

Comparative effectiveness of four-point versus two-point paracervical block using 1% lidocaine for manual vacuum aspiration (MVA) in incomplete abortion: a randomized controlled trial

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ABSTRACT:

Background: Paracervical block is one of the mainstays for pain control during Manual Vacuum Aspiration of incomplete abortions. This study assessed the effectiveness of four versus two needle points paracervical block of 1% lignocaine, need for additional analgesia and satisfaction among women undergoing manual vacuum aspiration for incomplete abortion in OAUTHC, Ile-Ife. **Objective:** Comparative effectiveness of four-point versus two-point paracervical block using 1% lidocaine for manual vacuum aspiration in incomplete abortion. **Methods:** One hundred and twenty women who were eligible for the study were randomized to two equal groups (A and B), a randomized controlled trial, conducted between January 2022 and February 2023. We analyzed the data using SPSS version 20. Paired T test, independent T test Chi square, and Fishers' exact tests were applied for continuous and categorical variables as appropriate. P value < 0.05 was considered as statistically significant. **Results:** The Intra-operative and Postoperative VAS was significantly higher in the two-point PCB group (group B) compared to the four-point PCB group (group A) (t = -3.37, CI -4.12 - -2.68. P < 0.05 intra-operative, t = 7.16, CI 2.63 - 4.63. P < 0.05 post-operative). The need for additional analgesia and mean VAS of those in the two-point group was significantly higher than that of the four-point group with higher overall satisfaction rate in the four-point group (t = 7.16. CI 2.63 - 6.88. P < 0.0001). **Conclusions:** The four-point Paracervical block with 1% lignocaine is more effective in reducing pain during manual vacuum aspiration compared to the two-point paracervical block. It equally has added advantage of a higher overall satisfaction rate and reduced need for additional analgesia.

Keywords: Abortion care, Manual vacuum aspiration, Four-point paracervical block, Two-point paracervical block

INTRODUCTION:

Abortion significantly contributes to maternal mortality and associated reproductive complications in Nigeria (Okonofua *et al.*, 2009; Ikuteyijo, Akinyemi

and Bankole, 2024). While most pregnancies proceed without issues, all pregnancies are susceptible to complications, especially during the first trimester when abortions are common (Parmar *et al.*, 2015).

Timely management is crucial for restoring women's reproductive health. Whether spontaneous or induced, first-trimester miscarriages are among the most frequent complications (Parmar *et al.*, 2015). Providing comprehensive care with appropriate pain management during aspiration procedures can greatly reduce morbidity. According to the World Health Organization (WHO), miscarriage involves the expulsion of a fetus or embryo weighing 500 grams or less, typically occurring before 28 weeks gestation (Joseph *et al.*, 2021). Despite advancements in neonatal care, approximately 73 million induced abortions occur annually worldwide, with a majority being unsafe, particularly in low-income countries like Nigeria, where they account for 97% of all unsafe abortions (WHO, 2021).

Almost all (75%) abortions in Latin America and Africa are unsafe; in Africa specifically, the majority (nearly half) of all abortions occur under the least safe conditions, leading to unsafe outcomes (Ganatra *et al.*, 2017). This situation arises due to the challenges faced by women with unplanned pregnancies in accessing safe, non-discriminatory, respectful, prompt, affordable and less painful abortion care. Induced unsafe abortions can lead to incomplete abortion, characterized by amenorrhea, lower abdominal pain, vaginal bleeding and open cervix (WHO, 2021). Surgical evacuation using Manual Vacuum Aspiration (MVA) is a key treatment for miscarriage, introduced in 1977 and considered safer and more effective than traditional methods like dilatation and curettage (WHO, 1993). Effective pain management during MVA is crucial, considering variations in pain perception among women (WHO, 2021). Adequate pain management options, ranging from pharmacological agents to regional anaesthesia like paracervical block or general anaesthesia, should be chosen based on individual patient needs.

