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(RESEARCH ARTICLE)

A randomized controlled study of intramuscular acetaminophen- diclofenac versus acetaminophen-pentazocine for pain relief during manual vacuum aspiration in university of Maiduguri teaching hospital

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Abstract

The management of first trimester miscarriages using manual vacuum aspiration is a cheap, fast and safe surgical method of uterine evacuation. However, this procedure generate pain as a result of cervical manipulation, insertion of cannula and suctioning of uterine cavity. This pain quite often, is intolerable to the patient. Therefore, an effective pain management intervention is necessary to abolish this pain.

Aim: The aim of this study was to compare combined acetaminophen-diclofenac with acetaminophen-pentazocine for pain relief during manual vacuum aspiration in a randomised controlled study at the University of Maiduguri Teaching Hospital.

Objective: To determine and compare the effectiveness of combined acetaminophen-diclofenac versus acetaminophen-pentazocine for pain relief during manual vacuum aspiration.

Methodology: This was a triple-blind randomised controlled study, that compared the effectiveness of combined acetaminophen-diclofenac versus acetaminophen-pentazocine as a multimodal analgesia during manual vacuum aspiration. A total of 112 participants were randomised into two groups. Participants in group A (56 patients) received combined acetaminophen-diclofenac while participants allocated in group B (56 patients) received acetaminophen-pentazocine for pain relief during manual vacuum aspiration.

The primary outcome, measured the occurrence of mild or no pain during the procedure. Secondary outcome measured the need for rescue analgesia used during the procedure. The data was entered into SPSS version 20.0 (IBM, Armonk, NY, USA 2011) for statistical analysis.

Result: There was statistically significant difference in the effectiveness, when combined acetaminophen-pentazocine compared to combined acetaminophen-diclofenac was used during manual vacuum aspiration (P value=0.001). Majority 44(78.6%) of the participants in combined acetaminophen-pentazocine group experienced mild pain compared to 25(44. 6%) of participants in acetaminophen-diclofenac group and their mean pain scores were 2.8929(SD±1.1067) and 4.1786(SD±1.7899) respectively. When the mean pain scores of both groups were compared using the independent t-test, there was a statistically significant difference (P value = 0.001), with participants in combined acetaminophen-pentazocine group suffered less pain.

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Conclusion: Combined acetaminophen-pentazocine as a form of analgesia during MVA was more effective when compared to combined acetaminophen-diclofenac.

Keywords: Manual Vacuum Aspiration; Acetaminophen; Diclofenac; Pentazocine; Effectiveness

1. Introduction

Miscarriage is the most common early pregnancy complication, which can be traumatizing to women and their clinicians.[1] Miscarriage is defined as loss of intrauterine pregnancy before the age of viability.[1] In Nigeria, age of viability is 28 weeks from the first day of the last normal menstrual period.[2] About 10-20% of known pregnancies end in miscarriage,[3] most of these occurrences happen before 12 weeks.[3] Complications related to miscarriage continue to make substantial contributions to maternal morbidity and mortality in Sub-Saharan Africa.[4,5] . Miscarriage is of great concern particularly in low resource countries because it can end in incomplete expulsion of products of conception and this may lead ultimately to excessive bleeding and infection.[6]

Various methods are currently available for management of first trimester miscarriages. These include: manual vacuum aspiration, electrical vacuum aspiration, sharp dilation and curettage and medical uterine evacuations.[7]

Manual vacuum aspiration (MVA) is a fast and cheap surgical method of uterine evacuation in first trimester abortion.[7,8,9] It is associated with few incidences of serious complications, reduced need for general anaesthesia and shorter duration of hospital stay when used as the mode of treatment of abortion.[8,10] Although it possesses all these good qualities, it causes pain during the procedure due to manipulation of the cervix and uterine suction.[10] About 97 % of women who undergo manual vacuum aspiration without analgesia report pain during the procedure.[11] The severity of pain experienced by women during surgical evacuation of uterine content differs with individuals. Post abortion care providers, should create pain management plan together with the patients through discussion and clinical assessment before the procedure.[12] All patients deserve adequate analgesia during manual vacuum aspiration and according to the Royal College of Obstetricians and Gynaecologists, analgesia should be provided for both medical and surgical uterine evacuations.[13] Adequate pain relief during the procedure is an essential aspect of managing miscarriages, as this will provide maximum satisfaction with minimal risk to the patients' health.[11,13]

There are various forms of managing pain during surgical uterine evacuation in miscarriage. They are divided into non-pharmacological and pharmacological methods. Non-pharmacological method also known as verbal anaesthesia, consists of verbal reassurance and gentle appropriate clinical technique.[14] Pharmacological methods involves the use of opioids, nonsteroidal anti-inflammatory drugs(NSAIDs), local anaesthesia (paracervical block), and general anaesthesia.[14] It is not always possible to provide a range of pain control options in every setting therefore, individualising pain medications as much as possible will go a long way in improving patient's satisfaction with manual vacuum aspiration experience.[15]

