UNIVERSITY OF CAPE TOWN

A STUDY COMPARING PARACERVICAL BLOCK WITH PROCEDURAL SEDATION

IN THE SURGICAL MANAGEMENT OF INCOMPLETE/MISSED MISCARRIAGES

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10/16/2014

SUPERVISOR: DR G PETRO CO- SUPERVISOR: DR A REED

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DECLARATION BY CANDIDATE

I, Dr Manasri Naiker, hereby declare that the work contained in this dissertation is my original work and work by others has been acknowledged as such.

This study was carried out while a registrar in the Department of Obstetrics and Gynaecology at the University of Cape Town as required by the College of Obstetricians and Gynaecologists of South Africa for the qualification of FCOG (SA).

Name of applicant: Dr Manasri Naiker

Signature: _____

Date: _____

DECLARATION BY SUPERVISORS

The research which was undertaken by Dr Manasri Naiker and the presentation of this dissertation was supervised by Drs G Petro and A Reed.

We are satisfied that this was Dr M Naiker's original work and that this dissertation should be submitted in part fulfillment of the requirements of the FCOG (SA) examinations.

Supervisor: Dr G Petro

Signature: _____

Date: _____

Co supervisor: Dr A Reed

Signature: _____

Date: _____

ABSTRACT

Objective: To compare the analgesic efficacy of Paracervical Block (1% lidocaine) with procedural sedation (Midazolam/Fentanyl) in the surgical management of incomplete/ missed miscarriages.

Study design: An efficacy trial with a naturally occurring control group who received what is standard practice. The study compared two methods of analgesia. The study group received paracervical block and the control group received procedural sedation. The study ran over two consecutive months (December 2012/January 2013).

Setting: Groote Schuur Hospital, a level three hospital situated in Cape Town, South Africa.

Population: All women between 18 and 55 years of age that were admitted to Groote Schuur Hospital requiring a uterine evacuation following either a spontaneous incomplete or a missed miscarriage that were not excluded by any of the exclusion criteria.

Methods: Over the two month period recruited participants (those patients who fit the inclusion criteria and were agreeable to participate) were allocated to either the control group (month 1) or the intervention group (month 2), depending on which month they had the uterine evacuation. Data was collected from the uterine evacuations of the recruited participants over the two month study period.

Main outcome measure: The participants perceived pain during and after uterine evacuation (10 minutes and two hours), scored by the participant on an eleven point numerical pain scale. Secondary outcomes were the surgeons' satisfaction with the analgesia, duration of procedure and complications/ side effects of the two methods of analgesia under study.

Results: A total of 111 participants were recruited over the study period, 57 in the control group and 54 in the intervention group. The average pain score during the procedure was lower in the Paracervical block group compared with the procedural sedation group, but this difference was not statistically significant at a 5% level (t=-1.8495, p=0.0671). For the Paracervical block group, the ‘’pain during” mean and the standard deviation (SD) were 5.56 and 2.50 respectively, whilst for the Procedural sedation group, the mean and SD were 6.49 and 2.81 respectively.

Conclusion: Paracervical block using 1% lidocaine is an effective and safe alternative to procedural sedation in the surgical management of incomplete/missed miscarriages.

ACKNOWLEDGEMENTS

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3. The nursing staff in C24 and my fellow registrars that helped to collect data, this would not have been possible without you.
4. Dr D Krick (Principal investigator of the Ketamine versus procedural sedation study) for her direction on the methodology and study design.
5. Katya Mauf for her help with the statistical analysis.

INTRODUCTION AND LITERATURE REVIEW

The incidence of first trimester pregnancy loss is around 14- 19% of registered pregnancies. [1, 2] Therefore it is no surprise that admissions for incomplete and missed miscarriages constitute a major proportion of the gynaecology workload of public sector hospitals in South Africa. [3] Approximately 50% of early pregnancy losses are caused by chromosomal abnormalities. Other causes include infection, reproductive tract abnormalities, exposure to toxins, and uncontrolled endocrine or auto immune disease in the mother. Diagnostic testing to determine etiology of the loss is limited [4]