Paracervical anaesthesia interrupts pain transmission through sympathetic, parasympathetic, and sensory nerves at the internal os level, avoiding the need for general anaesthesia equipment and specialized personnel (Ayegbusi *et al.*, 2021). This technique, dating back to 1925, substitutes for cervical dilatation and uterine intervention (Gomez *et al.*, 2004). By anesthetizing the second to fourth sacral nerve roots at a depth of 2 to 4mm, it ensures effective pain relief during procedures like aspiration for incomplete miscarriages (Gomez *et al.*, 2004). While numerous studies confirm its efficacy and tolerability in gynaecological procedures, including manual vacuum aspirations, the optimal number of needle pricks for pain management remains unclear, necessitating further research (Gomez *et al.*, 2004; Ayegbusi *et al.*, 2021).

METHODS:

This randomized controlled trial was carried out at the obstetrics and gynaecology department, Obafemi

Awolowo university teaching hospitals complex between January 2022 and February 2023. This hospital complex includes both Ife hospital unit in Ile-Ife, and the Wesley guild hospital unit in Ilesha, the study was carried out in the two units. Both of them are located in Osun state, south-west Nigeria and offer tertiary level of healthcare.

Women who were diagnosed with of incomplete miscarriage (essentially an incomplete expulsion of the products of conception and open cervix must be evident), (could be spontaneous or induced) and the period of amenorrhea should be equal or less than 12 weeks. The patients fulfilled the following inclusion criteria; age between 18 to 45 years, the PCV (Packed cell volume) $\geq 30\%$, and ability to give informed consent. While the exclusion criteria included; patients with sepsis, signs of peritonitis, depression, psychiatric or neurological disease, allergies to lidocaine, hypovolemic or septic shock, previous history of adverse side effects to lidocaine, patients with observable pelvic mass, a severe clinical condition e.g., neoplasia, previous participation in the study, patients who had taken analgesia before presentation in the hospital and patients who could not give or refused to give consent.

The required size of the sample for determining the mean score for pain perception of the two groups in this research was calculated using the sample size formula for the comparison of mean by Jekel *et al* (Jekel, 2007) as follows:

$$N = 2x \left(\frac{Z\alpha + Z\beta}{d} \right)^2 \times S^2$$

N/per group= minimum sample size of each group
 $Z\alpha$ =standard normal deviate of α at 95% confidence level, (i.e., probability of making a type 1 error) =1.96
 $Z\beta$ = standard normal deviate of β at 80% confidence level (i.e., probability of making a type 2 error) =0.84
 d = minimum difference in mean pain scores between the two groups that was willing to accept = 2 (scores on scale visual analogue).
 s = standard deviation of the pain scores during the aspiration using MVA kit across the paracervical infiltration in the two groups, that is the pooled estimate of the standard deviation in the two groups = 3.81 as extrapolated from findings in the study by Renner *et al* (Renner *et al.*, 2012)

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$$N = 2x \left(\frac{1.96 + 0.84}{2} \right)^2 \times 3.81^2$$

$$N = 2x (1.4)^2 \times 3.81^2$$

$$N = 2x (1.4)^2 \times 14.5$$

$$N = 56.9 = 60$$

The size of the sample was subsequently rounded up to 60 patients for each of the group.

Therefore, 120 women in total were involved in the study.

Training, recruitment and allocation of patients into groups

Before the research began, four doctors from each of the department's two hospital units were selected based on their proficiency and prior participation in IPAS drilling sessions on manual vacuum aspirations (MVA) and various techniques for administering anaesthesia, paracervical blocks inclusive. Additionally, we conducted training sessions for these eight doctors, who were at the registrar level, and added two senior registrars for coordination purposes. This training included familiarization with a protocol outlining the study's goals and methods, ensuring clarity on all aspects of the research. The two senior registrars, one from each hospital unit, received training on reducing preoperative anxiety, perioperative pain and postoperative satisfaction scores using the visual analogue score (VAS), conducted upon discharge from the hospital.

