ORIGINAL RESEARCH ARTICLE

Oral diclofenac potassium and intramuscular hyoscine-n-butyl bromide versus oral diclofenac potassium alone for pain relief during hysterosalpingography: a double blind randomized controlled trial

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Abstract

Hysterosalpingography (HSG) is an important diagnostic tool in infertility, often associated with pain and tubal spasms, potentially resulting in false proximal tubal occlusions. This randomised controlled trial compared oral diclofenac potassium plus intramuscular hyoscine-N-butyl bromide (HBB) with oral diclofenac alone in 138 women undergoing HSG at Central Hospital, Warri. Pain perception, the primary outcome, was assessed using the Visual Analogue Scale (VAS). Secondary outcomes were tubal spasm, patient satisfaction, and adverse effects. Baseline characteristics were similar across the groups. Median VAS scores were not significantly different immediately after HSG (3 vs. 4, P = 0.126) or at 30 minutes post-procedure (1 vs. 2, P = 0.083). No significant differences were found in tubal spasm rates (P = 0.526), satisfaction scores (P = 0.054), and Dizziness (26.1%, P = 0.062). The addition of intramuscular HBB to diclofenac potassium did not confer improved outcomes and was associated with more side effects. *(Afr J Reprod Health 2026; 30 [2]:121-129).*

Keywords: Hysterosalpingography, Infertility, pain-relief, tubal-spasm, diclofenac, hyoscine-N-butyl bromide

Résumé

L'hystérosalpingographie (HSG) est un outil diagnostique important dans le diagnostic de l'infertilité, souvent associée à des douleurs et des spasmes tubaires, pouvant entraîner de fausses occlusions tubaires proximales. Cet essai contrôlé randomisé a comparé le diclofénac potassique oral associé au bromure de N-butylhyoscine (HBB) par voie intramusculaire au diclofénac oral seul chez 138 femmes subissant une HSG à l'hôpital central de Warri. La perception de la douleur, critère d'évaluation principal, a été évaluée à l'aide de l'échelle visuelle analogique (EVA). Les critères d'évaluation secondaires étaient les spasmes tubaires, la satisfaction des patientes et les effets indésirables. Les caractéristiques initiales étaient similaires dans les deux groupes. Les scores EVA médians n'étaient pas significativement différents immédiatement après l'HSG (3 vs 4, p = 0,126) ni 30 minutes après l'examen (1 vs 2, p = 0,083). Aucune différence significative n'a été observée concernant les taux de spasmes tubaires (p = 0,526), les scores de satisfaction (p = 0,054) et les vertiges (26,1 %, p = 0,062). L'ajout d'HBB par voie intramusculaire au diclofénac potassique n'a pas amélioré les résultats et a été associé à une augmentation des effets indésirables.. *(Afr J Reprod Health 2026; 30 [2]: 121-129).*

Mots-clés: Hystérosalpingographie, infertilité, soulagement de la douleur, spasme tubaire, diclofénac, bromure de N-butylhyoscine

Introduction

Hysterosalpingography (HSG) is a key component of infertility assessment in low- and middle-income countries, including Nigeria, where tuboperitoneal factors in females are the most common cause of infertility.[1–3] This situation arises from a combination of pelvic inflammatory disease, post-abortal sepsis, and puerperal sepsis, which leads to damage and adhesions in the uterus and fallopian tubes.[1,2,4–7] Hysterosalpingography is a medical imaging procedure used to assess the shape and patency of the female upper genital tract, specifically the uterus and fallopian tubes. It is widely used and is cost-effective.[2,8] However, many women report substantial pain and discomfort during the procedure, with studies indicating that up to 80% experience moderate to severe pain.[5,9–11]

Additionally, tubal spasms can mimic proximal tubal blockage, leading to false-positive diagnoses and potentially unnecessary treatments.[12–14]

Pain during HSG arises from multiple sources: cervical instrumentation, uterine distention, contrast instillation, and peritoneal irritation.[10,15]. These stimuli provoke prostaglandin-mediated uterine cramps and autonomic responses transmitted through both pelvic splanchnic and hypogastric nerves.[16–19] Although various analgesic strategies have been employed to reduce associated pain, including nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, topical anaesthetics, and antispasmodics, the evidence supporting a universally effective protocol remains inconclusive, as authors have reported differing outcomes across multiple studies.[1,13,17,20,21]