World Health Organisation and RCOG recommendation on safe abortion favours local analgesia or parenteral sedation over general anaesthesia because they have been shown to minimise procedural and postoperative pain and still remain safe and satisfactory to patients.[16]

General anaesthesia is not routinely used for MVA because of the risks, costs, and clinical logistics of general anaesthesia. Local anaesthesia in form of paracervical block can be used for manual vacuum aspiration, as for other day care gynaecology procedures due to short duration of the procedure.[12,16,17] However, injection of paracervical block into the cervical tissue targets parasympathetic fibres from S2 to S4 that supply the lower part of uterine body and cervix, thus reducing pain caused by cervical dilation and movement. More so, paracervical block cannot totally access sympathetic fibres from T10 to L1 that run through inferior hypogastric nerve and ovarian plexus innervating uterine fundus and lower part of uterine body.[16,17] Therefore, adequate pain relief with paracervical block during MVA will need extra analgesics. [16]

Choice of analgesia used during manual vacuum aspiration is guided by effectiveness, availability, cost, doctor preference, individual preference, history of drug allergy or departmental/institutional protocol.[18,19] In developing countries, the ideal analgesia should be cheap, easily administered, and require minimal resuscitative equipment.[18]

Multimodal approach using a combination of various analgesia and different classes of drugs have been recommended for pain management.[16,18] The multimodal approach was recommended in order to provide a synergistic effect with

reduced side effect profile of each of the drugs.[18] The unimodal technique is commonly used in our environment.[7] Opioids are very effective analgesics and a primary component of multimodal pain management in surgical settings.[16]

Miscarriages are the commonest presentation in gynaecological emergency unit.[20] Most patients who present to the gynaecological emergency clinic with diagnosis of miscarriage that need uterine evacuation are usually offered manual vacuum aspiration as a mode of treatment in University of Maiduguri Teaching Hospital. However, women are requesting for a pain free procedure.[8,9]

In 2013, a retrospective study carried out at the department of Obstetrics and Gynaecology University of Maiduguri Teaching Hospital on experience with manual vacuum aspiration noted that intramuscular pentazocine or paracetamol was the analgesia used during MVA.[8] This current study was randomised controlled study and multimodal analgesia was used during the procedure.

Gynaecological emergency protocols produced at the department of Obstetrics and Gynaecology, University of Maiduguri Teaching Hospital, described MVA as a mode of treatment for miscarriage less than 12 weeks gestation but did not state a protocol for analgesia to be used during the procedure.[22] However, pentazocine or diclofenac is the common current pain management practices during the procedure.

A study has not been conducted in our centre to assess pain management during manual vacuum aspiration. Therefore, the aim of this study is to compare effectiveness of combined acetaminophen-diclofenac versus acetaminophen-pentazocine as a type of multimodal analgesia for management of pain in patients undergoing manual vacuum aspiration in a randomised controlled study.

The outcome of the study may assist to form a departmental protocol on pain management during manual vacuum aspiration and other field in gynaecological practices that involve manipulation of cervix. Findings from the study will add to the existing literature upon which subsequent research work in the same area can be conducted and assist in policy formulation.

2. Material and method

2.1. Study design

This was a triple blind randomised controlled equivalence study conducted from 15th April 2022 to August 20th 2022 to compare the effectiveness of intramuscular acetaminophen-diclofenac versus acetaminophen-pentazocine for pain relief during manual vacuum aspiration.

2.2. Study area and setting

The study was carried out in Maiduguri, Borno state. Maiduguri metropolis (Latitude 11.85°N, Longitude 13.156°E) is located in North-Eastern Nigeria. Major ethnic groups within the state are the Kanuri and Shuwa Arabs, while other ethnic communities include Babur, Marghi, Fulani, Hausa, Isge, Chibok. Farming, fishing and trading are the major occupation of the people of the state. The University of Maiduguri Teaching Hospital is a tertiary hospital located in a densely populated area within Maiduguri metropolis. The hospital is an 800-bed capacity health institution.

The Obstetrics and Gynaecology department run an antenatal, Gynaecological, family planning as well as oncology clinics. There is also a labour ward where deliveries or Obstetrics emergencies are managed and Gynaecological emergency clinic where Gynaecological emergencies are managed.

Patients are attended to at any time they present to the Gynaecological emergency clinic by nurses and doctors on duty. Over one thousand nine hundred (1,900) patients present to the Gynaecological emergency clinic annually, with an average of ten patients in a day, out of which 2-4 require MVA.