From January 2022 to February 2023, women diagnosed with incomplete miscarriage at the outpatient unit or gynaecology emergency of the two hospital units were recruited for the study. Those who met the selection criteria were invited to participate after receiving detailed counselling about the research and were asked to participate voluntarily. All participating women signed informed consent forms. Sociodemographic information, including gestational age determined by the date of the last menstrual period or, if uncertain, by ultrasound, was collected. The women's socioeconomic status was assessed using the Olusanya et al. social strata classification (Ibadin and Akpede, 2021). Additional data recorded included the timing of miscarriage onset, presence of pain, prior use of analgesics or abortifacients, pregnancy desirability and number of previous pregnancies. Physical examinations, assessing abdominal pain, uterine size and cervical state (open or closed) were conducted and documented in the patients' clinical charts and a specially designed case report form.

Patients received counselling on the procedure, explaining the roles of everyone in the operating room and addressing any concerns they had. Consent was obtained from participants, who were then managed in the casualty theatre. Using sequential consecutive sampling, participants were assigned to either Group A (receiving a four-needle point PCB) or Group B (receiving a two-needle point PCB). In Group A, patients received injections of 1% lignocaine at 2, 4, 8, and 10 o'clock, while in Group B, injections were administered at 3 and 9 o'clock before the MVA procedure. The lignocaine was stored in the refrigerator within the emergency pharmacy unit.

Procedure of MVA:

Before the procedure, patients were assessed for anxiety and preoperative pain using a VAS, with scores ranging from 0 (no anxiety/pain) to 10 (maximum

anxiety/pain). They were also instructed to mentally note any pain felt during the procedure. Patients were randomly assigned to receive either a four-needle point (16, 28, 31, 32) or two-needle point (Egziabher, Ruminjo and Sekadde-Kigonda, 2002) paracervical block injection of 20 ml or 12ml of 1% lignocaine, respectively. MVA was performed following the standard protocol: patients made to empty their bladders, assume lithotomy position and receive appropriate antibiotics. After cleaning the genital area with chlorhexidine solution and draping with sterile sheets, bimanual pelvic examinations were conducted. The assigned group-specific lignocaine dose was injected into the cervix using a 21-gauge spinal needle. For the four-needle point group, 2 ml was injected superficially at the tenaculum site, followed by 18 ml injected in four equal aliquots at 2, 4, 8, and 10 o'clock. For the two-needle point group, 2 ml was injected at the tenaculum site, followed by 10 ml injected in two equal aliquots at 3 and 9 o'clock. Injection was performed slowly to avoid vascular penetration. Five minutes later, MVA commenced under the guidance of a gynaecologist. Intraoperative pain was assessed by an external observer on a 0-4 VAS and by the patient on a 0-10 scale immediately postoperatively.

During this procedure, a trained external observer, unaware of the patient's group assignment, assessed intraoperative pain using a VAS with the following scoring criteria:

0: No observed signs of pain.

1: Facial expressions indicating pain.

2: Spontaneous verbal expression of pain.

3: Verbal and facial expressions of pain, but procedure continuation allowed.

4: Procedure halted due to pain without analgesia or anaesthesia, indicated by verbal or bodily expression.

Immediately post-procedure, patients self-assessed intraoperative pain using the same visual analogue scale. Histopathological examination was conducted on the products. Both paracervical block and MVA were performed aseptically, with procedure duration and any complications noted. Vital signs were monitored postoperatively until stable, and patients' overall satisfaction was assessed using a VAS upon discharge. Patients received standard follow-up care, including oral medications: ampiclox 500 mg every 6 hourly, metronidazole 400 mg every 8 hours for 5 days, and Paracetamol 1 g every 8 hours for 3 days.

Outcomes:

1. Mean intraoperative pain scores assessed by both patients and external observers in the two groups, measured using a visual analogue scale.

2. Assessment of patients' postoperative overall satisfaction scores at the time of discharge using a visual analogue scale.
3. Evaluation of the necessity for additional analgesics, administered when the visual analogue scale score by the external observer is 2 or greater (intramuscular diclofenac 75 mg stat and midazolam 5 mg stat).
4. Examination of side effects, including metallic taste, light-headedness, dizziness, blurred vision, convulsions, hypersensitivity reactions, restlessness and tremors.