Therapeutic options for incomplete miscarriages include expectant, medical and surgical management. [2, 5] Surgical treatment has been the method of choice for years and is effective but is not without complications, such as uterine perforation. Medical management usually involves the systemic and /or local administration of a prostaglandin analogue. [2] The effectiveness of different treatment modalities has been studied by several randomized controlled trials. A meta- analysis by Sotiriadis et al concluded that one additional successful evacuation is achieved for every three women treated surgically rather than medically. [2] A comparative review by Bygdeman et al concluded that both methods are equally well accepted provided the patient has the choice. [5]

There is a vast amount of literature comparing sharp curettage to suction aspiration (electrical/manual). A Cochrane Review by Tuncalp et al shows statistically significant decrease in blood loss, intra procedural pain and duration of procedure when using suction curettage. [6] A comparative study by Mohamed et al also showed that MVA (manual vacuum aspiration) was just as safe as an even more effective in achieving complete uterine evacuation than sharp curettage, and therefore has the potential to decrease health costs

and improve patient care. [7] Adinma et al concluded that the Karman's cannula and vacuum aspirator '*is considered to be an invaluable, safe, and efficient tool in routine gynaecological practice'.* [8]

Uterine evacuation is associated with varying degrees of pain and requires some form of analgesia /anaesthesia. The various methods available are oral non- steroidal anti-inflammatory drugs (NSAID), local anaesthetic (topical/injectable), intravenous/ inhalation procedural sedation and analgesia and general anaesthesia. It is recommended by the World Health Organisation (WHO) guideline of 2002 that for uncomplicated evacuations general anaesthesia be avoided. This is to decrease its associated morbidity/mortality, particularly the loss of airway control.

In the Western Cape public health sector, procedural sedation and analgesia (PSA) is commonly used for uterine evacuations.PSA reduces the discomfort, apprehension, and potential unpleasant memories associated with an evacuation. PSA involves the use of short acting analgesic and sedative medication thus allowing a clinician to perform the procedure effectively. PSA exists along a spectrum, of which some of the commonly used terms are listed below.

- Analgesia – relief of pain without sedation.
- Minimal sedation – able to respond normally to verbal commands, cognitive function and co ordination may be affected. Ventilation and cardiovascular function are not affected.
- Moderate sedation and analgesia- able to respond purposefully to verbal commands alone and to light touch. Ventilatory and cardiovascular function is not affected.

- Deep sedation and analgesia- patient not aroused easily responds purposefully to noxious stimulation. Ventilatory function may be affected. Cardiovascular function is unchanged.
- General anaesthesia- patient is not arousable, requires full ventilatory support. May have cardiovascular impairment.
- Dissociative sedation – is a trance- like cataleptic state. Patient experiences profound analgesia and amnesia. Ventilatory and cardiovascular functions remain stable. Ketamine causes dissociative sedation. [9]

The most common PSA used, is a combination of midazolam and fentanyl. Midazolam is a short acting benzodiapine that possesses a potent anxiolytic, amnesic, hypnotic, relaxant and sedative effect. Some of its side effects are hypotension, respiratory depression and impaired cognitive/ psychomotor function. Fentanyl is a potent synthetic analgesic that acts at the opioid receptor. It has a rapid onset and a short duration of action. One of the rare but more serious side effects is hypoventilation and apnea. Due to the potential side effects of the midazolam and fentanyl cocktail, the clinician performing the procedure must be skilled in the knowledge about the drugs being used. A recent retrospective case review done at a District Hospital in Cape Town demonstrated that PSA can be safely administered by medical officers with no official anaesthesiology training provided they kept to PSA guidelines and had knowledge on management of the upper airway. [10] An anaesthetic nurse must be present to monitor the patient for any possible side effects, and the administration of PSA necessitates a monitored recovery period. [9, 11]

For the reasons mentioned above uterine evacuations done under PSA often require the procedure to be done in an operating theatre environment. Awaiting theatre space may result in unnecessary delays. The following may be a consequence.

- Increase in pre- procedural blood loss.
- Increased risk of sepsis due to retained products of conception
- Increased duration of inpatient stay

The end result affects patient care and health care costs adversely.

The study aim was to look at an alternate to PSA, one that could possibly be more efficient and safer, (with less systemic side effects) therefore requiring less intra and post-procedural monitoring. This study investigated the efficacy and safety of a paracervical block (PCB) using lidocaine.