NSAIDs, particularly diclofenac potassium, are frequently used to manage procedural pain due to their cyclooxygenase inhibition and subsequent suppression of prostaglandin synthesis.[18,22–24]Hyoscine-N-butyl bromide (HBB), an anticholinergic antispasmodic, acts on smooth muscle to reduce spasms in the gastrointestinal and genitourinary tracts and is commonly used for abdominal colic and endoscopic procedures. Its role in HSG, particularly in lowering spasm-related pain and false tubal occlusions, is less clearly defined.[1,19,20]

Although several studies have investigated individual effects of either NSAIDs or HBB during HSG, limited data exist on their combined use.[15,19,20,25] Theoretical synergism suggests that NSAIDs may control prostaglandin-mediated pain while HBB targets spasm-induced discomfort. Combining these agents may therefore improve patient comfort, procedural accuracy, and satisfaction.

The aim of this study was to compare the analgesic and anti-spasmodic efficacy of combined oral diclofenac potassium and intramuscular HBB versus oral diclofenac alone during HSG.

Methods

Study design

This double-blind, randomized controlled trial was conducted from March to September 2021 at the Gynaecology and Radiology departments of Central Hospital, Warri, Delta State, Nigeria. The hospital offers specialized reproductive health services to over 500,000 residents of Warri and serves as a referral centre for hospitals in neighbouring communities. The trial was registered with the Pan African Clinical Trial Registry (PACTR202508901076970).

Recruitment, sample size, and allocation of participants

One hundred and thirty-eight (138) participants were enrolled in the study. The sample size was determined based on previously published VAS data to ensure 80% power and a 5% significance level.[21] with an adjustment for a 10% attrition rate, resulting in a total of 138 participants (69 per group). The women were adequately counselled on the purpose, risks, and benefits of the study. After giving informed consent, the baseline sociodemographic characteristics were obtained and recorded in the study proforma. Participants were randomized into two groups using computer-generated block randomization (block size of 10). Allocation was 1:1, and allocation concealment was maintained using sequentially numbered, sealed, brown, opaque envelopes. Group A received oral diclofenac potassium (50 mg) plus intramuscular hyoscine-N-butyl bromide (20 mg), while Group B received oral diclofenac potassium (50 mg) plus intramuscular sterile water. Both interventions were administered 30 minutes before HSG.

Participants, outcome assessors, and data analysts were blinded to group allocation. The allocating team and the hysterosalpingography team were kept separate to prevent selection bias. Identical syringes and unlabelled radiologic films were used to ensure allocation concealment and maintain blinding integrity.

Inclusion and exclusion criteria

These were women requiring HSG for infertility evaluation who consented to participate in the study. All women undergoing HSG for the first time (meaning they had no prior experience with the procedure's pain), with no cognitive or visual impairments (and therefore able to understand and complete the assessment tools), and at least 18 years old were included in the study.