All patients were assessed based on the groups to which they were initially assigned, following the intention-to-treat analysis.

Statistical Analysis:

The data collected in this research were analyzed using SPSS version 20. The study focused on comparing the effectiveness, as indicated by the mean VAS pain scores in patients undergoing MVA for incomplete abortion using either a Paracervical block with four-needle points or two-needle points with 1% lignocaine. Additionally, the study examined the side effects of lignocaine during the procedure, along with other factors such as the need for additional analgesia. Statistical analysis included the application of Paired T tests and independent T tests for continuous variables, while Chi-square tests and Fisher exact tests were utilized for categorical variables. A p-value < 0.05 was considered statistically significant.

RESULTS:

During the study period, there were a total of 606 gynaecological admissions, of which 332 were cases of abortion, resulting in an overall incidence of 54.8%. Among these, 162 (48.8%) were spontaneous abortions, while 170 (51.2%) were induced abortions. At presentation, 281 (84.6%) of these cases were

incomplete abortions, with 120 patients eventually recruited for the study.

Baseline characteristics between the two groups showed no statistically significant differences (Tables 1 & 2). This included mean age (27.8 vs. 31.7 years), parity (4.1 vs. 4.4), estimated gestational age (6.8 vs. 6.5 weeks), and social class (3.8 vs. 3.8). There were 102 married women in both groups, with 49 in Group A (four-needle points PCB) and 53 in Group B (two-needle points PCB), while 18 were single (11 in Group A and 7 in Group B). Among all pregnancies, 83 were wanted (39 in Group A and 44 in Group B), while 37 were unwanted (21 in Group A and 16 in Group B). Additionally, 49 pregnancies were induced abortions (32 in Group A and 17 in Group B), while 71 were spontaneous abortions (28 in Group A and 43 in Group B). Only 27 pregnancies were already booked at the time of abortion (14 in Group A and 13 in Group B), while the majority, 93 pregnancies, were unbooked (46 in Group A and 47 in Group B). Among the 120 women with incomplete abortions studied, 41 had previous experience with MVA (26 in Group A and 15 in Group B), while 79 had no previous history (34 in Group A and 45 in Group B). There were no significant differences in marital status, types of abortion, booking status, previous history of MVA, or pregnancy wantedness between the two groups.

Preoperative visual analogue scale scores for anxiety and pain showed no statistically significant differences between the groups (Table 3). However, during the intraoperative period, there were significant differences in the pain visual analogue scores observed by the external observer ($t = -3.37, P < 0.05$) and expressed by the patient ($t = -9.51, P < 0.05$). The mean VAS for pain was significantly higher in Group B compared to Group A. Additionally, there was a statistically significant difference in postoperative satisfaction visual analogue scores ($t = 7.16, P < 0.05$).

Table 1. Comparing the baseline characteristics between groups.

	Four-point group Mean \pm SD	Two-Point group Mean \pm SD	Mean Difference	T Value	P Value	95% CI Lower	95% CI Upper
Age	27.8 \pm 7.3	31.7 \pm 6.2	-3.01	-2.88	0.114	-5.96	-1.11
Parity	4.1 \pm 3.5	4.4 \pm 2.8	0.32	0.53	0.595	-0.84	1.49
EGA	6.8 \pm 1.9	6.5 \pm 1.8	0.48	1.42	0.163	-0.97	1.16
Social Class	3.8 \pm 0.8	3.8 \pm 0.5	0.02	0.13	0.899	-0.24	0.28

EGA: Estimated Gestational Age.

Table 2. Comparing the categorical baseline characteristics between both groups.