In 1850 an Austrian named von Scherzer brought an adequate quantum of coca from Peru to Europe, which permitted the isolation of cocaine. Sigmund Freud first suggested that coca had powerful anaesthetic properties, which led the Austrian, Koller in 1884 to perform the 1st operation under local anaesthetic with the administration of cocaine to the eye. The toxic effects of cocaine soon became evident, but with the development of modern organic chemistry, pure cocaine was synthesized in 1891. Between 1898 and 1972 amino amide local anaesthetics including lidocaine became available. [12]

Local anaesthesia is commonly used in various minor gynaecological procedures. [13] The ease and efficiency of the paracervical block makes it a popular choice, especially in an outpatient or office setting. [14] It has been shown to be a safe method of anaesthesia for hysteroscopy and transcervical surgery. [15]

Pain associated with cervical stretching and uterine contraction is transmitted through visceral afferent nerve fibres which accompany the sympathetic fibres that pass through aggregates of nerve fibres and enter the spinal cord at T11 and T12. These fibres, which are adjacent to the cervix, can easily be bathed in local anesthetic solution therefore making blockage possible. The transverse cervical ligaments lying just deep to the lateral fornices of the vagina are a good landmark.

The uterine artery and vein and their branches also lie in the lateral fornices. Their close proximity to these nerve fibres creates potential for an adverse outcome. Therefore meticulous technique needs to be followed to avoid injecting high doses of local anaesthetic into these vessels.

There are many variations with regard to the site of injection. Randomised clinical trials have not found differences with respect to the application of the anaesthetic at the 3, 5, 7 and 9 o' clock, the 4 and 8 o' clock positions or circumferential application in the cervix. [16, 17]

Local anaesthetic works by reversibly blocking calcium channels in membranes of nerve fibres resulting in the inhibition of action potentials and nerve impulse transmission. The degree of blockage is dependent on the diameter of the nerve fibre. The smaller the diameter, the quicker the onset of the block. The sensory modalities are lost in the following order, as the block takes it effect.

1. Pain
2. Temperature
3. Touch
4. Deep pressure
5. Motor function

This explains why a patient may have retained motor function with adequate analgesic effect.

Some local anesthetic agents are more lipophilic than others, and therefore are bound to receptor sites for longer, resulting in a longer duration of action. Eg. Bupivicaine>lidocaine

These drugs can be divided into two chemical classes, either Amides or Esters.

Amides are metabolized in the liver and therefore remain longer in circulation. There is a risk of accumulation and toxicity.

Esters are broken down rapidly in blood; therefore risk of toxicity is less. A byproduct p-amino benzoic acid (PABA) can be allergenic. [13]

This study will use lidocaine 1%, which is an Amide. Its onset of action is 4 -10 minutes. Duration of action is approximately 60 – 120 minutes. Its maximum dose is 4.5mg/kg.

Adverse effects are few and are largely dose related. Toxicity usually results from repeated doses.

Toxicity with increasing plasma concentration manifests as

1. Numbness of tongue
2. Lightheadedness
3. Auditory and visual hallucinations
4. Muscular twitching
5. Seizures
6. Unconsciousness
7. Coma
8. Respiratory arrest
9. CVS depression.

There is a vast amount of literature comparing PCB to either placebo or other analgesic and anaesthetic agents for uterine evacuation. There are also studies looking at using PCB in combination with other agents.

Two trials comparing PCB with 1% lidocaine to placebo (PCB with either normal saline or sterile water) showed a significant decrease in pain during uterine evacuation in the lidocaine group. The rationale for using normal saline or sterile water for paracervical injection was that the local anaesthetic mechanism may have been from distention of nerve capsules rather than blockage of specific autonomic nerves. [18, 19]

A randomized control trial by Mankowsi et al comparing PCB to an intracervical block showed no difference between the two groups, though a possible confounding factor was that both groups also received procedural sedation. [20] A prospective trial by Owolabi et al looked at PCB with NSAID (diclofenac) and intra-cervical block. The group receiving all three agents was superior to the group using NSAIDS alone. [21]A Cochrane review published in 2009 titled 'Paracervical local anaesthesia for cervical dilatation and uterine intervention' compared PCB and other anaesthetic and analgesics agents for women undergoing uterine intervention. No difference in effectiveness and safety was found between PCB and other anaesthetic and analgesic methods, however PCB using a local anaesthetic agent compared to placebo (injection of saline) reduced abdominal pain during uterine intervention (endometrial biopsy, fractional curettage, suction evacuation) by two or three points on a ten point scale. [22]There is interesting research looking at PCB in combination with local application of lidocaine spray or gel [23, 24] which has shown some benefit. The evidence seems to be somewhat conflicting, thus encouraging further investigation of the efficiency of PCB.

