	137 (72.1)	0.88	0.644
1-2	96 (25.3)	50 (26.3)	46 (24.2)		
≥3	17 (4.5)	10 (5.3)	7 (3.7)		
Type of infertility					
Primary	133 (35.0)	68 (35.8)	65 (34.2)	0.10	0.747
Secondary	247 (65.0)	122 (64.2)	125 (65.8)		
Duration of infertility (years)					
<5	239 (62.9)	113 (59.5)	126 (66.3)	1.93	0.381
6-10	111 (29.2)	61 (32.1)	50 (26.3)		
11-15	30 (7.9)	16 (8.4)	14 (7.4)		

Note: PCB-Paracervical block

Table 3: Past gynaecological history.

Characteristics	Total, N=380 (%)	Groups		Chi square	P value
		PCB, N=190 (%)	Placebo, N=190 (%)		
Dysmenorrhoea					
Yes	190 (50.0)	92 (48.4)	98 (51.6)	0.38	0.538
No	190 (50.0)	98 (51.6)	92 (48.4)		
Chronic pelvis pain					
Yes	105 (27.6)	72 (37.9)	33 (17.4)	20.02	0.001*
No	275 (72.4)	118 (62.1)	157 (82.6)		
Pelvic inflammatory diseases					
Yes	92 (24.2)	42 (22.1)	50 (26.3)	0.92	0.338
No	288 (75.8)	148 (77.9)	140 (73.7)		
Spontaneous abortion					
Yes	71 (18.7)	38 (20.0)	33 (17.4)	0.43	0.511
No	309 (81.3)	152 (80.0)	157 (82.6)		
Induced abortion					
Yes	231 (60.8)	124 (65.3)	107 (56.3)	3.19	0.093
No	149 (39.2)	66 (34.7)	83 (43.7)		

Note: PCB-Paracervical block; *Statistically significant

Table 4: Level of pain perception following hysterosalpingography.

Perception of pain	Total, N=380 (%)	Groups		Chi-square	P value
		PCB, N=190 (%)	Placebo, N=190 (%)		
Overall					
None	30 (7.8)	30 (15.9)	0 (0.0)	62.14	0.001*
Mild	117 (30.8)	81 (42.6)	36 (18.9)		
Moderate	210 (55.3)	70 (36.8)	140 (73.7)		
Severe	23 (6.1)	9 (4.7)	14 (7.4)		
Mean pain score ± SD	5.0±2.7	3.8±2.6	6.2±2.2	9.77	0.001*
During instillation of contrast media	348 (91.6)	158 (83.2)	190 (100)		

Note: PCB-Paracervical block; *Statistically significant.

DISCUSSION

Hysterosalpingography is an important investigative modality for the evaluation of infertile women. Many women experience mild to severe pain during and after the procedure, for which different forms and routes of analgesics have been used with varying results. This study looked at how effective the use of paracervical block will be in the reduction of procedure-associated pain of hysterosalpingography. The sociodemographic variables and past gynaecological history in both groups of women in this study were similar, with no statistical significance. This observation is in consonance with the reports from different studies.¹³⁻¹⁸ This may suggest that the randomization tool used in these studies were valid.

Our study revealed that paracervical block was effective in reducing the overall pain associated with hysterosalpingography. This is in tandem with reports by Chauhan et al, de Mello et al, and Unlu et al, but in contrast with the reports of Jain et al, Robinson et al, and Hacivelioglu et al.¹³⁻¹⁸ The plausible reasons for this difference may be due to the use of pre-procedure systemic analgesics/medications, the sample size used, the different times of the procedure in the various studies when analgesics were given, the skill of the personnel, and the procedure technique. The use of pre-procedure systemic analgesics and medications may have increased bias in these studies. In our study, pre-procedure systemic analgesics and medications were not used in order to prevent bias.

The expression of pain by patients varies with the various steps of hysterosalpingography. In our study, the expression of pain by patients was more at the instillation of contrast media into the uterine cavity. This is in agreement with the reports by Unlu et al, Jain et al, Robinson et al as well as the Hacivelioglu et al.¹⁵⁻¹⁸ However, Liberty and his colleagues reported in their study that it was during the insertion of cervical instruments that their patients expressed the most pain.¹⁹ To reduce the procedure-associated pain of hysterosalpingography, the patients have to be counselled on the investigative modality, the benefits and the possible complications, as we did in this study. Anxiety and stress can enhance the procedure-associated pain of hysterosalpingography.⁸

Two pain score scales were used in this research. The VAS was used to score the level of pain that the women expressed at different steps of this investigative modality, while the numerical rating scale (NRS) was used to score the overall pain perception at the end of the procedure. Although, the overall pain scores for the women in the PCB group was significantly lower compared to those in the placebo group, it was only 16% of the women in the PCB group that was pain-free during instillation of

contrast media, and none of the women in the placebo group was pain-free during the instillation of contrast media. This finding was similar to those of previous authors.¹⁵⁻¹⁸

Paracervical block has some side/adverse effects, which include drowsiness, allergic reaction to lignocaine, nausea, vomiting, constipation, hypotension, respiratory depression, cervicitis and haemorrhage. None of our patients presented with any of these side effects. This finding was in tandem with the reports of Jain et al and Robinson et al.^{16,17} However, some other studies have reported some side effects with paracervical block.^{13,18}

The strength of this research lies in the fact that it is a two-centre prospective randomised control trial where both the participants and radiologists were blinded to the intervention used for each group of women that participated in the study. Only two consultant radiologists performed the hysterosalpingography, and therefore reduced bias, and increased the reproducibility of the report of this investigative modality. The allocating team and the team performing the hysterosalpingography were different, to help prevent selection bias. No form of premedication was given to women in either of the groups. This further reduced bias. The limitation of this study lies in the fact that it is hospital-based, with a sample size of 380 participants. Consequently, the findings may not reflect what is obtainable in the general population of infertile women in our subregion. An international multi-centre randomised control trial with a larger sample size will be more representative.

CONCLUSION

Our study revealed that paracervical block improved the overall pain score of women undergoing hysterosalpingography, although a significant proportion of the women expressed some pain during instillation of contrast media. Any analgesic method or route that will remarkably reduce the pain associated with this step in hysterosalpingography would have solved the issue of pain in this investigative modality.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee and registered with the Pan African Clinical Trial Registry (PACTR202203697292254).

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