

# Comparison of Intramuscular Diclofenac and Paracervical Block during and after Hysterosalpingography in Women with Infertility in South-South Nigeria: A Randomized Controlled Trial

Enefia Kelvin Kiridi<sup>1,2</sup>, Peter Chibuzor Oriji<sup>3\*</sup>, Emily Gabriel Enefia Kiridi<sup>4</sup>, Akaninyene Esemé Ubom<sup>5</sup>, Johnpatrick Uchenna Ugwoegbu<sup>6</sup>, Isaac Joel Abasi<sup>7</sup>, Panebi Yao Bosrotsi<sup>8</sup>

Departments of <sup>1</sup>Radiology and <sup>2</sup>Obstetrics and Gynaecology, Niger Delta University Teaching Hospital, Okolobiri, <sup>3</sup>Silhouette Radiodiagnostic Consultants, Yenagoa, <sup>4</sup>Department of Obstetrics and Gynaecology, Federal Medical Centre, Yenagoa, <sup>5</sup>Department of Obstetrics and Gynaecology, Diète Koki Memorial Hospital, Yenagoa, <sup>6</sup>Department of Physiology, Niger Delta University, Wilberforce Island, Amassoma, Bayelsa, <sup>7</sup>Department of Obstetrics, Gynaecology and Perinatology, Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Osun, <sup>8</sup>Department of Radiology, Federal Medical Centre, Owerri, Imo, Nigeria

## Abstract

**Background:** Tubal patency testing is essential in the evaluation of infertile women, and the preferred investigation for determining tubal patency is hysterosalpingography (HSG). **Aim:** The aim of the study was to compare the effectiveness of intramuscular diclofenac and paracervical block for pain alleviation during and after HSG. **Patients, Materials and Methods:** This research was carried out at the Infertility and Radiology Units of four health facilities, from January 2021 to April 2022. The Pan African Clinical Trials Registry received this trial's registration (PACTR202203726718710). Through simple randomization, 520 women billed for HSG were assigned into Groups I (control) and II (study). Group I had 75 mg of intramuscular diclofenac, while Group II had paracervical block with 2% lignocaine hydrochloride. At various stages of HSG, pain scores were obtained. Statistical Product and Service Solutions for Windows® version 25 (SPSS Inc.; Chicago, USA). The Chi-square test was used to examine the number of women in Groups I and II who experienced pain at the various stages of HSG, while the Student's *t*-test was used to compare sample means. **Results:** The step that caused the most pain was injection of contrast media, with a mean pain score of  $3.85 \pm 1.43$  in Group I, and  $5.00 \pm 0.63$  in Group II. Group I reported considerably lesser pain during speculum insertion, contrast media injection, and 24 h after the surgery ( $P = 0.001$ ,  $P = 0.001$ , and  $P = 0.005$ , respectively). **Conclusion:** Intramuscular diclofenac is more effective than paracervical block (with lignocaine) for pain alleviation, both during and after HSG.

**Keywords:** Diclofenac, hysterosalpingography, infertility, pain, paracervical block, tubal patency

## INTRODUCTION

Globally, about 10%–15% of couples are infertile, and in 11%–30% of affected couples, infertility is related to tubal pathology.<sup>[1]</sup> The baseline investigation for determining tubal patency is hysterosalpingography (HSG) in infertility workup, owing to its high sensitivity and specificity of 65% and 85%, respectively, for diagnosing tubal occlusion.<sup>[2,3]</sup>

Due to the peritoneal irritation from dye spillage, and the local production of prostaglandins during cervical instrumentation and uterine expansion caused by the contrast media, HSG can be unpleasant.<sup>[4]</sup> It is important to give consideration to effective pain alleviation, both during and after the procedure,

because the pain linked with the HSG can discourage women from undergoing or fully cooperating with the procedure, thereby negatively impacting on its utility.<sup>[4,5]</sup> A number of

**Address for correspondence:** Dr. Peter Chibuzor Oriji,  
Department of Obstetrics and Gynaecology, Federal Medical Centre,  
Yenagoa, Bayelsa, Nigeria.  
E-mail: chibuzor54@gmail.com

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

**For reprints contact:** WKHLRPMedknow\_reprints@wolterskluwer.com

### Access this article online

Quick Response Code:



Website:  
www.njmonline.org

DOI:  
10.4103/NJM.NJM\_81\_22

**How to cite this article:** Kiridi EK, Oriji PC, Kiridi EG, Ubom AE, Ugwoegbu JU, Abasi IJ, *et al.* Comparison of intramuscular diclofenac and paracervical block during and after hysterosalpingography in women with infertility in South-South Nigeria: A randomized controlled trial. *Niger J Med* 2022;31:625-32.