HYPOTHESIS AND AIMS OF THIS INVESTIGATION

Hypothesis

Paracervical block with 1% lidocaine is an effective alternative analgesia compared to procedural with midazolam/fentanyl for the surgical management of incomplete and missed miscarriages.

Aims

The aim of this study was to determine the analgesic efficacy of paracervical block in patients undergoing suction curettage for incomplete and missed miscarriages.

Objectives

The primary objective of our study was to compare the analgesic efficacy of paracervical block with procedural sedation (midazolam/fentanyl) in women requiring uterine evacuation for incomplete/missed miscarriage as measured by the patients' perceived pain.

Secondary objectives were:

- Complications and side effects,
- Surgeon's satisfaction with analgesia and impact on the procedure.

Study Design

This was an efficacy trial with a naturally occurring control group who received what is current practice.

We followed a group of patients and tested a new treatment (analgesic option). The inclusion criteria consisted of all women requiring surgical management (uterine evacuation) following a miscarriage. In two consecutive months patients were allocated to

the control group (month 1) and the study group (month 2). Data was collected from all recruited participants who had a uterine evacuation in these months at Groote Schuur Hospital/ C24 (gynaecology triage area). The objectives, study design and data collection were purposefully similar to the Ketamine Trial that was undertaken in C24 for two reasons. The first reason was that it was familiar to the staff (doctors/ nurses) collecting the data. Secondly there is an interest in analysing and comparing outcomes of the two studies at a later stage, with the hope of carrying out a randomized control trial looking at different analgesic options for uterine evacuation.

Inclusion criteria

Patients considered eligible for the study were all women between the ages of 18 and 55years admitted to GSH for uterine evacuation following

- a spontaneous incomplete miscarriage
- a missed miscarriage

Exclusion criteria

Patients with the following findings were excluded from the study

- A ward haemoglobin concentration of 8g/dl or less (done using a Hemocue R machine)
- Signs of sepsis (temperature >37.5, foul smelling vaginal discharge)
- Evacuation for socio economic motivated termination of pregnancy
- Any uterine evacuation performed for a patient admitted into the general gynaecology wards due to logistic reasons

Also any women who refused informed consent was not included in the study and received standard procedural sedation.

Data collection commenced once approval was obtained from the Research Ethics Committee of the Faculty of Health Sciences at the University of Cape Town.

METHODOLOGY

All patients that were suitable received an information leaflet in English, Afrikaans or Xhosa (Addendum 1). The attending doctor explained the outline of the study to the patient and consent was obtained. (Addendum 2)

The current standard protocol for monitoring of patients undergoing procedural sedation for uterine evacuation includes the measurement of blood pressure before and after the procedure. The patient's pulse and oxygen saturation is monitored throughout the procedure using pulse oximetry. These basic monitoring measures were continued throughout the study duration. Values of blood pressure, maximum pulse and lowest oxygen saturation were recorded in the data collection sheet.

In the first month of data collection (December 2012 – control group) Fentanyl/Midazolam was administered. The doses used for procedural sedation were 100mcg Fentanyl and 5mg Midazolam administered as an intravenous injection.

In the second month of data collection (January 2013 – intervention group) all recruited patients received paracervical block (PCB). The block was administered by the doctor performing the evacuation. This was either a registrar or an intern under supervision. The doctor was deemed experienced in administering the block if he/she had previously performed a minimum of five PCB as a qualified doctor. If the attending doctor did not fulfill this criteria then the Principal Investigator (Dr M Naiker, who had performed approximately 40 PCB previously) demonstrated the block to the attending doctor and supervised him/her for the first five PCB performed.