This study was carried out at the Gynaecological emergency clinic of the department of Obstetrics and Gynaecology, University of Maiduguri Teaching Hospital. The Gynaecological emergency clinic has five beds. Women attending the Gynaecological emergency clinic in our centre were properly evaluated, in-depth history taken, clinical examination and ultrasound scan done. Laboratory investigations were also carried out. Patients with diagnosis of miscarriage by clinical evaluation using a combination of last menstrual period, uterine size and pelvic ultrasound scan and require MVA had the procedure carried out in Gynaecological emergency treatment room. The cases were first seen by the house officer and then subsequently reviewed by the registrar, senior registrar, and then communicated to the managing consultant.

2.3. Study population

The subjects were pregnant women who attend Gynaecological emergency clinic, that were diagnosed with miscarriage and require MVA.

2.4. Sample size determination

The sample size was calculated based on the formula below[27]:

$$n = \frac{2\left(Z_{\alpha} + Z_{\beta}\right)^2 p(1-p)}{(|P_T - P_S| - \delta)^2}$$

n= minimum sample size for each arm of the study group.
α= probability of making type I error.
β= probability of making type II error.
Za= level of significance of type I error probability; determined from a statistical table based on the value of the level of significance a; for this study, it is set at 0.05. The 95% confidence interval (Za) =1.96 for a two-tailed test.
Zb= this is type II error probability. It is determined from a statistical table based on the acceptance power of comparison between the two groups. For this study, a power of 80% (0.8) was used; therefore, Zb = 0.84.
P_T= proportion of participants in the study group (acetaminophen-diclofenac) who exhibited the primary outcome of interest (effectiveness) from a previous study[19]; 64.4% (0.644)
P_S= proportion of participants in the control group (acetaminophen-pentazocine) who exhibited the primary outcome of interest (effectiveness) from a previous study[19]; 40% (0.4) was used.
δ: clinically admissible margin of equivalence (0.8-1.25). In this study, it is taken as '1.1'.

$$P = P_S + + P_T$$

$$P = \frac{P_S + P_T}{2}$$

$$P = \frac{0.644+0.4}{2} \quad = 1.044/2 = 0.522$$

$$1\text{-}P = 1 - 0.522 = 0.478$$

$$P(1\text{-}P) = 0.522(0.478) = 0.2495$$

$$P_T\text{-}P_S = (0.644 - 0.4 \times 1.15)^2 = 0.08$$

Therefore $$\frac{2\ (1.96+0.842)2\ 0.522(0.478)}{0.08} = 50$$

With ten percent attrition rate, the total sample size was 56 per group. (100/90×50) =5000/90=56.

The total sample size was 112 participants.

2.5. Study procedure

Approval for the study was obtained from the ethics and research committee of the UMTH before the study was carried out. Nurses covering gynaecological emergency clinic and four junior residents served as research assistants during the period of the study. Prior to the commencement of the study, the research assistants were trained for two days on the study protocol by the researcher. This training includes; introduction to the study, patients' inclusion criteria, study procedures, intervention and side effect of analgesia used for the study. Adequacy of training was confirmed by pre- and post- testing of trainees. Participants was counselled and requested to sign a written informed consent, before recruitment into the study. A senior resident doctor covering the gynaecology emergency or on call, who is not part of the research assistants, was responsible for obtaining informed consent from a participant prepared for MVA in the Gynaecology emergency clinic before the participant underwent MVA. The women were assured that they could opt out of the study when they desired to do so, without any consequence. One of the nurses on duty was responsible for the withdrawal of the study drugs into 5 milliliters disposable syringes that were provided for the study by the researcher.

She was trained to withdraw the drugs into the syringes, label the syringes A(acetaminophen-diclofenac) or B(acetaminophen-pentazocine) and discard the ampoules into a safety box at the Gynaecological emergency treatment room without allowing the other nurse know the drug contained in each of the syringes. She then handed over the two syringes containing the study drugs to the second nurse on duty to administer to the participants. Participants were shown the visual analogue scale and were also taught how to point with their finger on the correct picture that describes their perceived pain, 30 minutes after the procedure by the researcher or research assistants.

