ORIGINAL RESEARCH ARTICLE

Patient and provider perspectives on pain management during manual vacuum aspiration

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Abstract

Manual vacuum aspiration (MVA) is a painful procedure often conducted without analgesia. The World Health Organization (WHO) recommends a paracervical block (PCB) as the mode of pain relief during MVA. Few studies have assessed patient perspectives on pain control during MVA. We investigated the perspectives of health workers and patients on MVA under PCB. This study was nested within a pilot randomized controlled trial (RCT) evaluating the Chloe SED (syringe extension device) for PCB provision. Eleven providers and 61 patients were enrolled. All providers had MVA experience. They had not provided pain relief on 20% of occasions, and only one had previously administered PCB for MVA. Both patients and providers indicated MVA was painful and deserving of analgesia. Pain was the most common reason for difficulty completing an MVA. Providers noted that PCB made the procedure more tolerable. For patients, efficacy, remaining conscious, and same-day discharge were key considerations when selecting pain relief. Notably, 84% of patients expressed satisfaction with MVA under PCB. PCB is a vital component of the MVA care package. Considering patient and provider perspectives is essential to optimizing a humane and effective procedural experience. *(Afr J Reprod Health 2024; 28 [12]: 21-28).*

Keywords: Manual vacuum aspiration; pain; abortion; Chloe SED; patient perspective; paracervical block

Résumé

L'aspiration manuelle intra-utérine (AMIU) est une opération douloureuse souvent réalisée sans anesthésie. L'Organisation mondiale de la santé (OMS) recommande le bloc paracervical (BPC) comme mode pour soulager la douleur pendant l'AMIU. Peu d'études ont évalué les points de vue de la patiente sur le contrôle de la douleur pendant l'AMIU. Nous avons enquêté sur les points de vue des agents sanitaires et des patientes sur l'AMIU sous le contrôle du dispositif d'extension de seringue. Cette étude était intégrée à un essai pilote randomisé et contrôlé évaluant le Chloe SED (dispositif d'extension seringue) pour administrer le BPC, explorer les points de vue des agents sanitaires et des patientes. 11 agents sanitaires et 61 patientes ont participé à l'enquête. Tous les agents sanitaires avaient l'expérience de l'AMIU. Ils n'avaient pas encore donné des antidouleurs à 20 % de cas, mais 1 seul agent sanitaire avait déjà administré le BPC avec l'AMIU. Les patientes et les agents sanitaires avaient tous indiqué que l'AMIU était douloureuse et nécessitait une anesthésie. La douleur était la raison la plus commune de difficulté pour l'AMIU. Les agents sanitaires avaient noté que le BPC avait fait de l'opération plus supportable. Pour les patientes, l'efficacité, l'état de conscience pendant l'opération et un retour rapide à domicile étaient les considérations importantes pour le choix de l'antidouleur. Au total, 84% de patientes étaient satisfaites de l'AMIU avec le BPC. Le BPC est un élément essentiel dans le soins d'AMIU. Prendre en compte les points de vue des patientes et des agents sanitaires est crucial pour optimiser une expérience procédurale humaine et effective. *(Afr J Reprod Health 2024; 28 [12]: 21-28).*

Mots-clés: Aspiration manuelle intra-utérine; douleur; avortement; Cloe SED; points de vue des patientes et bloc paracervical.

Introduction

It is estimated that each year there are 120 million unintended pregnancies of which over 70 million end up in abortion[1]. This would be in addition to the spontaneous abortions that occur in wanted pregnancies. Although not all women undergoing abortion need treatment, it is one of the leading

indications for acute admission to the gynaecological wards in sub–Saharan Africa. In Kenya the abortion rate is approximately 48 per 1000 women ages 15 – 49 years[2,3], many of them require manual vacuum aspiration (MVA). The MVA procedure is a combination of curettage and suction of uterine contents and is an expedient way of treating abortions and its complications[4,5]. It is a safe, quick method of evacuating the uterus, precluding the need for general anesthesia (GA) in an operating theatre, and allowing for same day discharge from hospital[6-9]. Unlike dilation and curettage that is performed only by doctors, MVA can be done by nurses and other lower cadre practitioners, making it less expensive and more accessible[10]. This procedure is very painful and should be conducted in a humane manner with adequate pain relief[11].