**Submitted:** 13-Jul-2022

**Revised:** 27-Oct-2022

**Accepted:** 27-Nov-2022

**Published:** 28-Feb-2023

analgesic agents have been utilized during HSG, but there is no general agreement on which agent is the best analgesic or the optimal dose or time to administer analgesic during HSG.<sup>[6,7]</sup>

Diclofenac, a nonsteroidal anti-inflammatory drug (NSAID), has anti-inflammatory and analgesic properties, and has up to eight-hour duration of action. It acts by inhibiting prostaglandin synthesis by inhibiting cyclooxygenase-1 and cyclooxygenase-2 enzymes.<sup>[8]</sup> On the other hand, lignocaine is an anesthetic of the amide group and a class 1b antiarrhythmic agent, widely used in medical practice as a local and regional anaesthetic. Its onset of action is <2 min (almost immediately for local infiltration), while its duration of action is 1–2 h.<sup>[9]</sup> It is also used in the prevention and treatment of ventricular arrhythmias.<sup>[10]</sup>

Paracervical block with lignocaine is an effective pain relief method. It is used as a form of analgesia in obstetric and gynaecological procedures (including HSG). There are conflicting reports in the literature about the effectiveness of paracervical block as a pain relief method for HSG. While some authors have reported its effective analgesic effect,<sup>[6,11-13]</sup> others have reported no benefit as a pain relief method for HSG.<sup>[14-16]</sup> In the centres of the authors, the pain relief method used is intramuscular diclofenac.

A Cochrane review found that apart from topical analgesics and intravenous opioids, there were insufficient data on the efficacy of using other analgesic agents during HSG.<sup>[17]</sup> On the other hand, it was concluded by a meta-analysis and systematic review that although both oral NSAIDs and local anaesthetics had insignificant analgesic effects during and 30 min after HSG, the use of local anaesthetic agents was linked to a considerable decline in mean pain score >30 min after HSG.<sup>[18]</sup> Both authors recommended further studies to provide more evidence on the efficacy, optimal route, timing and dose of local anaesthetics, and oral analgesics for pain alleviation during HSG.<sup>[17,18]</sup> The aim of the study was to compare the effectiveness of intramuscular diclofenac and paracervical block for pain alleviation during and after HSG in infertile women.

## PATIENTS, MATERIALS AND METHODS

### Trial design

This trial was carried out from January 2021 to April 2022.

### Participants

The trial was carried out in Bayelsa State, Nigeria, at the Infertility and Radiology Units of the Federal Medical Centre, Yenagoa (FMCY); Niger Delta University Teaching Hospital, Okolobiri (both are tertiary health centres that offer expert gynaecological services, and serve as centres where some health facilities in the southern part of Nigeria refer patients to); Diète Koki Memorial Hospital, Yenagoa (a secondary health institution); and Silhouette Radiodiagnostic Consultants, Yenagoa (the largest radiodiagnostic institution in the state).

### Inclusion criteria

All the women being evaluated for infertility with HSG, who gave their consent to be part of the study, were included.

### Exclusion criteria

Menstruation or abnormal vaginal/uterine bleeding, cervical pathology/stenosis, cervicovaginal discharge, evidence of pelvic inflammatory disease, allergy to diclofenac and/or lignocaine, previous history of contrast hypersensitivity, and women that improperly filled the consent form and questionnaire or declined consent were excluded.

### Interventions

Group I (control) had 75 mg of intramuscular diclofenac (Voltaren® – manufactured by GSK) and paracervical block with 10 ml of injection water (Medlab Pharmaceuticals, India) as placebo, while Group II (study) had 3 ml of water for injection as placebo and paracervical block with 200 mg (10 ml) of 2% lignocaine solution (Pfizer). Intramuscular diclofenac was administered five minutes before the commencement of the procedure, while paracervical block was administered 60 s before grasping the anterior lip of the cervix. Clinicians who were not directly involved in performing the HSG administered the interventions [Figure 1].

### Procedure

This investigative modality was carried out in the proliferative phase of their menstrual cycles (seventh to tenth day). The woman emptied her urinary bladder and changed into a hospital gown, and the radiologist put on a protective lead apron, thyroid, and eye shields. The patient laid on the X-ray table five minutes after administering the intramuscular diclofenac/placebo. Afterward, an advance supine anteroposterior pelvic image was captured. She was then put in the lithotomy position and covered with sterile drapes. The radiologist used 1% chlorhexidine solution (Savlon®) to clean the woman's perineum after washing his hands and donning sterile gloves. Afterward, the cervix was exposed using a lubricated, warm vaginal speculum, which was cleaned with Savlon® as well. Paracervical block with lignocaine/injection water was administered, and 60 s was allowed before continuing the procedure. In order to perform a paracervical block, lignocaine was injected 10 mm deep into the lateral fornices at the 5 and 7 o'clock positions, respectively.

An assistant who was not involved in the randomization process employed the Wong–Baker Faces Pain Rating Scale [Figure 2]<sup>[19,20]</sup> to record the degree of pain felt by the participants over the course of the HSG at insertion of vaginal speculum, grasping of the cervix, insertion of cannula, and injection of contrast media. A tenaculum was used to grasp the anterior lip of the cervix. The cervical canal was lengthened by gently lowering the tenaculum, which made it parallel to the X-ray beam. To increase the patient's comfort, the vaginal speculum was removed after a self-retaining cannula was passed into the cervical canal. Under fluoroscopic guidance,