2.6. Intervention

2.6.1. Group A

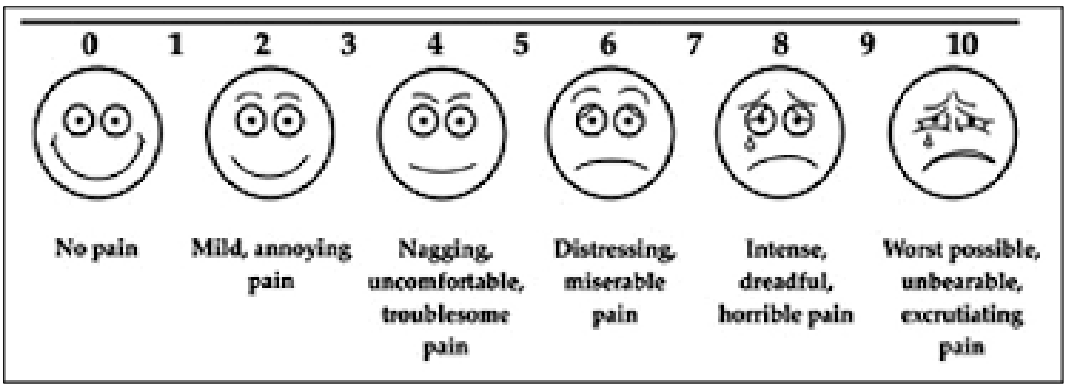
All eligible participants were given intramuscular acetaminophen (Drugfield^{R}) 600 mg and intramuscular diclofenac sodium (Voltaren) 75 mg 20 minutes before the procedure at the upper lateral gluteal region.

2.6.2. Group B

All eligible participants were given intramuscular acetaminophen (Drugfield^{R}) 600 mg and intramuscular pentazocine (Zolon) 60 mg 20 minutes before the procedure at the upper lateral gluteal region.

Manual vacuum aspiration was performed according to standard protocol by the junior resident covering the Gynaecology emergency or junior resident on call. All participants, regardless of assigned analgesia given, were managed according to the gynaecological emergency protocol of University of Maiduguri Teaching Hospital. Intravenous access with a wide bore cannula size was secured, while taking blood for packed cell volume, blood grouping and cross matching. Urinalysis was also done. Each participant was placed in lithotomy position. Bimanual pelvic examination was done. The perineum and vagina were cleaned with antiseptic solution and draped with sterile towel. Cusco's speculum was gently inserted into the vagina. The anterior or posterior lip of the cervix was held with tenaculum to straighten the endocervical canal depending on the position of the uterus. An appropriately sized Ipas Easy Grip cannula was inserted into the uterine cavity using non-touch technique and attached to the charged vacuum syringe. Uterine evacuation was done by rocking and rotatory movements of the cannula. Signs of completion of the procedure were aspiration of red or pink foam without more tissue seen the cannula, gritty sensation was felt, and uterus contracts around the cannula. The cannula, tenaculum and speculum were removed after confirming evidence of complete uterine emptying. The aspirated tissue was examined and sent for histology. Vital signs were monitored every 15 minutes in the first one-hour, then hourly for next 3 hours post operatively. All participants were given analgesia, antibiotics and haematinics. Also, injection anti D immunoglobulin was given to rhesus negative patients (all according to the department's protocol). All participants were monitored in the gynaecological emergency ward for 4 hours.

Thirty minutes after completion of the procedure, the participant was assessed on her experience with pain during the procedure using visual analogue scale. The visual analogue scale consists of a pictorial representation on a 10 cm straight line in which the far-left end indicates "no pain" while the far-right end indicates the "worst pain". Also, there was another line exactly the same length and parallel to the first one (10cm) calibrated from 0 – 10 with 0 corresponding to "no pain" and 10 to be "worst pain" as shown below. The participants were instructed to point to the position on the faces on the VAS to indicate how much pain they felt during the procedure. The numbered scale was not shown to the participants. This was used by the researcher or research assistant to quantify the level of pain on a scale of 0 – 10 corresponding to the point where the patient indicated on the pictorial line.



The visual analogue scale (VAS)[24]

The values on the pain scale correspond to pain levels are as follows

0 = no pain

1 – 3 = mild pain

4 – 7 = Moderate pain

8 – 10 = severe pain

2.7. Inclusion criteria

The following inclusion criteria was applied;

- Women diagnosed with miscarriage clinically and/or by pelvic ultrasound scan at a gestational age of 12 weeks or less that requires MVA.
- Patients that are informed, counselled, and consented to participate in the study.

2.8. Exclusion criteria

The following criteria was excluded

- Known peptic ulcer disease patients
- Allergic reaction to pentazocine, diclofenac and acetaminophen.
- Septic or hypovolemic shock
- Patients with chronic liver or kidney disease
- Known coagulation disorder

2.9. Randomisation

Pregnant women scheduled for manual vacuum aspiration for miscarriage in Gynaecology emergency clinic were counselled and informed written consent was obtained from them. A computer-generated random number using Stat Trek random numbers generator (manufactured by Stat Trek) was used to assign women to either intramuscular acetaminophen - diclofenac group or intramuscular acetaminophen-pentazocine group as A and B respectively. The allocation was written on cards and placed in consecutively numbered opaque sealed envelopes and kept by the research assistant. The research assistants (junior residents) that had been trained by the researcher removed the next envelope at random from the box and women who meet the inclusion criteria were assigned to the group indicated on the card in the study envelope. The participants, researcher and data analyst were blinded to the intervention.