When MVA was first introduced, the need for provision of adequate pain relief was downplayed and many times it was done under "verbocaine" variously referred to as "oral analgesia," which is when the provider or a support person provides words of comfort during the procedure[6]. Often in Kenya and other under-resourced settings, the procedure is done either without pain relief or with inadequate pain relief [11,12]. A variety of reasons to support this suboptimal care have been described and include the belief that the pain is bearable and "vocal local" is sufficient. For a long time, this has been accepted as a standard of care and the pain has been considered a fair exchange for the expediency of the procedure. However, many studies have shown that the pain endured by women during MVA is severe[11]. In addition to the physical pain, women may also be experiencing psychological and emotional trauma. Notably and unfortunately, the standards of care for MVA were made without taking patient autonomy and preferences into account and though it is widely performed around the world, studies examining patient and provider perspectives regarding pain management during MVA are few.

In 2022, the WHO issued new abortion care recommendations that prescribe paracervical block (PCB) as the minimum pain relief required during MVA, with additional conscious sedation provided where possible. In the context of the guidelines, conscious sedation is defined as the use of a combination of medicines – a sedative to relax and an anaesthetic to block pain – to induce a depressed level of consciousness during a medical procedure. The WHO notes that neglecting pain control compromises quality of care and increases the difficulty in performing the procedure[13].

A PCB involves the injection of local anesthesia into the cervix to prevent the transmission of afferent pain impulses from the cervix. It requires the use of a spinal needle to provide the additional length required to give the injection with a standard syringe. Unavailability of spinal needles and needle extenders in Kenya and other low-resource settings precludes provision of PCB. To address this barrier, we designed a syringe extension device (Chloe SED®) a low cost, plastic, reusable device, which when attached to a 10-cc syringe provides the additional length required to administer a PCB[14].

We conducted a single blinded non inferiority randomized control trial (RCT) to validate the utility of Chloe SED, comparing it to the standard spinal needle. The main outcome was assessment of pain scores during uterine evacuation. During the study, we also collected data on perspectives of both the patients and their caregivers on pain before, during and after the MVA procedure. Given that patient and provider experiential data on MVA is so limited, we conducted this study to better understand patient and provider experiences and preferences such that a more optimal and compassionate procedure protocol may be designed.

Methods

This study was nested within a single-blinded non inferiority RCT to compare the efficacy and safety of the Chloe SED to the standard spinal needle for administration of PCB during MVA.

The study sites were Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) and Kisumu County Hospital (KCH) both in western Kenya.

The study participants were health providers in the facilities who were designated to provide MVA in the gynaecological wards, and women who had been admitted with first trimester pregnancy for evacuation. The inclusion criteria were; women's health providers providing MVA services at the study sites, adult female patients receiving MVA at the study sites having been determined clinically eligible for MVA treatment by a licensed practitioner. All participants provided signed

informed consent to participate in the study. Exclusion criteria for the patient participants included: cervicitis, anticoagulant therapy or an abnormal bleeding tendency, severe anemia, heart disease, age under 18 years, and any contraindication to lidocaine such as known or suspected hypersensitivity.

Approval to conduct the study was obtained from the hospitals, the University of Illinois Chicago IRB (No. 2018-1269 of 4th March 2019); the Maseno University ERC (No. MSU/DRP/MUERC/00639/18 of 18th February 2019), JOOTRH IRC, and the Kenya Pharmacy and Poisons Board (ECCT/19/03/01). A data safety and monitoring board made up of three independent experts found no reasons to stop the study after a midpoint analysis.

Recruited providers were trained on the provision of PCB by the research assistants (RA) using the IPAS MVA curriculum on MVA with PCB. They were also trained on how to use Chloe SED. The RAs having been trained on Chloe SED by the innovators. A semi structured interview was conducted with the providers prior to the recruitment of the first patient that explored their experience with MVA and perceptions on pain control for the procedure. Another interview was conducted after completion of the last MVA to assess their experience with the Chloe SED compared to the standard spinal needle. With each patient an interview was conducted that included assessments before, during and after the procedure. We collected data on their demographic characteristics, previous experiences with MVA, perceptions about the procedure, preferences regarding pain control, pain scores during the procedure on an 11-point visual assessment scale (VAS) and levels of satisfaction after the procedure.

The primary outcome of the study was comparison of pain scores using the 11-point VAS during uterine evacuation. Other outcomes included assessment of pain scores at other time points of the procedure, documentation of adverse events, patient, and provider perceptions on MVA.

A sample size was arrived at based on a one tailed alpha of 0.05, with 80% power to detect a 2-point difference on the VAS with a mean pain level of 6 and a standard deviation (SD) of 3. This gave 28 patients to each arm which was then rounded off to 30. Microsoft Access 2000 was used for data entry, and data exported to Excel and Stata 17.0 for analysis.