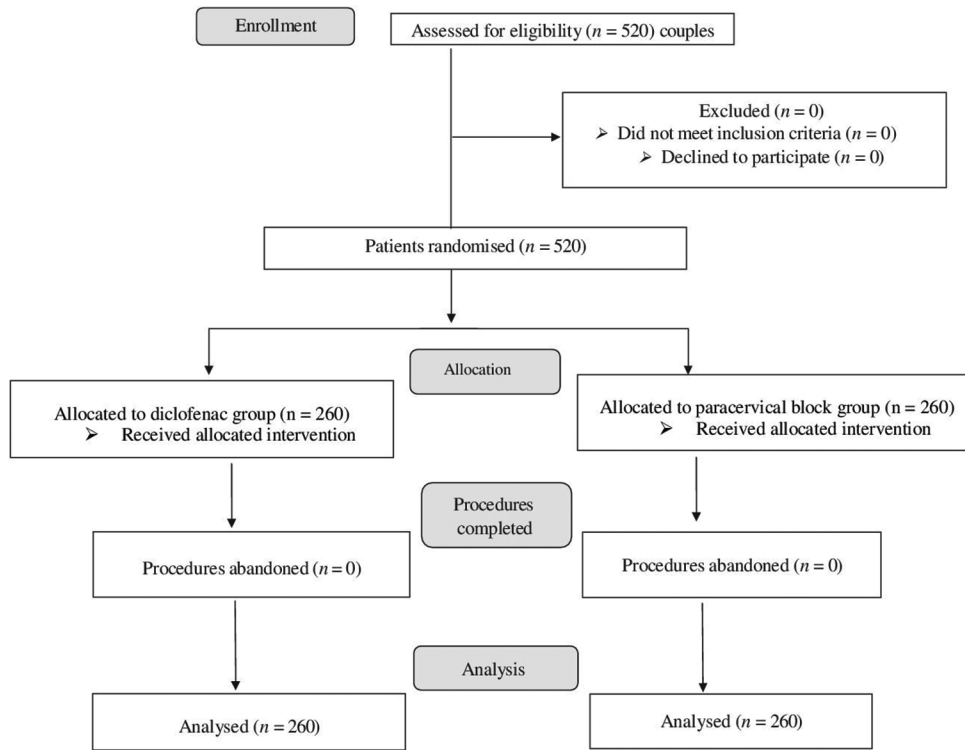


Figure 1: CONSORT flow diagram



Figure 2: Wong-Baker Faces Pain Rating Scale<sup>[19,20]</sup>

20 ml of heated urografin was injected into the uterine cavity. Spot pictures of the intraperitoneal spillage, fallopian tubes, and endometrial canal were taken. After the procedure, the woman’s vulva was cleaned from anterior to posterior, and the patient was asked to put on her clothes.

The consultant radiologists reported the HSG films. The women were informed of the procedure’s findings. The Numerical Rating Scale was employed to record the women’s level of pain 30 min and 24 h after HSG [Figure 3].<sup>[21,22]</sup> This is the scale that is most frequently used to grade pain. On a scale of 0–10, the patient rated her degree of pain. A score of 0 meant there was no pain, 1–3 meant it was mild, 4–6 meant it was moderate, and 7–10 meant it was severe.<sup>[21]</sup>

**Study outcome measures**

Pain ratings during various steps of the investigative modality as well as 30 min and 24 h afterward were the primary outcomes. Any negative effects on the women in any of the groups were included as secondary outcomes.

**Sample size**

The sample size for this randomized controlled trial was calculated using:

$$n = (Z\alpha + Z\beta)^2 \times 2 \times P(1 - p)/d^{2[23]}$$

where n = minimum sample size

$$Z\alpha = 95\% \text{ confidence level} = 1.96$$

$$Z\beta = 20\% \beta \text{ error (at 80\% power)} = 0.84$$

p = prevalence of women being assessed for infertility = 18.2% (0.182) from a previous study in our environment<sup>[24]</sup>

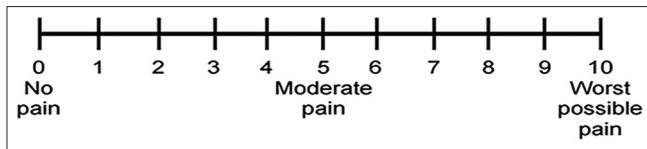
$$d = \text{margin of error} = 10\% = 0.1$$

therefore,

$$n = (1.96 + 0.84)^2 \times 2 \times 0.182(1 - 0.182)/(0.1)^2$$

$$n = 7.84 \times 0.364 \times 0.818/0.01$$

$$n = 2.33/0.01$$



**Figure 3:** Numerical Rating Scale<sup>[21,22]</sup>

$n = 233$  (minimum sample size for each of the groups)

considering an attrition rate of 10% = 23.3;  $n = 256.3$ , and was adjusted to 260.

With 260 participants in each study group, a total of 520 participants were enrolled in the trial.

## Randomization

### Sequence generation

From the Infertility Units of the centers, 520 infertile women for HSG who satisfied the study inclusion criteria were enrolled in the study. All the women taking part in the study gave written informed consent after receiving proper counseling. The women were informed of the study's purpose, its methodology, and its anticipated advantages. On a specially created pro forma, their background sociodemographic and gynecological information were collected and documented. A computer-generated list of random numbers was used to randomly assign eligible women to two Groups, I (control) and II (study), using the simple randomization procedure ([www.randomization.com](http://www.randomization.com)).

### Allocation concealment mechanism

Neither the principal investigator nor co-investigators were aware of the randomization sequence. Concealment of allocation by the statistician was done by writing the Groups (I and II) on sheets of paper, which were put inside sealed, sequentially numbered opaque envelopes. These envelopes were drawn consecutively to randomise eligible and consenting study participants, until the study sample size was reached. The women thereafter presented to the Radiology Departments for HSG.