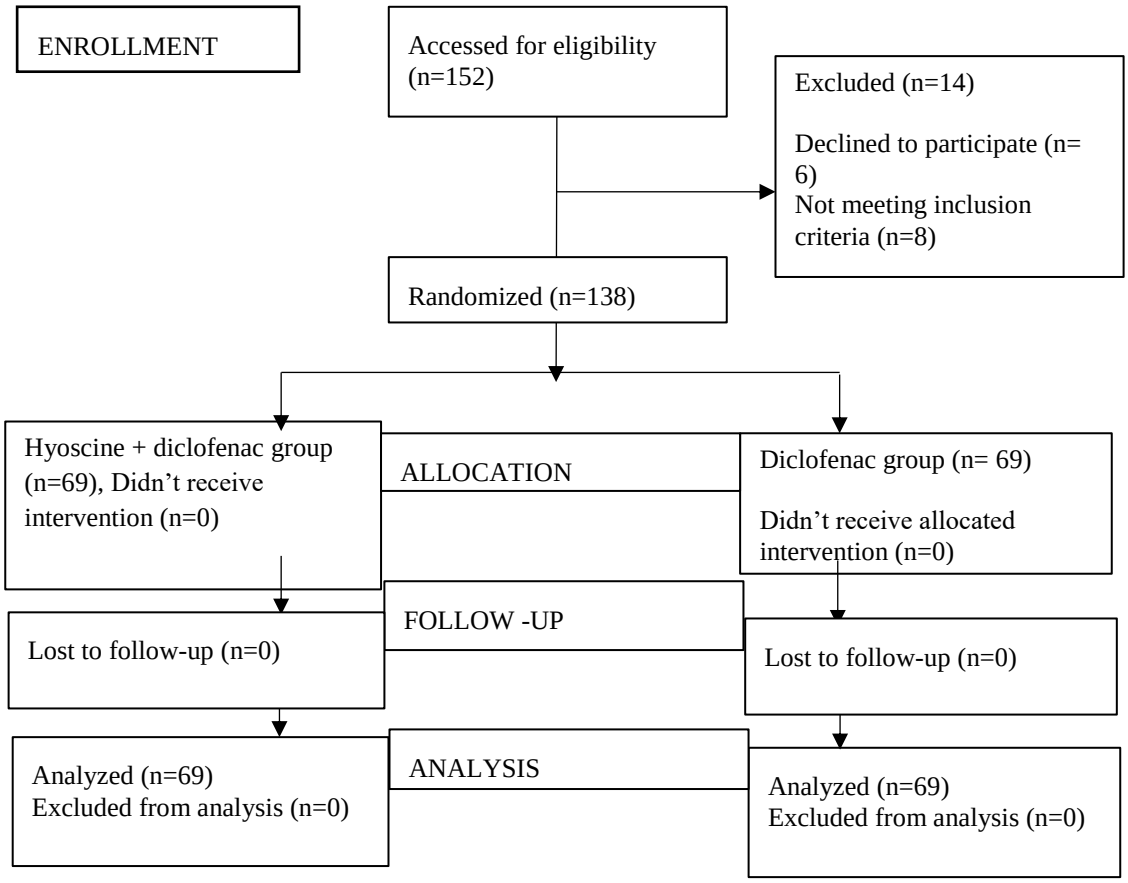

Figure 1: The CONSORT flow diagram

Exclusion criteria included women with documented allergies or known hypersensitivity to diclofenac potassium, hyoscine, or urografin dye, as well as those with gastroesophageal disease, cervical stenosis, acute pelvic inflammatory disease, active cervical lesions, endometrial infection, vaginal bleeding, or known reproductive tract malignancy, and all patients who declined consent.

HSG procedures

All HSGs were performed during the proliferative phase of the menstrual cycle using a standard technique. The procedure was conducted under aseptic conditions using a water-soluble contrast medium (Urographin). The study intervention was administered 30 minutes before starting the procedure. Pain scores were recorded at the completion of the procedure (0 minutes) and 30 minutes post-HSG using the Visual Analogue Scale (VAS).[16,19]

Measurement of outcome indicators

The VAS was used to determine and document the pain perception at 0 and 30 minutes after the procedure. The researcher or a trained research assistant gave a detailed description of the visual analogue scale (VAS) at enrolment into the study before the procedure. With each score spaced 1cm apart, the VAS uses a 10 cm linear scale where 0 indicates 'no pain' and 10 indicates 'worst pain imaginable.' Scores. The secondary outcomes included radiologic assessment of cornual spasm, patient satisfaction measured 30 minutes after the procedure using a validated satisfaction survey,[26] and documentation of adverse effects.

Although there are no absolutely pathognomonic features, radiologic visualisation of

a rounded or "breast-like" configuration at the uterine cornua on HSG is considered highly suggestive of functional tubal spasm rather than true occlusion.[13,14,27] Cornual spasm and cornual blockage were distinguished based on established radiologic criteria, as described in the literature.[13,14] An experienced consultant radiologist interpreted all HSG films following these established criteria.

Data analysis

Data entry and analysis were accomplished using a statistical package for the social sciences version 22 (IBM SPSS Statistics ® Inc., Chicago, USA). Frequency tables and cross-tabulations were generated to explore relationships among variables. Descriptive statistics were presented as means (±SD) or medians (IQR) as appropriate. Between-group comparisons were made using the Chi-square or Fisher's exact test for categorical variables and the independent t-test for continuous variables. Statistical significance was set at $p < 0.05$.

