

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

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ABSTRACT

Background: Hysterosalpingography (HSG) is the radiographic evaluation of the uterus and fallopian tubes and is used predominantly in the evaluation of infertility. HSG can cause discomfort or pain during or after the procedure, up to 72 % of women complain of significant discomfort with this test. This pain can hinder patient's co-operation, therefore limiting the usefulness of the procedure, and willingness to do other similar diagnostic studies. It can also result in fortuitous tubal blockade by provoking cornual spasms. **Objectives:** To compare the effect of intracervical block with 1% lidocaine and intramuscular diclofenac 75mg in decreasing pain perception during hysterosalpingography. **Methods:** The study was carried out between September 2016 and January 2017. One hundred and forty women with infertility referred for hysterosalpingography were randomly recruited and assigned to two study groups. Women in the study group A were given an intracervical block with 1% lidocaine while women in the Study Group B were given intramuscular diclofenac sodium 75mg 30 minutes before the procedure. Pain levels during specified stages of HSG were assessed using visual analogue score. The statistical package for social sciences (SPSS) version 16.0 was used to analyze the data. The data obtained were presented in tables. Categorical data were analyzed using chi-squared test and Fishers exact correction, continuous data were analyzed using student t-test; level of significance (p-value) was set at $p < 0.05$. **Results:** There was no statistically significant difference in the two study groups in their baseline characteristics; but there were statistically significant differences in some gynaecological characteristics that include previous vaginal delivery and previous pregnancy loss. The two most painful steps of the procedure were during grasping of the cervix and uterine distension with contrast medium mean visual analogue score (VAS) of 4.26 ± 1.62 and 6.37 ± 1.62 ($t = -7.726$, $p\text{-value} < 0.001$), 6.14 ± 1.85 and 7.37 ± 2.23 ($t = -3.543$, $p\text{-value} 0.001$) respectively in groups A and B. **Conclusion:** There was significant reduction in VAS pain scores with intracervical block with lidocaine when performing HSG for infertility.

Key words: hysterosalpingography, infertility, pain relief, intracervical block, diclofenac sodium.

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Introduction

Infertility is a major reproductive health problem in sub-Saharan Africa. An average of couples experience infertility in Africa, with a high percentage of 32% in some countries and ethnic groups within Africa.^{1,2} It causes severe emotional and social distress to the couples with the women more affected than men, this

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may even drain the couple of their self-belief and esteem leading to isolation and social stigmatization.^{3,4} Tubal disease attributed to infection is the most common cause of infertility and accounts for about 23.5, 45.1 and 63.6% of the female factor infertility in South-west, south-south and north-east Nigeria.⁵⁻⁷ Hysterosalpingography (HSG) is one of the common methods for the evaluation of anatomy and patency of the uterus and fallopian tubes due to its relative reliability and cost-effectiveness.^{8,9} It is the most common method of tubal evaluation in the developing countries because it is cheap, readily available and requires less expertise. Unfortunately, HSG can cause discomfort or pain in about 72% of the patients during or after the procedure, and this evokes anxiety and fear for many of them.⁸⁻¹⁰

The pain during HSG may arise from cervical irritation during instrumentation, uterine distension with contrast media and peritoneal irritation as a result of contrast spill into the peritoneal cavity.^{8,9,11} Grasping the cervix with a tenaculum, as well as distending the uterus, may release local prostaglandins which may initiate uterine cramps, reported as delayed pain after HSG.⁸ HSG has many integral steps with different intensity of pain perception level, various studies done identified the most painful steps to be at the cervical traction with introduction of cannula and the instillation of contrast as the most painful steps.^{10,12,13} Various researches have been carried out on pain relief during HSG but there appears to be no consensus in terms of the type and the timing of administration of analgesia and anaesthesia for the procedure. Non pharmacologic interventions that have been tried with slight decrease in pain perception compared to the traditional method include use of intrauterine insemination

catheter, cervical vacuum cap cannula and intrauterine HSG balloon catheter.¹⁴⁻¹⁶