3. Procedure for blinding

3.1. Blinding of participants

In order to blind the participants, the two drugs were of the same colour, same volume in the same size of 5mls syringes and were administered 20 minutes before starting the procedure. Both drugs were administered intramuscularly and both drugs are not known to be painful at the site of injection.

3.2. Blinding of the assessors and data analyst

The assessors were the researcher and research assistants (junior resident doctors). They were blinded by exclusion from participants recruitment and drug administration. There was a separate treatment sheet for drugs given to the participants before the procedure to further blind the assessors from the study. Data was sent to the data analyst as either group A or B.

3.3. Research drugs

Procurement of drugs was through pharmacy department of UMTH, who have the responsibility of pre-qualifying drugs products and brands before use in the hospital. The brands selected were of the same batch and shelf live. Storage of

the drugs were at well controlled ambience temperature specific of the selected drug products and drugs destruction was also through pharmacy department of UMTH.

3.4. Outcomes

The primary outcome was to determine and compare participant pain perception, when either combined intramuscular acetaminophen-diclofenac or acetaminophen-pentazocine was given for pain relief during manual vacuum aspiration. Secondary outcomes were the need for rescue analgesia (intramuscular tramadol 100 mg).

3.5. Data collection and analysis

Data was obtained by interviewing the participants and from the participants' record. The data was then transferred to a proforma. Information pertaining to the socio-demographic variables of the participants, management and outcome were extracted. The data was entered into SPSS version 20.0 (IBM, Armonk, NY, USA, 2011) for statistical analysis. Simple frequency tables were generated. Participants' characteristics were presented as numbers and percentages for categorical data, and as mean with standard deviations (SD) for continuous normally distributed data. Comparison was made using student t-test for continuous variables and chi-square or Fisher's exact test, as appropriate was used to analyse the variables which were grouped into categories. The analysis was done based on "intention -to-treat" principle.

3.6. Ethical approval and study registration

Approval of this study was obtained from the Ethics committee of the University of Maiduguri Teaching Hospital (UMTH). All records were identified only by code number and initials to maintain. The study was registered with the Pan African Clinical Trial Registry (www.pactr.org). My unique identification number for the registry is PACTR202209818432344.

4. Results

A total number of 140 women diagnosed to have miscarriage that required manual vacuum aspiration were assessed for eligibility, ten (10) women did not meet eligibility criteria while eighteen (18) women declined to participate in the study. One hundred and twelve participants with miscarriage that require manual vacuum aspiration were recruited for the study with 56 participants randomly assigned to either acetaminophen-diclofenac or acetaminophen pentazocine treatment group. Each participant received the allocated treatment.

Table 1 shows a comparison of the demographic characteristics of the participants in the two study groups. There was statistically significant difference in the age of participants and the mean age in both groups were 30.50±7.55 years and 27.77±6.30 years respectively (P = 0.043). There was no statistically significant difference in estimated gestational age and parity in both groups.