Ethical considerations

The study complied with the ethical principles of the Declaration of Helsinki (2013 revision). Ethical approval was obtained from the Central Hospital Warri Health Research Ethics Committee (Protocol number CHW/ECC/VOL 1/212). Written informed consent was obtained from all participants. Participation was voluntary, and confidentiality was maintained throughout the study. The research was self-funded by the investigators, who declared no conflicts of interest

Results

Table 1 shows that there was no statistically significant difference in the distribution of sociodemographic variables in the two groups of the study. This indicates that the randomization process was effective in ensuring that likely confounding variables were equally distributed in the two groups. The overall mean age of the study

Table 1: Sociodemographic parameters of participants

Variables	**Groups (N=138)**		**Total**	**P value**
	Hyoscine+ Diclofenac (N=69)	**Water + Diclofenac (N=69)**		
Age Categories n(%)				
21-25 yrs.	0(0.0%)	4(5.8%)	4(2.9%)	0.393*
26-30 yrs.	17(24.6%)	15(21.7%)	32(23.2%)	
31- 35 yrs.	16(23.2%)	16(23.2%)	32(23.2%)	
36 -40 yrs.	12(17.4%)	13(18.8%)	25(18.1%)	
41-45 yrs.	18(26.1%)	15(21.7%)	43(23.9%)	
46 - 50 yrs.	6(8.7%)	4(5.8%)	10(7.2%)	
>50 yrs.	0(0.00%)	2(2.9%)	2(1.4%)	
(Mean ± S.D)	36.76±6.79	35.88±7.26	36.32±7.01	0.461†
Educational level n(%)				
None	1(14.0%)	0(0.00%)	1(0.70%)	0.970*
Primary	10(14.5%)	10(14.5%)	20(14.5%)	
Secondary	17(24.6%)	19(27.5%)	36(26.1%)	
Tertiary	41(59.4%)	40(58.0%)	81(58.7%)	
Types of infertility n(%)				
Primary	26(37.7%)	24(34.8%)	50(36.2%)	0.430*
Secondary	43(62.3%)	45(65.2%)	88(63.8%)	
Parity				
Nullipara	45(65.2%)	56(81.2%)	101(73.2%)	0.048*
1-4	22 (31.9%)	13(18.8%)	35(25.4%)	
≥5	2(2.9%)	0(0.00%)	2(1.4%)	
Duration of infertility	3.89±1.50	3.74±0.52	3.73±0.67	0.277†
Height	1.60±0.06	1.61±0.07	1.60±0.07	0.323†
Weight	70.34±12.04	71.33±11.6	70.84±11.81	0.626†
BMI	27.53±4.50	27.60±4.73	27.56±4.60	0.361†

Table 2: VAS scores in the groups

Variables	Groups (N=138) Hyoscine + Diclofenac (n=69)	Water + Diclofenac (n=69)	P value
VAS Score			
0 min HSG	3(IQR: 1-5)	4(IQR: 2-6)	0.126*
30 min HSG	1(IQR: 0-3)	2(IQR: 0.5-4)	0.083*

*Mann-Whitney U test

population was 36.32±0.71 years, the mean age of the participants was 36.76±6.79 and 35.88±7.26, respectively, in the Hyoscine +Diclofenac (HD) and injection water + Diclofenac (WD) groups. The predominant type of infertility was Secondary infertility: 43(62.3%) and 45(65.2%) in the HD and WD groups, respectively, with a p-value = 0.430. The majority of women in both groups were nulliparous, with 45 (65.2%) and 56 (81.2%) in the HD and WD groups, respectively (Table 4.1)

Table 2 presents a comparison of the VAS scores between the two groups, illustrating that there was no statistically significant difference in Visual analgesic scores between the two groups at the end of HSG (p = 0.126) and 30 minutes after HSG (p = 0.083). The median VAS scores at 0 minutes were 3 (1-5) and 4 (2-6) in the HD and WD groups, respectively. The median VAS scores 30 minutes after the procedure were 1(0-3) and 2(0.5-4) in the HD and WD groups, respectively compares the tubal spasm in the study groups. It shows that 12 (17.4%) of the participants in the Hyoscine + Diclofenac group had tubal spasms, compared to 16 (23.2%) of participants in the Water + Diclofenac group; there was no statistically significant difference in the occurrence of tubal spasm between the groups (p = 0.526). Most of the tubal spasms were in both tubes, i.e., 15(23.6%).There was no statistically significant difference in the location of the tubal spasms; p =1.00.