However, their use in developing countries will be limited due to cost. Paracetamol was tried but its action is mainly peripherally, although it has some central effects but it has no anti-inflammatory activity. It is less irritating to the gastro-intestinal tract, cheap and readily available. It was not found to be more or less effective than placebo in alleviating pain during or after HSG.^{11,17} Non-steroidal Anti-Inflammatory Drugs (NSAIDs), are likely to have a significant effect on pain caused by prostaglandin release as a result of uterine distension or cervical instrumentation, the two recognized causes of pain during HSG. Therefore, NSAIDs would seem a logical intervention. Fenopfen and naproxen (both non-steroidal anti-inflammatory drugs) were found to reduce pain during the HSG procedure when compared with placebo.¹⁸ Intracervical block with lidocaine as an additional agent to an oral NSAIDs (Ibuprofen) was shown to make the overall experience of a HSG less painful.¹⁰

There is paucity of studies on the administration of analgesia and anaesthesia during HSG in this part of the country, where HSG is the main investigative tool for tubal infertility. Pain has been shown to cause tubal spasms thus interpreted as spasm or tubal blockage.¹⁹ This study aims to compare the effect of pain management during hysterosalpingography using intracervical block with 1% lidocaine and intramuscular diclofenac 75mg in a randomized control trial.

Methodology

The study was conducted in Obstetrics and Gynaecology and Radiology departments of Aminu Kano Teaching Hospital, Kano. It has about 500 beds and was established in 1988 as the Teaching Hospital of Bayero University



Kano medical school. The participants were recruited from the population of infertile patients attending gynaecological outpatient clinic referred for hysterosalpingography. All women with infertility referred for hysterosalpingography that gave consent were recruited into the study.

However, the following were excluded from the study; those with history of any allergies to local anaesthetics, radio-opaque dye, or anti-inflammatory medications, patients with active pelvic inflammatory diseases or chronic pelvic pain, with history of cervical surgery. Other indications for hysterosalpingography like Ashermanns syndrome, congenital uterine anomalies were also excluded from the study.

Ethical clearance for the study was obtained from the research ethics committee of Aminu Kano Teaching Hospital.

Methodology and purpose of the study were explained in clear terms to the subjects who fulfilled the inclusion criteria for the study. Informed consent was obtained from all the subjects stating clearly that they can withdraw at will at any time without any consequences. Fees for the injection were fully paid by the principal researcher. Sample size estimation was performed using the formula ⁸²

$$n = 2 \frac{(Z_{\alpha} + Z_{1-\beta})^2 \sigma^2}{(\mu_1 - \mu_2)^2}$$

Where n = minimum sample size in each group

Z_{α} = standard normal deviation corresponding to 5% level of significance =1.96 (obtained from normal distribution table)

$Z_{1-\beta}$ = standard normal deviation corresponding to a power of 80% = 0.84 (obtained from normal distribution table)

σ = standard deviation which is 2.0 from a study done by Hacivelioglu in Turkey.⁹

$\mu_1 - \mu_2$ = the difference the investigator wishes to detect given as difference of 1cm on the VAS.¹⁰

The sample size from the above formula gave 63 women in each group. Adding 10% as proportion of study participants who were expected to be lost to follow up we had a total of 70 women in each group. The planned sample size (70 patients per group) was calculated to detect a difference of 1cm on the VAS in both groups, and a common standard deviation of 2.0, with power of 80% and alpha level of significance 5% by a Student's t-test for independent samples. Participants were recruited from the population of patients that presented to the gynaecology outpatient department with infertility and referred for Hysterosalpingography. The principal researcher randomized and booked the patients for the appropriate day considering the last menstrual period. One hundred and forty women were recruited over a period of five months; the department performs about 60 hysterosalpingographies in a month thus about 300 women were available during the study period. Systematic sampling technique was used to recruit patients into the study. The first patient was selected at random using balloting of a coin, and every other second patient was selected henceforth (i.e. 300/140 =2.14 ~ 2) until the required sample size was achieved. Patients were adequately counselled on the procedure to minimize fear and anxiety. Sequentially numbered, opaque sealed envelopes were used to assign patients to receive either the intracervical block with 1% lidocaine i.e. Group A, or intramuscular diclofenac i.e. Group B. Seventy papers were marked as group A and another 70 were marked as group B. The papers were sealed in the respective opaque envelopes and mixed thoroughly by a research assistant not involved in the process of