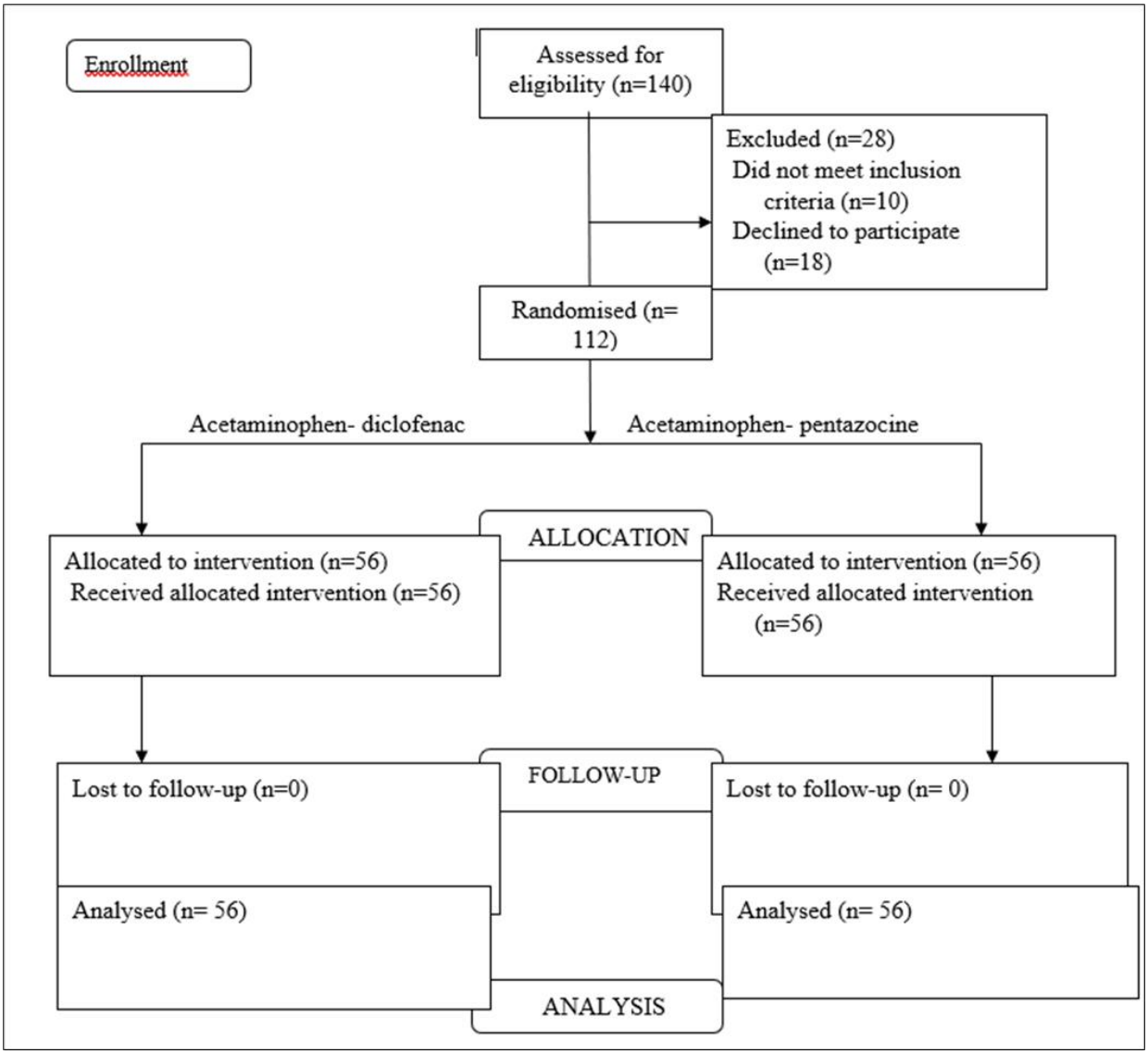


Figure 1 of participants assigned to acetaminophen-diclofenac (Group A) versus acetaminophen-pentazocine (Group B) during MVA

Table 1 Demographic characteristic of participants in acetaminophen-diclofenac (Group A) versus acetaminophen-pentazocine (Group B) during MVA

Variables	Group A	Group B	SST	P Value
Age(years) (Ẍ ± SD)	30.50±7.55	27.77±6.30	4.234**	0.043
EGA (weeks) (Ẍ ±SD)	8.96±1.54	9.07±1.48	0.378**	0.818
Parity				
Nullipara	12(21.4%)	12(21.4%)		
Para 1-4	33(59.0%)	37(66.1%)	1.117*	0.572
≥Para 5	11(19.6%)	7(12.5%)		

SST = Statistical Test, *Chi square, **student-t test EGA- Estimated gestational age. P value=< 0.05

Table 2 shows a summary of the indications for manual vacuum aspiration in both groups. There was a statistically significant difference in the indications for manual vacuum aspiration (P value =0.017). The commonest indication for manual vacuum aspiration for both groups was incomplete miscarriage, accounting for 85.7% and 69.6% in group A

and group B respectively. Blighted ovum was diagnosed in 14.3% in group A and 17.9% in group B, while 12.5% was diagnosed with missed miscarriage in group B.

Table 2 Indications for Manual Vacuum Aspiration (MVA) in both groups

Variables	Group A n (%)	Group B n (%)	χ^2	P Value
Incomplete miscarriage	48(85.7)	39(69.6)		
Blighted ovum	8(14.3)	10(17.9)	8.153	0.017*
Missed miscarriage	0(0.0)	7(12.5)		
Total	56(100)	56(100)		

$\chi 2 = 8.153$, P = 0.017, *Statistically significant at < 0.05

The effectiveness of acetaminophen-diclofenac versus acetaminophen-pentazocine as a form of analgesia during manual vacuum aspiration was shown on table 3. The effectiveness was defined in this study as adequate pain control during manual vacuum aspiration with pain score ≤ 3 using VAS. There was a statistically significant difference in the effectiveness of analgesia used in both treatment groups ($\chi 2 = 13.56$, P value =0.001). The analgesia used was effective in 25(44.6%) of the women assigned to the acetaminophen- diclofenac and 44(78.6%) of those assigned to the acetaminophen- pentazocine arm. Half 28(50%) of the participants in acetaminophen-diclofenac group also reported moderate pain. None of the participants in acetaminophen -pentazocine group had severe pain score. Four (7%) of participants in acetaminophen-diclofenac group required additional analgesia and they were given a stat dose of intramuscular tramadol 100 mg as a rescue analgesia. There was statistically significant difference in the mean pain score ((P value =0.005). The mean pain score for participants in acetaminophen-diclofenac group was 4.1786±1.7899 and acetaminophen-pentazocine group was 2.8929±1.1067. When the mean pain scores of both groups were compared using independent t-test, the results showed that the overall mean pain scores were mild to moderate. However, there was a statistically significant difference in mean pain score between the two groups, with the participants in acetaminophen-pentazocine group experiencing lesser pain than those in the acetaminophen-diclofenac group (P value = 0.001).