Table 3: Tubal spasm in both groups

Variables	Groups (N=138) Hyoscine + Diclofenac (n=69)	Water + Diclofenac (n=69)	Total	P value
Tubal Spasms				
Absent	57(82.6%)	53(76.8%)	110(79.7%)	0.526**
Present	12(17.4%)	16(23.2%)	28(20.3%)	
Total	69(100.0%)	69(100.0%)	138(100.0%)	
Site of Tubal spasm				
Right Tubal Spasm	2(16.7%)	3(18.8%)	5(17.9%)	1.000*
Left Tubal Spasm	3(25.0%)	5(31.3%)	8(28.6%)	
Both Tubes	7(58.3%)	8(50.0%)	15(53.6%)	
Total	12(17.4%)	16(23.2%)	28(20.3%)	

*Fishers test, ** Chi-square test †=Independent sample t-test

Table 4 : Level of satisfaction between the two groups

Variables	Groups (N=138) Hyoscine + Diclofenac (n=69)	Water + Diclofenac (n=69)	P value
Satisfaction Levels			
Very Satisfied	13(18.8%)	13(18.8%)	0.054*
Satisfied	51(73.9%)	41(59.4%)	
Not sure	2(2.9%)	11(15.9%)	
Dissatisfied	3(4.3%)	4(5.8%)	
Mean Satisfaction Score	1.92±0.62	2.08±0.76	0.182†

*Fishers test, †=Independent sample t-test.

Table 4 illustrates the level of satisfaction, and it shows that 13(18.8%) patients in both groups were very satisfied with the amount of pain relief in both groups, while 51(73.9%) and 41(59.4%) were only satisfied in the HD and WD groups, respectively, as shown in Figure 4.2 below. There was no significant difference in satisfaction levels between the two groups, p = 0.054. The mean satisfaction in the HD group was 1.92 ± 0.62, compared to 2.08 ± 0.76 in the WD group. There was no significant difference in satisfaction scores between the two groups, with a p-value of 0.182.Table 5. demonstrates the adverse effects recorded in both groups. Four participants had Nausea in both

Table 5: Adverse effects

Variables	Groups (N=138) Hyoscine + Diclofenac (n=69)	Water + Diclofenac (n=69)	Total	P value
Adverse Effects				
Nausea	4(5.8%)	4(5.8%)	8(5.8%)	0.062*
Vomiting	1(1.4%)	1(1.4%)	2(1.4%)	
Dizziness	18(26.1%)	7(10.1%)	25(18.1%)	
Fainting	0(0.0%)	2(2.9%)	2(1.4%)	
Others	46(66.7%)	55(79.7%)	101(73.2%)	

*Fishers test, ** Chi-square test †=Independent sample t-test

groups, while 18(26.1%) and 7(10.1%) reported Dizziness in the HD and WD groups respectively.

Discussion

This randomised controlled trial was designed to assess the effect of combining oral diclofenac potassium with intramuscular hyoscine-N-butyl bromide (HBB) compared to oral diclofenac alone in resolving pain and tubal spasm during hysterosalpingography (HSG).

This study found no statistically significant analgesic benefit from adding intramuscular hyoscine-N-butylbromide to oral diclofenac before HSG. The median Visual Analogue Scale (VAS) score immediately after the procedure in the diclofenac-only group was 4.0 (IQR: 2.0–6.0), similar to findings in the diclofenac group by Hassa et al'.[24] Also, studies using other NSAIDs, such as those by Owens et al.[28] and Anserini et al.[29], found no significant reduction in post-HSG pain scores. Contrary to our finding, the RCT by Kiridi et al.[15] reported a significant reduction in pain during HSG. Our finding aligns with Abbas et al.[1] report of no pain reduction with oral HBB (20 mg) versus placebo during or 30 minutes after HSG (VAS: 3 and 2, respectively). Similarly, Safi et al.[20] found no benefit from intramuscular HBB in reducing pain at dye injection or 30 minutes post-HSG, with Numeric Pain Rating Scale (NPRS) scores of 1.0 (IQR: 0–5) and 1.5 (IQR: 0–7), respectively. The NPRS shows high correlation with the VAS (r = 0.86–0.95)[30].