## Implementation

Generation of the numbers was done by a statistician, who was blinded to the objectives and protocol of the study. Clinicians who were not directly involved in the trial enrolled and assigned participants to interventions.

## Blinding

The participants, clinicians, and statisticians were blinded.

## Data analysis

The Statistical Product and Service Solutions for Windows<sup>®</sup> version 25 was used to analyze the data after it was entered into a predesigned pro forma (SPSS Inc.; Chicago, Illinois, USA). For categorical variables, the findings were shown as frequencies and percentages, and for continuous variables, as mean and standard deviation. The Chi-square test was used to evaluate the perception of pain at various stages of the procedure, while the Student's *t*-test was employed to compare

sample means.  $P = 0.05$  or less was considered statistically significant. Figure 1 shows the CONSORT flow diagram for this randomized controlled trial.

## RESULTS

### Baseline characteristics of women undergoing hysterosalpingography

The mean age of the women was  $34.80 \pm 4.41$  years, and the modal age group was 31–35 years (264, 50.8%), with majority of the women having tertiary education (239, 46.0%). One-half (267, 51.3%) of the women were overweight/mildly obese (body mass index [BMI] of  $27.41 \pm 4.55$  kg/m<sup>2</sup>). Age ( $P = 0.542$ ), education ( $P = 0.786$ ), and BMI ( $P = 0.711$ ) did not differ (statistically) significantly between the women in Groups I and II [Table 1].

### Infertility and gynecological characteristics of women undergoing hysterosalpingography

Nearly two-third (324, 62.3%) of the women were nulliparous. The predominant type of infertility was secondary (317, 61.0%), with the mean duration of infertility and marriage being  $3.79 \pm 1.98$  years and  $4.72 \pm 2.90$  years, respectively. Additionally, there were no statistically significant variations in parity ( $P = 0.378$ ), type of infertility ( $P = 0.285$ ), duration of infertility ( $P = 0.478$ ), or length of marriage ( $P = 0.808$ ) between Groups I and II [Table 2].

### Pain perception at different steps of hysterosalpingography

The least painful step of HSG in this trial was the insertion of speculum, when the mean pain score was  $0.56 \pm 0.55$ , whereas the most painful stage was injection of contrast media, the mean pain score at this step being  $4.43 \pm 1.25$ . Women in Group I felt significantly less pain at speculum insertion (mean pain score of  $0.42 \pm 0.59$  vs.  $0.70 \pm 0.46$ ;  $P = 0.001$ ), injection of contrast media (mean pain score of  $3.85 \pm 1.43$  vs.  $5.00 \pm 0.63$ ,  $P = 0.001$ ), and 24 h postprocedure (mean pain score of  $0.36 \pm 0.65$  vs.  $0.50 \pm 0.50$ ;  $P = 0.005$ ), compared to women in Group II. Sixty percent (158) of the women in Group I felt no pain at speculum insertion, whereas only 30% (78) of those in Group II felt no pain at this step. At injection of contrast, an overwhelming majority (242, 93.1%) of the women who received diclofenac had either mild (100, 38.5%) or moderate pain (142, 54.6%), whereas all the women who had paracervical block had moderate pain. More of these findings are shown in Tables 3 and 4 and Figure 4.

## DISCUSSION

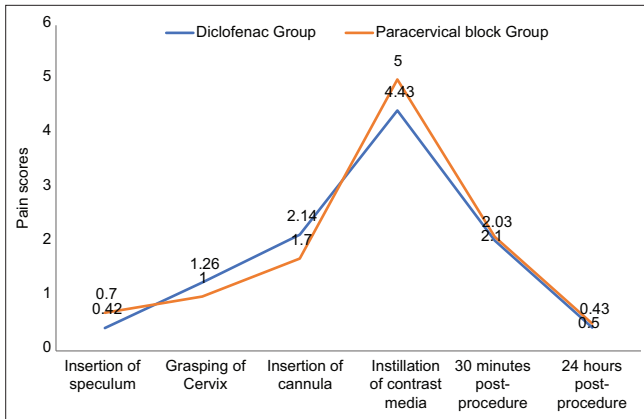
In our study, the mean age of the women was  $34.8 \pm 4.4$  years, with a modal age group of 31–35 years. Various studies have observed comparable mean age and modal age range.<sup>[25-33]</sup> Age is very significant in pain perception. Although our study found no link between age and pain, some authors have observed that procedure-associated pain increased with age of the patient.<sup>[34,35]</sup> The plausible explanation for this may be related to the fact that as women age, their likelihood of