hysterosalpingography. The envelopes were subsequently numbered and arranged serially in a box. Allocation was done by opening a sealed opaque envelope. The sealed envelopes were secured and placed in the radiology department from where they were drawn serially until completion of the study. Neither the researcher nor the participants were aware of the allocation of participants to any particular group prior to opening the envelopes.

The study group i.e. Group A comprised patient that received the intracervical block. The patient was in a modified lithotomy position at the end of a fluoroscopic table; the vagina and the cervix were checked using a sterile bivalve speculum. Local cleaning and preparation of the vagina and the cervix was performed using a chlorhexidine solution. The patient received a total of 60 mg (6 mL) of 1% lidocaine injected at four points (12, 4, 6, and 8 o'clock) circumferentially into the cervix (1.5 mL at each point) 5 minutes before proceeding with the hysterosalpingogram. The four points was standardized and illustrated on a diagram available in the radiology suite. The second group i.e. Group B were managed according to the present practice in the department, where patients were given premedication with the addition of intramuscular diclofenac sodium 75mg 30 minutes before the procedure.

The HSG procedure was performed during the early follicular phase, 2 - 3 days after menstrual cessation. Each patient was administered intravenous 20mg hyoscine butylbromide as pre-medication. The patient was placed in a modified lithotomy position at the end of a fluoroscopy table; the vagina and the cervix were checked using a sterile bivalve cuscus speculum. Local cleaning and preparation of the vagina and the cervix was performed using a chlorhexidine solution. A

single-toothed tenaculum was attached to the anterior lip of the cervix, while an appropriately sized metal Leech Wilkinson's cannula corresponding to the cervical os opening was advanced gently into the external cervical os. The cannula and tenaculum were secured together while removing the speculum. Traction was placed on the tenaculum, and a water-soluble contrast medium (urographin) was slowly instilled via the cannula while the necessary images were obtained. The cannula and tenaculum were removed after the procedure was completed. Excess of the contrast medium was cleaned from the body of the patient and a pad was given to her.

Pretested interviewer administered questionnaires were used prior to the procedure, to obtain information on socio-demographic characteristics, parity, indication for HSG, type of infertility, duration of infertility, history of bilateral tubal ligation, dysmenorrhoea, weight, and height. Complications from the procedure and anaesthetic agent were documented. The report of the HSG test was also documented. A detailed description of the visual analogue scale (VAS), as reviewed by Katz et al. (1999), was given personally to each woman prior to the procedure. The VAS included a 10 cm linear scale on which 0 represents 'no pain' and 10 represents 'worst pain imaginable'. All patients were asked to grade their perceived lower abdominal pain levels during specified stages of HSG using the VAS as explained to them. The scale was used at five different stages of the procedure: (1) before beginning the procedure; (2) after speculum application but before instrumentation; (3) after the application of the tenaculum and metal cannula and just before the injection of contrast medium; (4) at the end of uterine filling with contrast medium; and (5) at 30



min after the procedure. A research assistant was reminding the patients on how to fill the VAS score during the procedure.

Data obtained from the questionnaires were entered into Microsoft Excel sheet and subsequently entered into the statistical package for social sciences (SPSS) version 16.0 which was used to analyze the data. The planned sample size (70 patients per group) was calculated to detect a difference of 1cm on the VAS in both groups, and a common standard deviation of 2.0, with power of 80% and alpha level of significance 5% by a Student's *t*-test for independent samples. Categorical variables were summarized as frequencies and percentages, and compared using Chi-squared test with Fishers exact correction where applicable.