Procedure for Paracervical Block: With the patient in the lithotomy position, a cuscos speculum was inserted into the vagina so that the cervix could be visualized in its entirety. Any blood or pieces of retained products of conception that was obscuring vision, was

gently wiped away. Then the 4 o'clock and 8 o'clock positions at the junction of the cervix and the vaginal fornices were identified. A 10ml syringe was used to draw up 10mls of 1 % (100mg) lidocaine solution. A 22 gauge needle(or a black spinal needle) connected to the syringe was then injected into the sites mentioned above to the depth of 3mm- 7mm, drawing back first to ensure that the needle was not in a vessel. Then 5mls of the 1% lidocaine was injected into each site. A chart with step by step instructions on how to administer the block was put up in C24 to serve as a reminder (Addendum 3).Once the block was given the clinician removed the cuscos speculum and waited approximately 5 minutes before the uterine evacuation was commenced.

Routine uterine evacuation involved the bladder being emptied with an in and out catheter. Then a bimanual examination was performed to determine the uterus size and position. An Auvard speculum was inserted into the vagina, so that that the cervix could be visualized. The anterior lip of the cervix was grasped with a sponge holding forceps and any products of conception at the cervical os were removed with an ovum or polyp forceps. The ovum or polyp forceps was introduced into the uterine cavity to remove remaining tissue. At this point an oxytocin infusion (20 units of oxytocin in one liter of normal saline over 2-4 hours) was commenced if found necessary.

Evacuation was completed by either sharp curettage or suction aspiration (wall suction at –50mmHg or manual vacuum aspiration) with the largest Karman cannula that could pass through the cervix. If severe blood loss occurred it was managed with rubbing up the uterus and by giving oxytocin (intravenous infusion) or misoprostol (600mcg per rectum). The procedure was completed once all retained products of conception were removed and the uterus contracted. This was detected clinically when no more products were seen coming

through the cannula, a gritty feel was felt when the cannula moved against the endometrium and the uterus contracted down.

When pain relief was thought to be inadequate to the point at which the procedure was unable to continue, the surgeon then administered extra analgesia, being either 5mg midazolam, 100mcg fentanyl or both.

During the procedure the attending nurse asked the patient to score her perceived pain on an 11 point numerical rating scale (0-10) (Addendum4). The pain score was repeated at 10 minutes post procedure by the nurse in recovery and then at 2 hours.

Other data recorded on the data collection sheet included:

- time interval from PCB to procedure starting
- length of procedure
- ease of procedure
- surgeons' satisfaction with the anaesthetic/ analgesia (patient's co- operation)
- estimated blood loss
- need for additional analgesia over the primary agent
- any adverse effects

Safety considerations

Uterine evacuations of stable patients at Groote Schuur Hospital occur in the gynaecology triage suite (ward C 24). There is a specially allocated theatre and scrub area in C24 for the main purpose of uterine evacuations and other minor gynaecological procedures. Medical staff that where present were the surgeon (registrar), trained theatre sister and a nurse. Blood pressure and pulse were checked prior to the administration of the anaesthetic/analgesia. The patient was monitored throughout the procedure with pulse

oximetry. Monitoring was continued in the recovery /post procedure short stay area (also in C 24) for about 15 minutes. The patient was then observed for about 6 -8 hours post evacuation and if stable was subsequently discharged. C24 is equipped with a cardiovascular/ respiratory emergency trolley. In the case of a cardiovascular/ respiratory arrest there was always either an emergency medicine registrar (in C15) and/or an anaesthetist from main theatre (D16) that could have been requested to assist in resuscitation. All medical staff in C24 was informed of the possible side effects of paracervical block with special mention of the fact that most adverse effects are dose related. Staff training sessions/ briefings were given, as well information sheets.

Patient follow up

The patient was reviewed and assessed before discharge as is routine practice (either by registrar or intern). That included checking the vital signs (blood pressure, pulse and temperature), haemoglobin and vaginal bleeding. If the patient was deemed fit for discharge she was informed that if bleeding continued or if she developed a fever or a foul smelling vaginal discharge, she was to return to hospital. All patients with pregnancy related complications had their blood grouping done and were screened for syphilis and treated accordingly. Routine discharge medication for patients post evacuation were simple analgesia (paracetamol/ibuprofen), oral antibiotics (metronidazole and doxycycline) if indicated, and iron supplements if their haemoglobin was less than 10g/dl. Family planning options were discussed with the patient and dispensed accordingly.