Table 3 Comparing participants pain perception when either acetaminophen-diclofenac (Group A) or acetaminophen-pentazocine (Group B) is given during MVA

Level of pain	Group A n (%)	Group B n (%)	χ^2	P value
Mild pain (1-3)	25(44.6)	44(78.6)	13.56	0.001
Moderate pain (4-7)	28(50.0)	12(21.4)	9.87	0.002
Severe pain (8-10)	3(5.4)	0(0.0)	3.06**	0.080

**=Fischer exact test, *Statistically significant at < 0.05

5. Discussion

This study showed that combined acetaminophen-pentazocine was more effective than combined acetaminophen-diclofenac as a form of analgesia during manual vacuum aspiration. The mean pain score in the group that had acetaminophen-pentazocine combination was lower than acetaminophen-diclofenac group. This shows that the combination of acetaminophen-pentazocine was more effective than acetaminophen-diclofenac during manual vacuum aspiration in this study. This could be due to differences in the mechanism of action between the study drugs. Pentazocine is a mixed agonist and antagonist opioid, which produces sedation in addition to analgesic property, thus reducing anxiety, while diclofenac is an NSAID which inhibits prostaglandin production from arachidonic acid by inhibiting cyclooxygenase, thus reducing inflammation.[28] This superiority in analgesic property of acetaminophen-pentazocine combination in this study is similar to the finding of Natalia et al.[19]19 Another study,[20] noted that there was no difference in effectiveness between the use of meperidine (an opioid like pentazocine) plus diclofenac and use of meperidine alone during manual vacuum aspiration. This could be explained by the difference in mechanism of action of pentazocine when compared to meperidine(pethidine). Meperidine(pethidine) is a pure agonist opioid with an opposing effect on anxiety.[28]

It is unethical to allow the participant to be in pain in order to assess the analgesic effectiveness of the study drugs combinations, hence rescue analgesia was given to participants who requested (one participant) or who had pain scores greater than[8]. Request for additional analgesia was also used to assess the analgesic effectiveness of the study drugs combinations. A request for additional analgesia was noted in acetaminophen-diclofenac group in this study. This was comparable to request for additional analgesia observed in studies by Natalia et al and Ali et al, where a single agent was used for pain relief during manual vacuum aspiration.[19,26] The need for additional analgesia in the acetaminophen-diclofenac group in this study and other studies may not be unrelated to the analgesic property of the drugs, either as a single agent or in combination.

6. Conclusion

Based on the results of this study, it can be concluded that combined acetaminophen-pentazocine as a form of analgesia during MVA was more effective compared to combined acetaminophen-diclofenac.

Limitation and strength of the study

The limitation of this study was that it is a single centre study and did not represent all the women in Borno state that need manual vacuum aspiration for surgical uterine evacuation, especially low-income women that receive free medical services in the state-owned hospitals.

The strength of this study was that it is a triple blind, randomised controlled study.

Recommendation

We recommend that patients presenting with miscarriage that require manual vacuum aspiration in University of Maiduguri Teaching Hospital should use combined acetaminophen-pentazocine for effective pain management.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

References

[1] Ahmed SR, El-Sammani Mel-K, Al-Sheeha MA, Aitallah AS, Jabin Khan F, Ahmed SR. Pregnancy outcome in women with threatened miscarriage: a year study. Mater Sociomed. 2012;24(1):26-28.

[2] Adeniran AS, Fawole AA, Abdul IF, Adesina KT. Spontaneous abortions (miscarriages): Analysis of cases at a tertiary centre in North central Nigeria. J Med Trop 2015; 17:1: 22-26.

[3] Dugas C, Slane V, Cope A, Hozayen S, Nookala V. Miscarriage [Internet]. Knowledge.statpearls.com. 2019 [cited 3 September 2019]. Available from:

[4] http://knowledge.statpearls.com/chapter/internalmedicine/25187/

[5] Fabamwo A, Akinola OI, Akpan AE. Correlates of abortion related maternal mortality at the Lagos State University Teaching Hospital, Ikeja. Afr J Reprod Health 2009; 13(2):139-146.