While quantitative variables were summarized as means and standard deviations or median and range as appropriate, and compared using student *t*-test.

The studied population was subsequently divided into two new groups according to the pain experienced during the procedure, regardless of the analgesic used.

To investigate which variables were responsible for pain during the HSG, a painful experience was defined as all the procedures in which the patients reported a VAS score ≥ 7 . Patients were divided into two groups.

The first group had a VAS score < 7 and a second group with a VAS score ≥ 7 . Factors that were significantly associated at bivariate level were included in a binary logistic regression model using a VAS score ≥ 7 as the dependent variable and all factors potentially responsible for intense pain as independent variables.

The level of all tests of statistical significance was set at $< 5\%$ (0.05).

Results

A total of 140 patients were randomly recruited into the study. The patients were randomized into two cohorts, one cohort comprised of 70 patients i.e. Group A received intracervical block with 6ml of 1% of lidocaine and the other cohort comprised of 70 patients were randomized to receive 75mg of IM diclofenac. The baseline demographic data and characteristics were as shown in Table 1. The two groups were statistically similar in the parameters. The mean age of respondents was 31.64 ± 6.86 years and 29.93 ± 5.69 years in group A and B respectively ($t = 1.610$, p -value 0.110). The gynaecological characteristics that may affect pain perception were as shown in table 2. The study groups were statistically similar in most of the characteristics assessed. However, there was statistically significant difference in two of the parameters i.e. history of previous vaginal delivery and pregnancy loss, thus these two parameters that were significant at bivariate level were entered into logistic regression to adjust for any possible confounding of each of the variables as shown in in table 4.

The indication for the HSG was mainly secondary infertility 61% and primary in 39% of the recruited patients. There was no statistically significant difference between the two group's baseline anxiety scores. The baseline anxiety level was assessed using anxiety component of hospital anxiety depression scale (HADS). Sixty-seven percent had no anxiety based on the HADS scores.

Visual analogue score was used to assess pain threshold in both groups at various level of the procedure as shown in table 3. The baseline mean VAS at the beginning of the procedure was found to be 0.04 ± 2.7 and 0.16 ± 0.47 ($t = -1.770$, p -value 0.079), thus there was no statistical difference at the baseline pain



score. The mean pain score after speculum application but before instrumentation was not significantly different. The mean pain score after the application of tenaculum and metal cannula, just before the injection of contrast medium was found to be statistically different with mean pain scores higher in group B (4.26 ± 1.62 in group A vs 6.37 ± 1.62 in B), ($t = -7.726$, p -value < 0.001). The most painful step was found to be at the end of uterine filling with contrast medium and the mean pain scores was 6.14 ± 1.85 vs 7.37 ± 2.23 ($t = -3.543$, p value 0.001) in groups A and B respectively. This difference was therefore statistically significant. The mean pain scores 30 mins after the procedure was found to be similar in both groups.

Fifty patients (36%) had a VAS score ≥ 7 (group VAS ≥ 7) amongst which 4 were in the study group and 46 were in the control group. Ninety patients (64%) had a VAS score < 7 (group VAS < 7) where 66 were in the study group and 24 were in the control group. Significant correlation with a VAS score ≥ 7 was seen with the age of patients (p -value = 0.001), parity (p -value = 0.006), type of infertility (p -value = 0.002), previous pregnancy loss (p -value = 0.008), previous uterine evacuation (p -value = 0.019) and the use of intracervical lidocaine for pain relief during the procedure (p -value < 0.001).