Data Management and Statistical Analysis

Data collection sheets and participant information leaflets with consent forms were readily available in C 24. The study was outlined by the attending doctor to the possible participant (recruited patient). Consent was obtained once a participant had read through the participant information leaflet and was agreeable to participate. The Participant Information Leaflet was then separated from the consent form and given to the participant to take home. The Data Collection Sheet was then placed into the participant's hospital folder and was available at time of uterine evacuation. Data was collected by a sister/doctor and was entered into the Data Collection Sheet. At discharge the Data Collection Sheet was handed to the Principal Investigator, who then captured the data.

The participant's Data Sheet included a random 'study ID number'. The participants name, hospital number and corresponding study ID number was recorded on the participant's consent form. The Principal Investigator had sole access to this information and it was kept in a secure location to ensure patient confidentiality. Data was entered into an Excel spreadsheet on a password protected computer. The original paper data was filed and kept in a secure location, only accessible to the Principal Investigator.

Data was analyzed using standard statistical techniques. Categorical data were compared using odds ratio with a 95% confidence interval. Continuous variables were analyzed using the t test if normally distributed and with the Wilcoxon rank sum test if data was skewed. A P – value of less than 0.05 was regarded as 'statistically significant'.

Sample sizes were expected to be approximately 50 to 80 patients per group. This was estimated from the average number of uterine evacuations performed in patients over the age of 18 years using procedural sedation over 6 month duration at Groote Schuur Hospital (C24).

Study Duration

September 2012 : Protocol handed into the Research Ethics Committee of the Faculty of Health Sciences of the University of Cape Town.

November 2012 : Ethics approved

December 2012 : Control group data collected

January 2013 : Study group data collected

February 2013 : Statistical analysis

March 2013 : Write up and completion of dissertation

Anticipated problems

We anticipated an adequate number of patients willing to participate. The 2 hour pain score was anticipated to be a problem, for the staff may be occupied with other work. Thus this follow up was allowed the leeway of happening between 120- 180 minutes post procedure.

Ethics

Ethical approval for the study was granted from the Research Ethics Committee of the Faculty of Health Sciences of the University of Cape Town. HREC NO: 521/2012

Enrolment was on a voluntary basis. The participant gave written consent once she had read through the Participant Information Leaflet (the procedure and study explained in lay terms) and had agreed to participate. The surgeon/ investigator also signed the consent stating that he/she had adequately outlined the study and that the participant understood the information given. The consent included one witness.

Budget

The costs of the study were the responsibility of the Principal Investigator, Dr Manasri Naiker. The UCT Department of Obstetrics and Gynaecology will be approached with possible assistance/reimbursement from the Registrars Research Fund.