Parameters	Classification	Four-point group N (%)	Two-point group N(%)	Total N(%)	χ^2 Fischer exact test	P value
Marital Status	Married	49(40.8)	53(44.2)	102(85)	0.005	0.061
	Single	11 (9.2)	7 (5.8)	18(15)		
	Total	60 (50)	60 (50)	120(100)		
Types	Spontaneous	28(23.3)	43(35.8)	71(59.1)	0.002	0.249
	Induced	32(26.7)	17(14.2)	49(40.9)		
	Total	60 (50)	60 (50)	120(100)		
Booking Status	Booked	14(11.7)	13(10.8)	27(22.5)	0.788	0.397
	Unbooked	46(38.3)	47(39.2)	93(77.5)		
	Total	60(50)	60(50)	120(100)		
Previous history of MVA	Yes	26(21.7)	15(12.5)	41(34.2)	0.017	0.117
	No	34(28.3)	45(37.5)	79(65.8)		
	Total	60(50)	60(50)	120(100)		
Pregnancy	Wanted	39(32.5)	44(36.7)	83(69.2)	0.140	0.071
	Unwanted	21(17.5)	16(13.3)	37(30.8)		
	Total	60(50)	60(50)	120(100)		

MVA: Manual Vacuum Aspiration**Table 3. Comparing the visual analogue scale of pain and anxiety scores between the two groups.**

	Four-point group mean \pm SD	Two-point group mean \pm SD	Mean difference	T value	P value	95% conf interval of the difference Lower	95% conf interval of the difference Upper
Preoperative period: Anxiety VAS	9.5 \pm 1.7	9.2 \pm 2.4	0.33	0.77	0.439	- 0.46	1.10
Preoperative period: Pain VAS	7.1 \pm 1.8	6.0 \pm 1.7	1.02	3.05	0.301	0.39	1.70
Intraoperative period: Pain VAS by ext observer	1.1 \pm 0.6	1.9 \pm 0.8	-0.48	-3.37	0.003	-0.78	-0.21
Intraoperative period: Pain VAS by patients	3.3 \pm 2.3	6.6 \pm 1.7	-3.40	-9.51	0.001	-4.12	-2.68
Postoperative period: Satisfaction Visual Analogue	8.9 \pm 1.8	5.2 \pm 3.3	3.61	7.16	0.001	2.63	4.63

VAS: Visual Analogue Score.**Table 4. Comparing the secondary outcomes by the two groups.**

	Four-point group N (%)	Two-point group N (%)	Total	Fisher exact test	P value	
Needs for additional analysis	No	57(95.0%)	32(53.3%)	89(74.2%)	0.001	0.001
	Yes	3 (5.0%)	28 (46.7%)	31 (25.8%)		
	Total	60 (50.0%)	60 (50.0%)	120(100%)		
Side effect	Nil	Nil	Nil			

Table 5. Comparing the mean VAS of the requirement for additional analgesia in the two groups.

	Four-point group No (mean VAS)	Two points group No (mean VAS)	Chi square χ^2	P value
Required	3 (2.91)	28 (6.88)	10.21	0.006
Not required	57 (2.11)	32 (4.07)	2.76	0.233

VAS: Visual Analogue Score.

The comparison of secondary outcomes between the two groups regarding the need for additional analgesia yielded statistically significant results (P value < 0.05) (Table 4). Among the women requiring additional analgesia, 90.3% (28) were from Group B, while only 9.7% (3) were from Group A. Further analysis of the mean visual analogue scores of patients requiring additional analgesia showed a significant difference between the groups (P value < 0.05). The mean VAS in Group B (6.88) was significantly higher compared to Group A (2.91). However, there was no significant difference in mean VAS among women not requiring additional analgesia in both groups. No patients in either group experienced any side effects, and all MVA procedures were completed without the need for suspension.

DISCUSSION:

Abortion is a common reason for gynaecological consultation and hospital admission, whether spontaneous or induced; providing timely and appropriate care is crucial for safeguarding women's reproductive health, with pain control being a key aspect in managing incomplete abortion, which was the focus of this study (Okonofua *et al.*, 2009).

The incidence of abortion in this study was 54.8%, higher than previously reported in the institution (Fasubaa *et al.*, 2002; Awowole *et al.*, 2020). This disparity may be attributed to previous retrospective studies with potential data loss due to poor record-keeping practices. Additionally, previous studies were conducted only in the Ife hospital unit.