The multivariate analysis revealed a direct relationship between intervention i.e use of intramuscular diclofenac (OR 48.5; 95% CI 13.533-173.517; $P < 0.001$) and a VAS score ≥ 7 ; whereas parity (OR 0.122; 95% CI 0.16-0.920; $P=0.041$) is indirectly related to a VAS score ≥ 7 . There was no statistically significant difference in the radiographic findings in both study groups. Eighty-two (58.5%) of the respondents had normal radiographic findings, 48.8% in group A and 51.2% in group B ($\chi^2 = 0.118$, p -value 0.731). Sixteen respondents (11.4%) had bilateral tubal blockage, 50% in each group ($\chi^2 = 0.000$, p -value 1.000). Eighteen respondents (12.8%) had unilateral tubal blockage, 44.4% in group A and 55.6% in group B ($\chi^2 = 0.255$, p -value 0.614). sixteen respondents (11.4%) had hydrosalpinges, 62.5% in group A and 37.5% in group B ($\chi^2 = 1.129$, p -value 0.288). Ten respondents (7.1%) had intra-cavitary filling defects, 40.0% in group A and 60.0% in group B ($\chi^2 = 0.431$, p -value 0.512). However, there was statistically significant difference among those with others as findings; these include those cases that were not completed due to intravasation of contrast. The complications and side effects from the procedure and intervention are demonstrated in table 5.



Table 1 Socio-demographic profile of study population

Variable	Group A	Group B	Statistical Test	p-value
Mean Age± SD (years)	31.64±6.86	29.93±5.69	t = 1.610	0.110
Mean Weight± SD (kg)	66.94±12.15	63.06±11.94	t = 1.908	0.058
Mean Height ±SD (m)	1.610±0.06	1.594±0.06	t = 1.514	0.132
MEAN BMI± SD (Kg/m²)	25.98±4.29	24.74±4.07	t = 1.754	0.082
Educational Status			Fisher's exact = 2.178	0.872
None n (%)	0 (0.0)	2 (100.0)		
Quranic Education n (%)	4 (50.0)	4 (50.0)		
Primary Education n (%)	10 (45.5)	12 (54.5)		
Secondary Education n (%)	22 (50.0)	22 (50.0)		
Diploma/NCE n (%)	20 (52.6)	18 (47.4)		
Degree n (%)	14 (53.8)	12 (46.2)		
Religion			$\chi^2 = 0.805$	0.370
Islam n (%)	56 (48.3)	60 (51.7)		
Christianity n (%)	14 (58.3)	10 (41.7)		
Tribe			$\chi^2 = 1.023$	0.906
Hausa n (%)	38 (48.7)	40 (51.3)		
Fulani n (%)	4 (40.0)	6 (60.0)		
Yoruba n (%)	2 (50.0)	2 (50.0)		
Igbo n (%)	10 (50.0)	10 (50.0)		
Others n (%)	16 (57.1)	12 (42.9)		
Occupation			$\chi^2 = 0.590$	0.899
Housewife n (%)	28 (48.3)	30 (51.7)		
Civil Servant n (%)	18 (52.9)	16 (47.1)		
Business n (%)	18 (52.9)	16 (47.1)		
Student n (%)	6 (42.9)	8 (57.1)		
Marital Status			Fisher's Exact	0.496
Married n (%)	68(49.3%)	70(50.7%)		
Divorced n (%)	2(100.0%)	0(0.0%)		