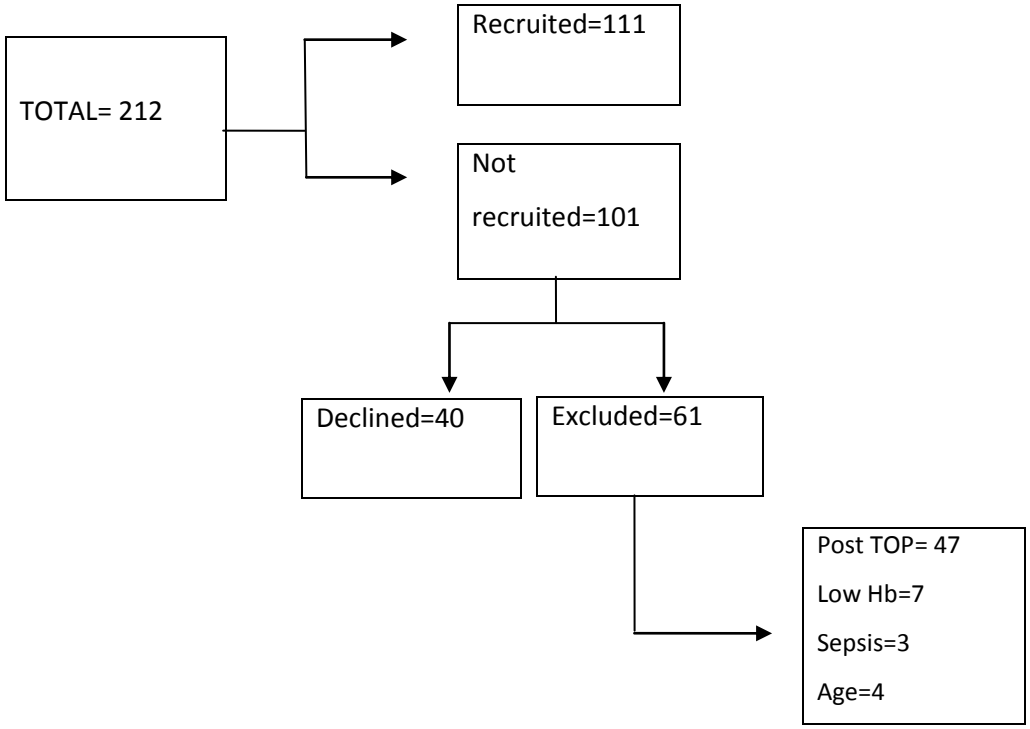
Dissemination of results

The data collected will be presented at relevant seminars and scientific meetings. We hope to carry out a large randomised controlled trial comparing different methods of analgesia during uterine evacuation.

RESULTS

Over the two month study period a total of 212 uterine evacuations were performed in C24. 111 (52%) participants were recruited and 101 (48%) were not. Of the 101 patients that were not recruited, 40 (39.6%) patients declined participation and 61 (60.4%) were excluded according to the exclusion criteria.

Figure 1: flow diagram of study participants and reasons for non recruitment



Of total number of 111 participants were recruited, there were 57 participants in the control group (procedural sedation) and 54 participants in the intervention group (paracervical block -PCB).

Table 1: Depicts participants per group.

GROUP	FREQUENCY	PERCENTAGE
PARACERVICAL BLOCK	54	48.65
PROCEDURAL SEDATION	57	51.35
TOTAL	111	100

There were 72 incomplete miscarriages and 39 missed miscarriages in total over both groups:

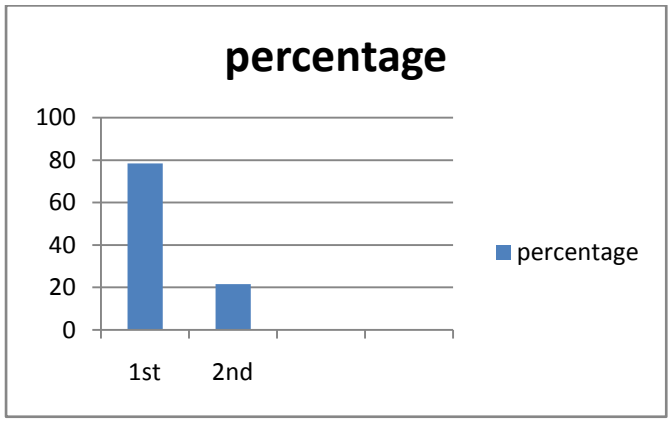
Table 2: Depicts different types of miscarriages

TYPE	FREQUENCY	PERCENTAGE
INCOMPLETE	72	64.86
MISSED	39	35.14
TOTAL	111	100

All participants who had a missed miscarriage received pre procedural vaginal misoprostol for cervical ripening (600mcg), and 2 participants who had an incomplete miscarriage received misoprostol (600mcg). Only 8 of the total number of participants required cervical dilatation before uterine evacuation and all 8 of these participants had a missed miscarriage.

There were 87 participants that had a 1st trimester miscarriage and 24 participants that had a 2nd trimester miscarriage.

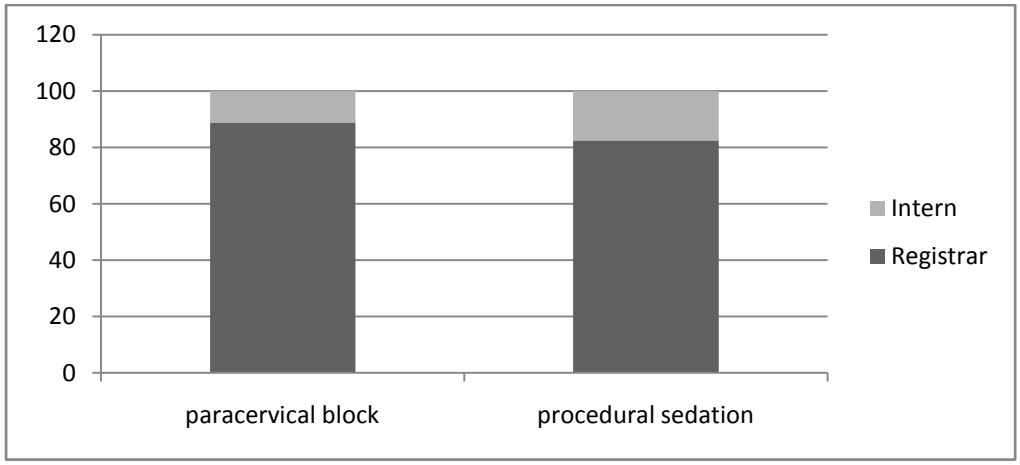
Figure 2: Percentage of 1st and 2nd trimester miscarriages of total recruited participants.