Results on the pain scores and inferiority testing have been documented in a separate paper [15]. Since no differences in pain scores were found between procedures using Chloe versus the standard needle, this paper combines the results from all participants in the trial to examine provider and patient perspectives on MVA. All data were collated and are presented here in narrative form and tables

Results

Results from Provider Interviews

Eleven providers were enrolled in the study; they included one registered clinical officer, three medical officer interns, four medical officers and three registrars (gynecologists in training). Nine (82%) were male; their mean age was 28.3 (range 23 – 38) years. They had an average of 5.5 years in practice, four of them were in their first year of medical practice, while the rest had been in practice for between four and 12 years. Most (8/11) had received their initial training on MVA as part of their professional training, while two indicated that they had undergone formal training by an NGO. One was informally trained on the job by someone who was proficient in the procedure. After their formal training, five (45.5%) had received follow up training. Prior to recruitment into the study, the providers conducted on average 22.4 MVAs per month (range 0 to 100) in the facilities where they worked.

Patients being in excessive pain was cited by seven (63.6%) of the 11 providers as the most common reason for difficulty in completing an MVA prior to the study. Only two indicated difficulties with using the MVA kit.

Provision of improved pain control was mentioned by 6 (54%) providers as the primary thing they would wish could be improved during MVA. One indicated that there was a need to improve pre-procedure counseling, while three indicated that better or complete MVA equipment was needed. When the providers were asked how painful they thought the MVA procedure is they gave it an average VAS score of 6.5 (SD 2.5).

Table 1: Characteristics and perceptions of 11 health providers conducting manual vacuum aspiration (MVA): pre-study interview

Variable	Number	%age[1]
Type of Provider		
Medical Officer	4	36
Medical Officer Intern	3	27
Registrar*	3	27
Clinical Officer	1	9
Sex		
Male	9	82
Female	2	18
Age		
Mean (range)	28.3(23-28)	
Years in Practice		
Mean (range)	5.5 (1-12)	
Number MVA Done Monthly		
Mean (range)	22.4(0-100)	
Reasons for Difficulty with MVA		
Excessive patient pain	7	64
Problem with MVA kit	2	18
Other	2	18
Best Means to Improve MVA		
Improved pain control	6	55
Better equipment	3	27
Improved pre-procedure counseling	1	9
Other	1	9
Estimated Patient Pain Level		
Mean VAS[2] (SD)	(2.5)	

[1]The percents may not total 100 due to rounding
[2]VAS = Visual Analog Scale
* A registrar is a gynaecologist in training.

All the providers indicated that prior to the study, they provided pain relief to patients during MVA, with most (7/11) providing diclofenac injection and just one a PCB. Pain relief was not provided for all the procedures with an estimated 20% being done without analgesia. The inability to offer PCB was mostly (57.1%) attributed to lack of spinal needles or syringe extenders. One individual cited lack of training in PCB, while the remainder of the cohort (28.6%) did not provide a reason.

Five providers reported that there were no protocols on pain management for MVA at their facility. Six described protocols consisting mainly of parenteral diclofenac used singly or combined with tramadol. Only one of them described the use of PCB as part of a pain management protocol.

The providers reported that when PCB was administered, patients were more tolerant of the MVA procedure, yet syringe extenders, which were required for effective PCB, were not always available.

Once the study was completed, all (100%) providers noted that they would use syringe extenders in the future to provide PCB if they became available because they are efficient to use and they make administration of PCB easy.

"With paracervical block, patients were more cooperative during the procedure and this makes our work easier."

Results from Patient Interviews

The median age of participants was 26 years (IQR 22, 32). Most (67.2%) had received secondary schooling and had had at least one prior pregnancy. The mean gestational age at time of MVA was 10.1 weeks with a range of 3 to 14 weeks.

Six (10%) had prior experience of an MVA; among these, all but one were dissatisfied with their previous experience. Only one had been offered pain medication, which was a PCB, and she was not given a choice on the mode of pain relief provided. The majority (63.9%) of patients chose their MVA provider based on whether that provider was known to be skilled at the procedure.

Prior to the MVA more than half (51%) of the 61 patients enrolled in the study indicated that pain was their biggest concern, with anxiety and fear of the unknown expressed by 12 (20%). Sixteen (26%) reported no fears nor concerns. When asked on how painful they thought the MVA would be, the mean score on the VAS was 6.8 (SD 2.3) This contrasted with the 4 (SD 2.1) mean pain score they reported during evacuation.

In describing the desirable characteristics of pain provision during MVA, the need to remain awake and aware during the procedure was the most common (42%), with efficacy of analgesia being second. Some of the participants indicated they would tolerate some pain if this was necessary for the safe completion of the procedure. A fear of not awakening from sedation or anesthesia was also expressed.