Table 2: Gynaecological history of study groups

Variable	Group A	Group B	Statistical Test	p-value
Parity			Fisher's exact = 1.511	0.506
Nullipara <i>n</i> (%)	48 (47.1)	54 (52.9)		
Para 1-4 <i>n</i> (%)	18 (56.3)	14 (43.8)		
Para ≥5 <i>n</i> (%)	4 (66.7)	2 (33.3)		
Indication			$\chi^2 = 3.015$	0.083
1 ⁰ Infertility <i>n</i> (%)	22 (40.7)	32 (59.3)		
2 ⁰ Infertility <i>n</i> (%)	48 (55.8)	38 (44.2)		
Mean Duration of Infertility ± SD (years)	4.84±4.34	5.84±4.39	t = -1.355	0.178
Previous vaginal delivery	20 (66.7)	10 (33.3)	$\chi^2 = 4.242$	0.039
Previous pregnancy loss	42 (58.3)	30 (41.7)	$\chi^2 = 4.118$	0.042
Previous caesarean section	10 (55.6)	8 (44.4)	$\chi^2 = 0.255$	0.614
Previous history of Uterine evacuation	20 (50.0)	20 (50.0)	$\chi^2 = 0.000$	1.000
BTL	0	0		
Relation with LMP			Fisher's exact = 0.591	1.000
Before day 10	13 (48.1)	14 (51.9)		
Day 10-12	53 (50.0)	53 (50.0)		
After day 12	2 (50.0)	2 (50.0)		
Prolonged amenorrhoea	2 (66.7)	1 (33.3)		
Dysmenorrhoea			$\chi^2 = 4.381$	0.112
No	20 (40.0)	30 (60.0)		
Mild	26 (61.9)	16 (38.1)		
Severe	24 (50.0)	24 (50.0)		

Table 3: VAS (Pain) Scores at individual steps of HSG by study group

	Group A	Group B	Statistical Test	p-value
Pain score before beginning the procedure Mean ± SD	0.04±0.27	0.16±0.47	t = -1.770	0.079
Pain score after speculum application but before instrumentation Mean ± SD	1.27±1.048	1.60±1.08	t = -1.825	0.070
Pain score after the application of the tenaculum and metal cannula and just before the injection of contrast medium Mean ± SD	4.26±1.62	6.37±1.62	t = -7.726	<0.001
Pain score at the end of uterine filling with contrast medium Mean ± SD	6.14±1.85	7.37±2.23	t = -3.543	0.001
Pain score at 30 min after the procedure Mean ± SD	2.51±1.87	2.60±2.06	t = -0.258	0.797



Table 4: Binary logistic regression using VAS score of ≥ 7 as the dependent variable

Variables	B(coefficient of regression)	p-value	Adjusted OR	95% CI
Intervention	3.881	<0.001*	48.5	13.533- 173.517
Age	-0.075	0.147	0.927	0.837-1.027
Parity	-2.106	0.041*	0.122	0.16-0.92
Previous pregnancy loss	-0.760	0.508	0.468	0.049-4.428
Type of infertility	0.940	0.480	2.561	0.188-3.479
Previous uterine evacuation	-1.352	0.056	0.259	0.065-1.033

Table 5: Complications and Side effects in both groups

	Group A	Group B	Statistical test	p-value
General				
Mild abdominal pain	18 (50.0)	18 (50.0)	$\chi^2=0.000$	1.000
Moderate abdominal pain	18 (64.3)	10 (35.7)	$\chi^2=2.857$	0.091
Severe abdominal pain	4 (66.7)	2 (33.3)	Fisher's exact	0.681
Abdominal cramps	2 (50.0)	2 (50.0)	Fisher's exact	1.000
Venous intravasation	6 (75.0)	2 (25.0)	Fisher's exact	0.275
Central nervous system				
Light-headedness	16 (100.0)	0 (0.0)	$\chi^2=18.065$	<0.001
Cardiovascular system				
Hypotension	6 (100.0)	0 (0.0)	Fisher's exact	0.028

Discussion

This study showed that the most painful part of the procedure in the intracervical block group was at the end of uterine filling with contrast medium where the VAS was 6.14. This was similar to the mean pain score reported by Robinson et al but were higher than the values reported by Chauhan et al where he reported the VAS at this step to be 2.64 in the intracervical group but lower than 7.2 reported by Hacivelioglu et al.⁸⁻¹⁰ However, Stoop et al reported that the most painful part was during uterine filling and tubal spillage; his findings may not be unrelated to the fact that he divided the stage

of uterine filling into two which was not the case in most studies.²⁰ The pain was more at this stage due to distension of the uterus with contrast leading to release of local prostaglandins which may initiate uterine cramps.⁸ The result of this study however contradicts the findings reported by Liberty et al who indicated that the most painful step was insertion of cervical instruments.¹³ The pain during insertion of cervical instruments was abolished in the study group with the intracervical block with lidocaine.