**Table 1: Baseline characteristics of women undergoing hysterosalpingography**

Characteristics	Total (n=520), n (%)	Study groups		Test of significance (P)
		Diclofenac (n=260), n (%)	PCB (n=260), n (%)	
Age group (years)				
26-30	60 (11.5)	34 (13.1)	26 (10.0)	2.15 <sup>a</sup> (0.542)
31-35	264 (50.8)	134 (51.5)	130 (50.0)	
36-40	150 (28.8)	72 (27.7)	78 (30.0)	
>40	46 (8.8)	20 (7.7)	26 (10.0)	
Mean age±SD (years)	34.80±4.41	33.72±3.80	35.87±4.72	5.72 <sup>b</sup> (0.001*)
Level of education				
None	62 (11.9)	34 (13.1)	28 (10.7)	1.06 <sup>a</sup> (0.786)
Primary education	75 (14.4)	35 (13.5)	40 (15.4)	
Secondary education	144 (27.7)	70 (26.9)	74 (28.5)	
Tertiary education	239 (46.0)	121 (46.5)	118 (45.4)	
Occupation				
Unemployed	54 (10.4)	28 (10.8)	26 (10.0)	3.31 <sup>a</sup> (0.653)
Civil servant	76 (14.6)	32 (12.3)	44 (16.9)	
Trader	139 (26.7)	73 (28.1)	66 (25.4)	
Professional	93 (17.9)	47 (18.1)	46 (17.7)	
Farmer	47 (9.0)	21 (8.1)	26 (10.0)	
Artisan	111 (21.3)	59 (22.7)	52 (20.0)	
Body mass index categories				
Normal weight	140 (26.9)	66 (25.4)	74 (28.5)	1.38 <sup>a</sup> (0.711)
Overweight	218 (41.9)	110 (42.3)	108 (41.5)	
Obesity class I	49 (9.4)	23 (8.8)	26 (10.0)	
Obesity class II	113 (21.7)	61 (23.5)	52 (20.0)	
Weight (kg)	70.98±11.99	71.46±8.13	70.50±14.89	0.92 <sup>b</sup> (0.360)
Height (m)	1.61±0.06	1.61±0.06	1.61±0.06	1.20 <sup>b</sup> (0.230)
Body mass index (kg/m <sup>2</sup> )	27.41±4.55	27.55±3.53	27.27±5.38	0.70 <sup>b</sup> (0.482)

\*Statistically significant, <sup>a</sup>Chi-square test, <sup>b</sup>t-test. PCB: Paracervical block



**Figure 4:** Pain perception at different steps of HSG. HSG: hysterosalpingography

developing morbidities that will heighten their experience of pain increases. Other authors have found no association between age and pain perception.<sup>[4,36]</sup>

In our study, almost 75% of the women were overweight or obese. Thirteen percent of individuals globally, according to the data from the World Health Organization (WHO), are obese,<sup>[37]</sup> and the list of global health issues maintained by the WHO now includes obesity. Researchers have found a relationship

between pain and an increase in body weight.<sup>[38,39]</sup> As the BMI increases, pain perception also increases. C-reactive protein, tumor necrosis factor-alpha, and interleukin-6 are known to be elevated in obese people.<sup>[40,41]</sup> Perception of pain is significantly influenced by interleukin-6.<sup>[42]</sup> In order to effectively manage pain in obese women undergoing HSG, it is essential to comprehend the link between obesity and pain.

Our study revealed that intramuscular diclofenac was superior to paracervical block with lignocaine for the control of HSG-associated pain. This observation is at variance with the finding of Avidime *et al.* in Kano, Nigeria, who reported that intracervical block with lignocaine was more effective than intramuscular diclofenac for procedure-associated pain of HSG.<sup>[43]</sup> Conversely, NSAIDs were recommended by Gupta *et al.* and Anserini *et al.*, as the drug of choice for pain management during HSG.<sup>[44,45]</sup>

The most painful part of HSG, observed in Groups I and II, was the injection of the contrast media. This is in tandem with the observations of other authors who identified the injection of contrast media as the stage that was the most painful.<sup>[4,6,14-16,34,46]</sup> However, cervical instrument insertion was described by authors as the most painful part of HSG.<sup>[47]</sup> Furthermore, Avidime *et al.* reported both injection of contrast media and grasping of the cervix as the most

**Table 2: Gynecologic and infertility characteristics of women undergoing hysterosalpingography**

Characteristics	Total (n=520), n (%)	Study groups		Test of significance (P)
		Diclofenac (n=260), n (%)	PCB (n=260), n (%)	
Parity				
Nulliparity	324 (62.3)	159 (61.2)	165 (63.5)	1.95 <sup>a</sup> (0.378)
Primiparity	81 (15.6)	46 (17.7)	35 (13.5)	
Multiparity	115 (22.1)	55 (21.2)	60 (23.1)	
Median parity (range)	0 (0-5)	0 (0-5)	0 (0-3)	43,608 <sup>b</sup> (0.001*)
Age at menarche (years)				
11-13	209 (40.2)	105 (40.4)	104 (40.0)	0.57 <sup>a</sup> (0.751)
14-16	252 (48.5)	123 (47.3)	129 (49.6)	
17-19	59 (11.3)	32 (12.3)	27 (10.4)	
Mean age at menarche±SD (years)	13.8±1.7	13.6±1.6	14.1±1.8	2.87 <sup>c</sup> (0.004)
Duration of marriage (years)				
1-5	314 (60.4)	160 (61.5)	154 (59.2)	0.43 <sup>a</sup> (0.808)
6-10	177 (34.0)	85 (32.7)	92 (25.4)	
>10	29 (5.6)	15 (5.8)	14 (5.4)	
Mean marriage duration±SD (years)	4.72±2.90	4.07±2.80	5.37±2.86	5.22 <sup>c</sup> (0.001*)
Number of children				
None	360 (69.2)	178 (68.5)	182 (70.0)	2.05 <sup>a</sup> (0.358)
1-2	34 (6.5)	21 (8.1)	13 (5.0)	
3-4	126 (24.2)	61 (23.5)	65 (25.0)	
Median number of children (range)	0 (0-2)	0 (0-2)	0 (0-1)	32,461 <sup>b</sup> (0.332)
Type of infertility				
Primary	203 (39.0)	103 (39.6)	101 (38.8)	1.15 <sup>a</sup> (0.285)
Secondary	317 (61.0)	157 (60.4)	159 (61.2)	
Duration of infertility (years)				
1-5	391 (75.2)	199 (76.5)	192 (73.8)	0.51 <sup>a</sup> (0.478)
6-10	129 (24.8)	61 (23.5)	68 (26.2)	
Mean duration of infertility±SD (years)	3.79±1.98	3.11±1.44	4.47±2.20	8.35 <sup>c</sup> (0.001*)