Pain scores were higher immediately after dye injection than at 30 minutes post-procedure in both groups, consistent with previous studies that identify dye injection as the most painful part of HSG.[16] Although the theoretical basis for combining an NSAID with an antispasmodic suggests a potential synergistic effect with diclofenac reducing prostaglandin-mediated uterine cramps and hyoscine-N-butylbromide inhibiting smooth muscle spasm, our findings did not demonstrate a measurable analgesic advantage. Several explanations may account for the absence of the expected effect. Cervical manipulation, uterine distension, intraperitoneal contrast spill, and autonomic responses all contribute to nociception, and these pathways are not uniformly responsive to prostaglandin inhibition or smooth muscle relaxation. Also, a mismatch between the timing of the analgesic effect and the peak pain stimulus may be relevant. It is therefore possible that the relative contribution of tubal spasm to overall pain was smaller than anticipated in this study population. This study reinforces existing research on HSG-related pain and demonstrates that HBB provides minimal additional pain relief when combined with diclofenac.

Although the proportion of tubal spasm differed numerically between the two groups, this difference did not reach statistical significance (p = 0.526). It is possible that a larger sample size might have yielded a detectable difference, particularly because the sample size calculation was powered for pain reduction (the primary outcome). Consequently, our study may have been underpowered for the secondary outcome (tubal spasm). This is comparable to findings by Safi *et al*.'s where intramuscular HBB did not reduce spasms during HSG (p = 0.37).[20] However, Akarawit et al.[13] reported a statistically significant decrease in tubal spasm with HBB (p = 0.04), and Alper *et al*.[31] found that 20 mg HBB effectively

alleviated proximal tubal spasm in women with tubal obstruction. Discrepancies may stem from differences in the causes of tubal occlusion. The higher prevalence of pelvic inflammatory disease (PID) in our study population, compared to Caucasian cohorts, might explain tubal occlusion caused by structural damage rather than transient spasm, potentially accounting for the limited effectiveness of hyoscine butylbromide (HBB).

Despite the limited analgesic effect of HBB, patient satisfaction scores were similar between the combination (mean: 1.92 ± 0.62) and diclofenac-only groups (mean: 2.08 ± 0.76; p = 0.182). This may reflect non-pharmacological factors, such as emotional support or patient-provider interactions, as suggested by Cengiz et al.[32] [40], who noted that care expectations influence satisfaction. Although not statistically significant, adverse effects were more common in the combination group (26.1% vs. 10.1%, p = 0.062). This trend warrants further investigation.

The strengths of this study are evident in its randomized controlled design and comprehensive blinding of patients, data collectors, and analysts. Randomization minimizes confounding variables. Blinding reduces ascertainment, observer, and participant-related bias, which enhances the accuracy and objectivity of the findings. The primary constraints of our investigation include its single-centre design, which limits generalizability to broader populations and varied clinical settings. Moreover, as the statistical power was calculated exclusively for pain outcomes, the sample size may have been insufficient to detect subtle, yet clinically significant effects on tubal spasm, and a type II error cannot be excluded. Furthermore, although standardised radiologic criteria were used, there exists a small risk of classification bias stemming from the radiologist's subjective interpretation in distinguishing between functional spasm and true structural obstruction. Finally, our assessment of discomfort was restricted to the immediate post-procedure period, potentially missing delayed analgesic effects.

Conclusion

Adding intramuscular hyoscine-N-butyl bromide to oral diclofenac does not significantly enhance pain relief or prevent fallopian tube spasms during hysterosalpingography (HSG). It is associated with more, but statistically insignificant side effects. These findings suggest that oral diclofenac alone is sufficient for effective pain management during HSG, offering a safer and equally effective option.

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