The mean pain score at the fifth step of the procedure i.e. 30 minutes after completion of



the study was 2.51 ± 1.87 which was similar to 1.7 ± 1.4 reported by Hacivelioglu et al.⁹ The pain at this stage was studied to ascertain if the pain score will be higher after the effect of local anaesthetic agent has waned off but the level of pain was not increasing. The pain score at 30 minutes was less compared to during the procedure but is a little bit higher than during speculum placement. Other studies evaluated pain perception within 1 minute of completion of the procedure.^{8,10,13}

In the control group, this study showed that the painful steps were after the application of tenaculum and metal cannula and just before the injection of contrast medium; and at the end of uterine filling with contrast medium. The mean pain score after the application of tenaculum and metal cannula and just before the injection of contrast medium in the study group was 6.37 which was higher than the pain score observed by Hacivelioglu.⁴⁴ He used intramuscular dexketoprofen in his study.⁹ This was also higher than the report by Robinson et al where he reported the pain score as 4.961 in the control group at this step.¹⁰ This might be attributed to the difference in pharmacology between the drugs used in both studies though diclofenac is also a potent NSAID with good analgesic effect.²¹ Another reason is that their study was among military officers who may have higher pain threshold than non-officers. In our study most of the participants (41%) were unemployed house wives. The mean pain score at the fourth step of the procedure was 7.37 which was similar to the mean pain score reported by Hacivelioglu et al.^{7,6,9} Our values of the VAS were higher than the values reported by Robinson et al where he reported the VAS at these step to be 5.229 in the control arm of his study where he gave all groups ibuprofen 30 mins before the procedure.¹⁰ We found that these two steps were the most

painful step of the procedure and these were in agreement with most studies done on pain relief during HSG.^{8-10,13} Hassa et al compared misoprostol, oral diclofenac potassium and no analgesic, the pain scores were not divided based on HSG steps but the mean pain score during the procedure was reported to be 5.5 which was lower than our value of 7.6.²² This may be attributed to the lumping of pain scores in their study. Costello et al did a study comparing transcervical intrauterine topical lidocaine with placebo, both study groups received naproxen sodium 2 hours before the procedure. The mean pain score though it was reported for the whole procedure was 7.6 which was similar to our value of 7.37.¹¹

The mean pain score at the fifth step of the procedure i.e. 30 minutes after completion of the study was 2.60 which was similar to 1.3 reported by Hacivelioglu et al.⁹ Other studies evaluated pain perception within 1 minute of completion of the procedure.^{8,10,13} The pain score at 30 minutes was less compared to during the procedure but is a little bit higher than during speculum placement as earlier commented.

According to this study the first two steps of the HSG procedure were not painful, the mean pain scores according to VAS was statistically similar in both groups in this study. This was similar to other studies done on pain relief during HSG^{8-10,13}.

According to our results the most painful steps from this study were the third and fourth steps which were (1) after the application of the tenaculum and metal cannula and just before the injection of contrast medium and (2) at the end of uterine filling with contrast medium. These steps are the most painful steps from previous studies, thus any intervention aimed at reducing the pain or discomfort during the procedure should target these steps.⁸⁻¹⁰ Stoop et al



reported that the most painful steps were the steps of uterine filling and tubal spillage, he reported less pain at cervical grasping.²⁰ The innervations of the cervix shows occasional free nerve endings entering papillae of the stratified squamous epithelium of the pars vaginalis, the endocervix contains a rich plexus of free endings that is most pronounced in the region of the cervical os.²³ In this study there is a reduction in VAS pain score of about 33% in the study group A compared to group B at the third step of the procedure. This difference may be attributed to the intracervical block with lidocaine thus decreasing the perception of pain in the study group. A reduction in pain score of 15% was considered significant by Costello et al, thus we will deduce that there is significant reduction in pain score at this step of the procedure.¹¹ This was similar to the reduction reported by Liberty et al though he used Lidocaine /Prilocaine cream in his study.¹³ This was lower than the 50% reduction in Chauhan et al study.⁸ This may be attributed to cultural difference between the study environments.