[6] Fawole AO, Diop A, Adeyanju AO, Aremu OT, Winikoff B. Misoprostol as first-line treatment for incomplete abortion at a secondary-level health facility in Nigeria. Int J Gynaecol Obstet. 2012;119(2):170-173

[7] Leke R.J, Philip N.N. Abortions in low resource countries. A. Darwish. Basic gynaecology –some related issues. 2012; Intech: Rijeka, Available at: http://www.intechopen.com/books/basic-gynecology-some-related-issues/abortions-inlow-resource-countries-case-study-of-cameroon

[8] Isa B, Mairiga AG, Ibrahim SM, Bako BG, Usman H A. Experience with Manual Vacuum Aspiration at University of Maiduguri Teaching Hospital. BOMJ 2013; 10(2): 31-35

[9] Koontz SL, Molina de Perez O, Kathleen L, Foster-Rosoles A. Treating incomplete abortion in El Sal-vador: Cost saving with Manual Vacuum Aspiration. Contraception 2003; 68(5):345-351.

[10] Kullima AA, Kawuwa MB, Mairiga AG, Bako B, Audu MB, Bimba J. Effectiveness of MVA in the management of first trimester miscarriages: Experience in a specialist centre in North eastern Nigeria. Ph Med J. 2009; 3(3):278-282.

[11] Tasnim N, Mahmud G, Fatima S, Sultan M. Manual vacuum aspiration: a safe and cost-effective substitute of electrical vacuum aspiration for the surgical management of early pregnancy loss. J Pak Med Assoc. 2011;61(2):149-153.

[12] Gweneth BL, Nicholas SF, Tod F. Impact of paracervical block on postabortion pain in patients undergoing abortion under general anaesthesia. Contraception 2009; 80:78-82.

[13] Ipas. Uterine evacuation procedure with Ipas MVA Plus. In: Turner KL, Huber A, editors. Woman centred postabortion care reference manual. 2nd ed. Chapel Hill, NC 2013; 163-198.

[14] RCOG. The care of women requesting induced abortion. London (England): Royal college of Obstetricians and Gynaecologists (RCOG); Evidence based clinical Guideline, No.7; 2011:130.

[15] W.H.O. Safe abortion: Technical and policy guidance for health systems. 2nd ed. Geneva: WHO;2012.

[16] Meckstroth KR, Mishra K. Analgesia/pain management in first trimester surgical abortion. Clin Obstet Gynaecol 2009;52(2): 160-170.

[17] Renner RM, Jensen JT, Nichols MD, Edelman A. Pain control in first trimester surgical abortion. Cochrane Database of Systematic Reviews 2009; 2:CD006712.

[18] Micks EA, Edelman AB, Renner RM, Fu R, Lambert WE, Bednarek PH, Nichols MD, Beckley EH, Jensen JT. Hydrocodone–acetaminophen for pain control in first-trimester surgical abortion: a randomised controlled trial. Obstet Gynaecol. 2012;120(5):1060-9.

[19] Natalia A, Galadanci H, Ibrahim SA, Mohammed Z. Comparison of effectiveness of pain management during Manual vacuum aspiration using single agent analgesic and combination: A randomised double-blind controlled trial. Open J Obstet Gynaecol 2015; 5(05): 244-250.

[20] Lopez JC, Vigil-De Gracia P, Vega Malek JC, Ruiz E, Vergara V. A randomised comparison of different methods of analgesia in abortion using manual vacuum aspiration. Int J Obstet Gynaecol 2007; 99: 91-94.

[21] Takai IU, Omeje IJ. Gynaecological emergencies seen in a referral hospital in Northwest Nigeria. A 3- year retrospective study. Trop J Obstet Gynaecol 2017; 34:152-159.

[22] Chama CM. Gynaecology emergency protocols: a practical guide developed by department of Obstetrics and Gynaecology University of Maiduguri Teaching Hospital 2014;7: 9-12.

[23] Samuels E. A randomised control trial comparing paracervical block with pentazocine for pain relief during manual vacuum aspiration. Faculty of obstetrics and gynaecology. 2017.

[24] Ain Q, Tabassum A, Hamid S, Saeed N. Comparison of rectal diclofenac sodium versus intramuscular tramadol for pain relief in manual vacuum aspiration. Pak J Physiol 2018;14(4):28-31.

[25] Sun YT, Wu JS. The visual analogue scale for rating, ranking and paired comparison (VAS-RRP): A new technique for psychological measurement. Behaviour research methods 2018;50: 1694-1715.

[26] Ali MA, Shamim F, Chughtai S. Comparison between intravenous paracetamol and fentanyl for intraoperative and postoperative pain relief in dilatation and evacuation: Prospective, randomised interventional trial. J Anaesthesiol, Clin Pharmacol. 2015;31(1):54-8.

[27] Bolarinwa OA. Sample size estimation for health and social science researchers. The principles and considerations for different study designs. Niger Postgrad Med J 2020; 27(2): 67-75.

[28] Walter L, Leong W, Howard L. Opioid analgesics and antagonists. In: Katzung BG, editor. Basic and clinical Pharmacology. 6th edition. New Jersey (US): Prentice-Hall Intel Inc; 1995:460-77.