Table 2: Characteristics and perceptions of 61 patients undergoing manual vacuum aspiration

Variable	Number	%
Age		
Median (IQR)	26 (22,32)	
Education		
None	1	1.6
Any primary	19	30.6
Any secondary	50	50.0
Any post-secondary	11	17.7
Number Previous Pregnancies	1 (0,2)	
Gestational Age of Fetus (wks)	11 (9.5, 12)	
Prior Experience with MVA		
Yes	6	10
None	55	90
Biggest Concern		
Pain	31	51
Anxiety/Fear of unknown	12	20
No fears	16	26
Desired qualities of pain control		
Retains consciousness	26	42
Effectiveness of analgesia	17	27
Wanted to be unconscious	14	23
Others [1]	4	6
Mean reported pain score on VAS (SD)		
Expected	6.8 (SD 2.3)	
Actual pre procedure	3.1 (SD 2.6)	
During uterine evacuation	4 (SD 2.1)	
Post procedure 30 Min	0.4 (SD 0.8)	
Experience of MVA with PCB		
Satisfied	52	85
Tolerable	8	13
Unhappy	1	2
Would Recommend MVA with PCB to a Friend		
Yes	59	97
No	2	3

[1] Others include – memory erasing, oral, injectable, allows same day discharge
[2] patient indicates she was not given any analgesia

Some patients felt the need to be able to witness the procedure and thus later explain it to their friends and kin. Fourteen (23%) expressed a desire to be totally asleep during the procedure. The ability to leave the facility on the same day was also listed as a good attribute. Parenteral medication was preferred to oral.

"I prefer less pain. I hate hospitals so that is why I said to leave immediately. I don't like taking oral medications. I prefer to remain awake due to fear of not waking up from sedation."

Fifty-one (84%) were satisfied with the provision of MVA under PCB and nearly all (95%) would want to be offered PCB again if they were to have MVA, with 97% indicating they would recommend it to a friend. Of the patients who were not satisfied, reasons for dissatisfaction included pain with speculum insertion, pain with injection of the PCB, and a desire for the procedure to be done under general anesthesia. When asked if they would be willing to pay an additional cost to receive pain medication during an MVA, 44.3% said they would with 43% saying they would be willing to pay more than KES 200 (1.67 USD). Of those who said they would not pay an additional cost, 83% cited financial instability.

"My previous expectation was of pain. The experience of the injection was good."

Discussion

This study is one of few documenting perceptions of pain among women during MVA treatment. In addition, our results contribute insights gained from providers practicing MVA.

The wide range in experience of the providers (1 – 12 years) is not unusual in internship centres where newly qualified practitioners practice under the wings of their more experienced mentors. Providers pointed out that excessive pain was a common reason that made the MVA procedure difficult to perform.

They perceived the procedure as painful for their patients, giving it a score of 6.5 on the VAS. Notably, this was little different from the 6.8 that the patients reported as expecting prior to the procedure. Despite their perception that the procedure is painful, the providers reported that in 20% of the instances they offered no pain relief whatsoever. This is in keeping with Solo's description that, after training on MVA, most aspects of care improve except pain management [16].

A study in Malawi when MVA was being introduced to the country reported 25% of the participants describing the procedure as painful and intolerable, and yet half saying the pain was tolerable[6]. The

paucity of data on and wide heterogeneity in patients' experiences of pain during MVA, sometimes even with provision of analgesia, might have contributed to the delay in recommending humane care for the service [16,17].

Lack of equipment and proper training were pointed out as the reasons for inadequate pain control. These have been described in previous publications [16]. Other causes for poor pain control have been described and include the opinion of some providers that the procedure can be completed with only prior counseling and verbal reassurance, or that an open cervix obviates the need for analgesia[16]. Studies have also reported that some providers have personal biases on abortion care that make them see patient pain as a deserved punishment for terminating an unwanted pregnancy[16,18]. Indeed, incidences have been described where patients will be interrogated to establish whether they had an induced or spontaneous abortion as a determinant of whether they deserved pain relief. This discriminates against the unmarried and young, yet some studies have demonstrated that adolescents are biologically more susceptible to higher pain scores than adults [11,19].

The varied responses from the providers on pain control during MVA highlights the lack of standard facility-based protocols for MVA analgesia and are similar to findings in Kilifi, Kenya [11]. That MVA is a painful procedure is not a recent realization, with papers going back decades advocating for the provision of wholistic pain relief for women undergoing MVA[16].