At the fourth step of the procedure after uterine filling with contrast medium, the reduction in pain score was 16%, slightly above Costello's assumption. These may be attributed to the fact that during uterine filling there is uterine distension which leads to production of prostaglandins that may lead to cramps, effect of which the local anaesthetic lidocaine will not block.⁸ The NSAIDS group will have additional advantage of the decreasing pain perception by the action of the drug on prostaglandin release, however during HSG the cervix has to be pulled while injecting the contrast medium this might have led to the higher pain score in group B.²⁴ While considering our results we should take note of a recent

meta-analysis done in 2008 that concluded that there's little evidence of benefit in terms of pain relief of any of the interventions during and up to 29 min after HSG.²⁵

There was no statistically significant difference in terms of the HSG findings in both groups. However there are more cases of inconclusive findings (7.1%) as a result of intravasation of contrast or poor film in some patients which are more in group A (80%), however there has not been known relationship between intravasation and intracervical lidocaine in previous studies involving intracervical lidocaine.⁸⁻¹⁰ Intravasation is more related to the period when HSG was done however there was no statistically significant difference in the days of the menstrual period HSG was done in both groups.^{26,27} It could also occur if there is tubal obstruction in which case there are no differences between the groups.

The complication rates are almost similar in both groups but the occurrence of moderate abdominal pain was higher in the intracervical block group; this may be due to the localized effect of the injection to the cervix.

Another reason could have been tubal spasm but both groups were given an antispasmodic to counteract its effect on the study outcome. Light-headedness occurred in 11.4% of the patients in group A which was higher than what was reported (2%) in the study by Chauhan et al.⁸ Hypotension was also present in only group A (4.2%) which was not present in the study by Chauhan et al. However, all these were self-limiting and did not result in any significant morbidity in the patients, the safety profile of the drug has already been established.¹⁰

Most of the studies done on pain relief during HSG were done in the white population mostly in Turkey, United States of America,



Israel and India. There has not been report of the studies done in West Africa and Nigeria in particular where HSG is one of the main modalities of investigating infertility. Response to pain is affected by so many factors that include culture and ethnicity.^{19,28,29} Some of the studies use varying techniques which may affect the outcome of their result that include use of tenaculum in some groups, use of metal cannula versus balloon catheter in some studies, however this study used a uniform technique for the procedure. There has been variation in the analgesic used, some use two analgesics at the same time which may have an influence on the result of the study. The documentation of the pain score was done at once or twice in some studies without indicating the stage of HSG at which the recording was done and it has been shown that pain score varies with the stage of HSG. Some of the studies did not look for side effects of the drugs used in the study in which this study did.

The administration of intracervical block required an additional 5-10 minutes to perform the block and there was some bleeding from the injection site which led to some delay before the HSG was done. Pain scores during administration of the intracervical block may be higher in the group and may adversely affect patient satisfaction with the procedure. Psychological factors that affect pain perception have not been assessed for which include emotional state, fatigue, anxiety, fear and presence of stressful life events. However, to overcome this effect the patients were adequately counselled before the procedure was conducted and the base line anxiety level was assessed to ensure that the anxiety level is low and similar in both groups.

In conclusion this study found that there is significant reduction in VAS pain scores associated with intracervical block with lidocaine when performing HSG for infertility. Thus it can be said that intracervical block with 1% lidocaine is a more efficacious form of pain relief during hysterosalpingography when compared to intramuscular diclofenac.

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