\*Statistically significant, <sup>a</sup>Chi-square test, <sup>b</sup>Mann-Whitney U-test, <sup>c</sup>Student's t-test. SD: Standard deviation, PCB: Paracervical block**Table 3: Duration of hysterosalpingography and pain perception at different steps of hysterosalpingography**

Characteristics	Total	Mean±SD		t-test (P)
		Study groups		
		Diclofenac	PCB	
Procedure time (min)	4.72±1.18	4.61±1.21	4.81±1.30	1.82 (0.070)
Mean pain scores at different steps of HSG				
Insertion of speculum	0.56±0.55	0.42±0.59	0.70±0.46	6.16 (0.001*)
Grasping of the cervix	1.26±0.74	1.53±0.75	1.00±0.63	8.67 (0.001*)
Insertion of cannula	2.14±1.32	2.57±1.44	1.70±1.01	8.01 (0.001*)
Instillation of contrast media	4.43±1.25	3.85±1.43	5.00±0.63	11.86 (0.001*)
30 min postprocedure	2.03±0.90	1.95±1.06	2.10±0.70	1.85 (0.064)
24 h postprocedure	0.43±0.58	0.36±0.65	0.50±0.50	2.81 (0.005*)

\*Statistically Significant, HSG: Hysterosalpingography, SD: Standard deviation, PCB: Paracervical block

painful steps of HSG.<sup>[43]</sup> Even though the instillation of contrast media was the step in our trial that caused the most pain, the women who were administered intramuscular diclofenac reported feeling considerably lesser pain. This finding is not surprising, because the major mechanism of pain during instillation of contrast media is the local release of prostaglandin, which is inhibited by diclofenac, an inhibitor of prostaglandin synthesis. Lignocaine does not have this property.

When compared to the sample sizes of other studies conducted in our region, this study's strength is that it is a multicenter, randomized controlled trial with a somewhat higher sample size. The interventions employed in this trial were hidden from both the doctors and the participants. There were different teams for group allocation of patients and for performing HSG. This significantly minimized the risk of selection bias. Only four consultant radiologists (one for each study center) performed all the HSG procedures.

**Table 4: Pain intensity at the different steps of hysterosalpingography**

Characteristics	Total	Study groups		$\chi^2$ (P)
		Diclofenac (n=260), n (%)	PCB (n=260), n (%)	
Insertion of speculum				
No pain	236 (45.4)	158 (60.8)	78 (30.0)	49.56 (0.001*)
Mild pain	284 (54.6)	102 (39.2)	182 (70.0)	
Grasping of the cervix				
No pain	54 (10.4)	2 (0.8)	52 (20.0)	51.56 <sup>a</sup> (0.001*)
Mild pain	466 (89.6)	258 (99.2)	208 (80.0)	
Insertion of cannula				
Mild pain	458 (88.1)	224 (86.2)	234 (90.0)	1.83 (0.176)
Moderate pain	62 (11.9)	36 (13.6)	26 (10.0)	
Instillation contrast media				
Mild pain	100 (19.2)	100 (38.5)	0	152.64 <sup>a</sup> (0.001*)
Moderate pain	402 (77.3)	142 (54.6)	260 (100.0)	
Severe pain	18 (3.5)	18 (6.9)	0	
30 min postprocedure				
No pain	15 (2.9)	15 (5.8)	0	18.64 <sup>a</sup> (0.001*)
Mild pain	502 (96.5)	242 (93.1)	260 (100.0)	
Moderate pain	3 (0.6)	3 (1.2)	0	
24 h postprocedure				
No pain	318 (61.2)	188 (72.3)	130 (50.0)	27.18 (0.001*)
Mild pain	202 (38.8)	72 (27.7)	130 (50.0)	

\*Statistically significant, <sup>a</sup>Chi-square test

Performance bias was greatly reduced as a result, improving the validity and reproducibility of our research findings. The localised nature of this study makes it difficult to generalise its results, which is one of its limitations. We, therefore, recommend a larger, highly powered population-based randomized controlled trial.

## CONCLUSION

This study revealed that for pain management during and up to 24 h following HSG, intramuscular diclofenac is superior to paracervical block (with lignocaine). Therefore, we recommend intramuscular diclofenac for pain management during HSG.

## Ethics

The Research and Ethics Committee of the FMCY gave ethical approval for this trial (FMCY/REC/ECC/2022/474), and registered with the Pan African Clinical Trials Registry (<https://pactr.samrc.ac.za/>)-PACTR202203726718710.