Our study participants listed pain along with fear of not waking up from the procedure as their main concern prior to the procedure. This is similar to other work in Tanzania, Kenya, and India[3,16,20]. Infertility, incomplete abortion and death have variously been described as other principal concerns for women seeking abortion care either by medication or surgery [3,16,20]. Across these studies, as in ours, one encounters the ardent voice of women's lamentation for adequate pain relief during MVA. In an exploration of the lived experiences of girls receiving MVA treatment in Kilifi, all the study participants described MVA as very painful, some saying it was worse than child birth; whereas some women screamed, others bore the excruciating pain in silence, fearing that their expression would breach confidentiality. We have witnessed the screams of patients receiving an MVA and have seen how inadequate pain control during one procedure can impact many others. Women waiting for MVA care hearing the screams of those before them will sometimes leave treatment facilities, exposing them to risk of severe morbidity or even death. This highlights the need for adequate analgesia in addition to comprehensive pre-procedure counselling [11].

Abandonment of the MVA procedure due to severe pain has also been described in other studies[11]. This is particularly distressing considering the consequences of incomplete abortion include death. In the Kilifi study the health provider turned around to blame the uncooperative patient for the failure of treatment[11]. All six of our study participants who had ever had an MVA reported a negative experience during which pain relief had not been provided except in one instance. Even when pain control was provided, that patient was not given a choice or preference in the matter. Abandonment of the procedure lends credence to assertions that provision of MVA without pain relief can be traumatizing to the provider and unsafe for the patient [16].

The ideal pain relief experience described by the patients in our study would include parenteral medications that are effective and do not induce loss of awareness and allow one to go home on the same day.

The need for provision of pain control should not lead to over medicalization of the procedure or a loss of access to the procedure outside of an operating theatre; general anesthesia would be excessive and undesirable in most cases[16]. A fear of not reversing after general anesthesia should not be downplayed. This is similar to a fear of death during the procedure that was expressed by women seeking abortion services in Kenya and India [16].

Paracervical block fits many of these criteria and most of the clients (95%) were agreeable to having the block if ever they would undergo MVA again. Our findings support the WHO change in guidelines to offer PCB at a minimum with every MVA conducted. Importantly, we recommend that pain control options and recommendations be part of the informed consent discussion prior to any MVA procedure and that shared decision making between a patient and provider take place to create a pain management plan that best respects her humanity

and bodily autonomy. As seen in our findings, there was a small subset of women for whom PCB alone was not adequate for pain control during MVA. Paracervical block is but one tool in the armamentarium of possible pain management options. We advocate for thoughtful pre-procedural counseling where a patient is given all the options with risks and benefits to decide a best approach with the provider.

Strengths and limitations

Both the study sites were public facilities and may not be reflective of the experiences of abortion services in the general population considering a widely held perception in Kenya that provider and client experiences in public facilities are different from those in private facilities [3] The sample size especially of the providers is small. Because our results are based on face-to-face interviews, they may be subject to social desirability bias and the observer's paradox. We minimized this by establishing a rapport with the participants and by constructing questions in a neutral, non-leading manner. Six (10%) of the clients were asked about MVAs done in the past, their responses may be subject to a recall bias, that could have been influenced by their imminent procedures

Conclusions

The experiences shared in this study reveal the need for adequately addressing pain management during MVA. The current WHO guidelines on pain management during MVA can be adopted as the default template that hospitals could use in formulating domesticated protocols. Health workers who conduct MVA should be trained on pain provision, including PCB for MVA and to be sensitive to the varied expectations of their clients. Facility managers should ensure commodity safety that guarantees provision of humane treatment for abortion. It is no longer acceptable to provide MVA without taking into consideration a patient's concerns regarding pain relief.

Data availability

The data supporting this study will be shared by the corresponding author on reasonable request.

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This work was funded by the Obstetrics and Gynaecology department of the University of Illinois Chicago. The funders played no role in the conduct of the trial including writing of the report. The university does not own any part of the Chloe SED® and has no financial stake in it. The results of the clinical trial were used to seek funding from Grand Challenges Canada (GCC) to undertake and complete a larger validation trial, analysis of the results is still ongoing. Two start-up companies, Chloe Innovations LLC and Chloe SED LLC have been formed by AR, KHT, SG and EK to hold the device intellectual property.

Contribution of authors

AR, KS, EK, and SG invented the Chloe SED device and provided instruction for its use and maintenance during the study. JCD provided mentorship in device design use/maintenance protocol development. The study was conceived by AR, KS, RB, JCD, and SG. JI and SO collected and curated the data. AR, SG, and RB conducted the data analysis. SG wrote the original manuscript and KS, RB, JI, AR, EK, JCD and SO reviewed and edited the manuscript. SG, AR, and KS, had final responsibility for the decision to submit for publication

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