While the current study is prospective and conducted in both arms of the hospital (Ife Hospital Unit, Ile-Ife and Wesley Guild Hospital, Ilesha), the incidence rate of 54.8% aligns closely with figures reported in Maiduguri and Uyo, which were 53.2% and 53.7%, respectively (Jibril *et al.*, 2014; Abah *et al.*, 2020).

There were no significant differences observed in marital status and pain experienced with paracervical block during MVA for incomplete abortions between the two groups. Similarly, parity, mean estimated gestational age, social class, and types of abortion showed no significant differences. Booking status, previous MVA, and pregnancy wantedness also did not differ significantly. These baseline characteristic similarities indicate successful randomization and suggest that most patients share similar environmental factors, likely influencing their baseline characteristics and other psychosocial factors.

Preoperative anxiety scores were high and comparable in both groups, indicating generalized anxiety among patients. This underscores the association between preoperative anxiety and perceived pain during manual vacuum aspiration of incomplete abortion. Previous studies by Wiebe *et al.* and Stubblefield found that anxiety exacerbates pain perception during uterine evacuation, while detailed pre-procedural explanations could alleviate anxiety (Stubblefield, 1986; Wiebe and Rawling, 1995).

Comparison of intraoperative pain levels between the two groups, assessed by both external observers and patients, revealed significant differences, with Group B experiencing more pain. This finding aligns with various studies, including one by Egziabher *et al.*, who reported greater pain in patients poorly infiltrated with xylocaine during manual vacuum aspiration of the uterus (Egziabher, Ruminjo and Sekadde-Kigundu, 2002). Other studies comparing paracervical blocks using xylocaine/lignocaine to placebo or no injection have shown mixed findings, attributed to factors such as sample size, use of misoprostol, dilation before aspiration, waiting period between injection and aspiration, and the predominance of two-needle point blocks (Gomez *et al.*, 2004; Ayegbusi *et al.*, 2021).

This study highlights the superiority of Group A (four-needle points PCB) over Group B (two-needle points PCB) in terms of pain control efficacy, as assessed by both patients and external observers, and the reduced need for additional anaesthesia. By comparing the efficacy of four-needle points versus two-needle points PCB in a larger sample size and with a 5-minute waiting period before manual vacuum aspiration (MVA), this study focused on cases of incomplete abortions where misoprostol or dilation before the procedure was unnecessary.

Furthermore, there was a statistically significant increase in postoperative overall satisfaction, measured on the Satisfaction Visual Analogue scale, among women in Group A compared to Group B. This finding aligns with a study by Renner *et al.*, where satisfaction scores, particularly regarding pain control and the procedure itself, were notably higher in the paracervical block group (Renner *et al.*, 2012).

In analyzing secondary outcomes between the two groups, it was found that 31 women required additional analgesia, with only 3 in Group A and 28 in Group B. The statistically significant difference in the mean visual analogue scale of those requiring additional analgesia suggests the superior efficacy of

paracervical block in Group A during MVA for incomplete abortions, particularly evident in the notably higher mean VAS observed in Group B. Importantly, no side effects or complications were recorded, echoing findings from Gomez et al., who similarly reported no adverse reactions to paracervical block. Proper administration, correct dosage, and avoiding inadvertent vessel injection can mitigate potential side effects.

The study's strengths include its randomized controlled trial design, utilization of a blinded external observer for intraoperative pain assessment, comprehensive training sessions for all involved doctors and a protocol outlining clear objectives and methodologies. Additionally, the deliberate selection of a paracervical block technique involving more needle sticks, higher local anaesthetic concentration, and a longer waiting time distinguish this study from others. However, pain perception is inherently subjective and may be influenced by emotional factors, particularly in cases of pregnancy loss; this can introduce potential biases such as recall errors.

CONCLUSION:

In conclusion, the study findings indicate that employing a four-point injection approach for paracervical block with 1% lignocaine is more efficacious in mitigating pain during manual vacuum aspiration for incomplete abortions compared to a two-point injection approach. Additionally, the four-point group exhibited advantages including higher overall satisfaction rates, shorter hospital stays, decreased requirement for additional analgesia and a lack of reported side effects during the procedure in both groups.

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