## Acknowledgment

We appreciate all the patients and staff of our study facilities for the various roles they played in making this research successful. For the data analysis for this study, our profound gratitude goes to Dr. Adedotun Daniel Adesina.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

## REFERENCES

- Li J, Ren L, Li M, Yang C, Chen J, Chen Q. Screening of potential key genes related to tubal factor infertility based on competitive endogenous RNA network. *Genet Test Mol Biomarkers* 2021;25:325-33.
- Overview. Fertility Problems: Assessment and Treatment. Guidance. NICE. Available from: <https://www.nice.org.uk/guidance/cg156>. [Last accessed on 2022 Jul 10].
- Dutta S, Mazumder P, Mishra D, Saha JK. Study on comparative diagnostic efficacy of HSG & laparoscopy in infertility. *J Evol Med Dent Sci* 2020;9:937-42.
- Szymusik I, Grzechocińska B, Marianowski P, Kaczyński B, Wielgoś M. Factors influencing the severity of pain during hysterosalpingography. *Int J Gynaecol Obstet* 2015;129:118-22.
- Nyengidiki TK, Oriji VK. Comparative study of pain perception among infertile women undergoing Hysterosalpingography and office hysteroscopy in Port Harcourt, Nigeria. *Clin Obstet Gynecol Reprod Med* 2020;6:1-5.
- Unlu BS, Yilmazer M, Koken G, Arioz DT, Unlu E, Dogan Baki E, *et al.* Comparison of four different pain relief methods during hysterosalpingography: A randomized controlled study. *Pain Res Manag* 2015;20:107-11.
- Hassa H, Oge T, Aydin Y, Burkankulu D. Comparison of nonsteroidal anti-inflammatory drugs and misoprostol for pain relief during and after hysterosalpingography: Prospective, randomized, controlled trial. *J Minim Invasive Gynecol* 2014;21:762-6.
- Diclofenac (Topical) Monograph for Professionals. *Drugs.com*. Available from: <https://www.drugs.com/monograph/diclofenac-topical.html>. [Last accessed on 2022 Jul 10].
- Collins JB, Song J, Mahabir RC. Onset and duration of intradermal mixtures of bupivacaine and lidocaine with epinephrine. *Can J Plast Surg* 2013;21:51-3.
- Weinberg L, Peake B, Tan C, Nikfarjam M. Pharmacokinetics and pharmacodynamics of lignocaine: A review. *World J Anesthesiol* 2015;4:17-29.
- Kiridi EK, Oriji PC, Ugwoegbu JU, Abasi IJ. Effectiveness of paracervical block for pain relief in women undergoing hysterosalpingography in Bayelsa State, South-South Nigeria: A randomized control trial. *Int J Clin Trials* 2022;9:53-9.

12. Chauhan MB, Lakra P, Jyotsna D, Nanda S, Malhotra V. Pain relief during hysterosalpingography: Role of intracervical block. *Arch Gynecol Obstet* 2013;287:155-9.
13. de Mello JF Sr, Abrao MS, Cerri GG, de Barros N. Evaluation of pain in three hysterosalpingography techniques: Metal cannula with and without paracervical blockage and balloon catheter. *AJR Am J Roentgenol* 2006;187:86-9.
14. 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.
15. Robinson RD, Casablanca Y, Pagano KE, Arthur NA, Bates GW, Propst AM. Intracervical block and pain perception during the performance of a hysterosalpingogram: A randomized controlled trial. *Obstet Gynecol* 2007;109:89-93.
16. Hacivelioglu S, Gencer M, Cakir Gungor A, Kosar S, Koc E, Cosar E. Can the addition of a paracervical block to systemic or local analgesics improve the pain perceived by the patient during hysterosalpingography? *J Obstet Gynaecol* 2014;34:48-53.
17. Hindocha A, Beere L, O'Flynn H, Watson A, Ahmad G. Pain relief in hysterosalpingography. *Cochrane Database Syst Rev* 2015;2015:CD006106.
18. Ahmad G, Attarbashi S, O'Flynn H, Watson AJ. Pain relief in office gynaecology: A systematic review and meta-analysis. *Eur J Obstet Gynecol Reprod Biol* 2011;155:3-13.
19. Yeung AW, Wong NS. The historical roots of visual analog scale in psychology as revealed by reference publication year spectroscopy. *Front Hum Neurosci* 2019;13:86.
20. Pain Management. Victorian Adult Burns Service; 2016. Available from: <https://www.vicburns.org.au/minor-burns/minimise-infection/pain-management-1/>. [Last accessed on 2022 Jul 10].
21. Downie WW, Leatham PA, Rhind VM, Wright V, Branco JA, Anderson JA. Studies with pain rating scales. *Ann Rheum Dis* 1978;37:378-81.
22. Almarzouki AF, Brown CA, Brown RJ, Leung MH, Jones AK. Negative expectations interfere with the analgesic effect of safety cues on pain perception by priming the cortical representation of pain in the midcingulate cortex. *PLoS One* 2017;12:e0180006.
23. Zhong B. How to calculate sample size in randomized controlled trial? *J Thorac Dis* 2009;1:51-4.
24. Oriji PC, Kiridi EK, Ubom AE, Okoye CN, Oriji VK, Awotundun B. Pattern of infertility among infertile couples in a tertiary health institution in Bayelsa State, South-South Nigeria. *Int J Sci Rep* 2022;8:136-41.
25. Aduayi OS, Akanbi GO, Akintayo AA, Aduayi VA. Hysterosalpingography findings among women presenting for gynecological imaging in Ado-Ekiti, South Western Nigeria. *Int J Reprod Contracept Obstet Gynecol* 2017;5:1906-11.
26. Okafor CO, Okafor CI, Okpala OC, Umeh E. The pattern of hysterosalpingographic findings in women being investigated for infertility in Nnewi, Nigeria. *Niger J Clin Pract* 2010;13:264-7.
27. Olatunji AA, Jagun OE, Toyobo OO, Ashaolu OA, Adekoya OA. Hysterosalpingogram findings among women with infertility in Ogun State, Nigeria. *Ann Health Res* 2017;3:75-81.
28. Danfulani M, Haruna Y, Mohammed M, Ahmed S. Hysterosalpingographic findings in women with infertility in Sokoto North Western Nigeria. *Afri J of Med Health Sci* 2014;13:19.
29. Igoh EO, Chom ND, Pam SD, Ekedigwe JE, Ani CC, Atsukwei D, *et al.* Risk factors for abnormal tubal hysterosalpingographic findings in women presenting with infertility in Jos. *Jos J Med* 2015;9:47-52.
30. Imo AO, Sunday-Adeoye I. Radiological assessment of the uterus and fallopian tubes in infertile women at Abakaliki, Nigeria. *Niger J Clin Pract* 2008;11:211-5.
31. Kiguli-Malwadde E, Byanyima RK. Structural findings at hysterosalpingography in patients with infertility at two private clinics in Kampala, Uganda. *Afr Health Sci* 2004;4:178-81.
32. Kiridi EK, Oriji PC, Ugwoegbu JU, Abasi IJ. Hysterosalpingography findings among women presenting for infertility evaluation in Bayelsa State, South-South Nigeria. *J Adv Med Med Res* 2022;34:7-17.
33. Kiridi EK, Oriji PC, Abasi IJ, Ubom AE, Ugwoegbu JU. Predictors or abnormal findings in infertile women undergoing hysterosalpingography in Bayelsa State, South-South Nigeria. *Int J Clin Obstet Gynaecol* 2022;6:22-30.
34. Oriji PC, Kiridi EK, Abasi IJ, Ubom AE, Ugwoegbu JU. Predictive factors for the severity of procedure-associated pain in infertile women undergoing hysterosalpingography in Bayelsa State, South-South Nigeria. *Int J Trop Dis Health* 2022;43:43-54.
35. Olson K. Pain and aging. *Pract Pain Manag* 2015;15:1-4. Available from: <https://www.practicalpainmanagement.com/pain/pain-aging>. [Last accessed on 2022 Oct 17].
36. Park A, Quaes A, Hansen KR, Porter B, Burks H, La Tasha BC. Predictors of pain associated with hysterosalpingography (HSG): A prospective cohort. *Austin J Women's Health* 2014;1:4.
37. Obesity and Overweight. Available from: <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>. [Last accessed on 2022 Oct 17].
38. Hitt HC, McMillen RC, Thornton-Neaves T, Koch K, Cosby AG. Comorbidity of obesity and pain in a general population: Results from the Southern pain prevalence study. *J Pain* 2007;8:430-6.
39. Somers TJ, Wren AA, Keefe FJ. Understanding chronic pain in older adults: Abdominal fat is where it is at. *Pain* 2011;152:8-9.
40. Das UN. Is obesity an inflammatory condition? *Nutrition* 2001;17:953-6.
41. Okifuji A, Donaldson GW, Barck L, Fine PG. Relationship between fibromyalgia and obesity in pain, function, mood, and sleep. *J Pain* 2010;11:1329-37.
42. McVinnie DS. Obesity and pain. *Br J Pain* 2013;7:163-70.
43. Avidime AR, Muhammad SD, Adamu IS. The effect of intracervical lidocaine versus intramuscular diclofenac for pain relief during hysterosalpingography among infertile women in a tertiary hospital in Kano: A randomised controlled trial. *BOMJ* 2020;17:1-14.
44. Gupta N, Ghosh B, Mittal S. Comparison of oral naproxen and intrauterine lignocaine instillation for pain relief during hysterosalpingography. *Int J Gynaecol Obstet* 2008;102:284-6.
45. Anserini P, Delfino F, Ferraiolo A, Remorgida V, Menoni S, De Caro G. Strategies to minimize discomfort during diagnostic hysterosalpingography with disposable balloon catheters: A randomized placebo-controlled study with oral nonsteroidal premedication. *Fertil Steril* 2008;90:844-8.
46. Abbas AM, Abo-Elela NA, Mosa EM. Effect of oral hyoscine-N-butyl bromide on pain perception during hysterosalpingography: A randomized, double-blind, placebo-controlled trial. *Middle East Fertil Soc J* 2018;23:57-62.
47. Liberty G, Gal M, Halevy-Shalem T, Michaelson-Cohen R, Galoyan N, Hyman J, *et al.* Lidocaine-prilocaine (EMLA) cream as analgesia for hysterosalpingography: A prospective, randomized, controlled, double blinded study. *Hum Reprod* 2007;22:1335-9.