Surgeon performing procedure

Most uterine evacuations were performed by registrars. Only 16 out of the total 111 uterine evacuations were performed by interns, of those 6 and 10 were in the PCB and the procedural sedation groups respectively, with an OR 0.587 [95% CI 0.198-1.740]. This finding is not statistically significant.

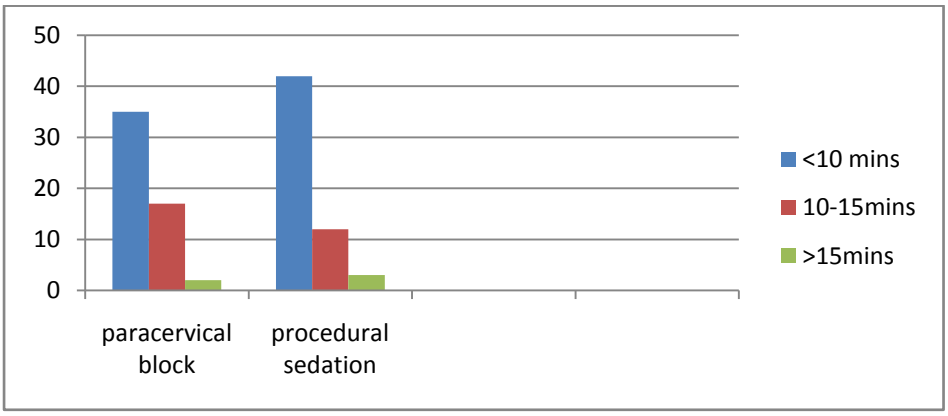
Figure 3: Percentage of uterine evacuations performed by intern/registrars across the 2 groups.



Procedure length

Most procedures were less than ten minutes. There were 35 and 42 uterine evacuations that took less than ten minutes in the PCB and procedural sedation group respectively and 17 and 12 uterine evacuations were between 10 -15 minutes respectively. The number of uterine evacuations that were longer than 15 minutes duration was 2 in the PCB group and 3 in the procedural sedation group. OR 0.692 [95% CI 0.111-4.309]. This finding is not statistically significant.

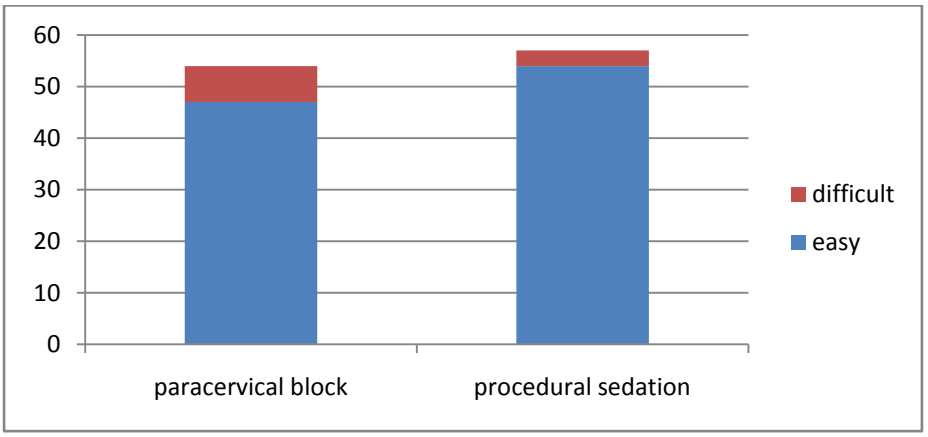
Figure 4: Frequency of procedure length between groups.



Difficulty

Seven of the uterine evacuations in the PCB group were difficult to perform compared the 3 in the procedural sedation group, with an OR 2.680 [95% CI O.680-10.560]. This finding was not statistically significant.

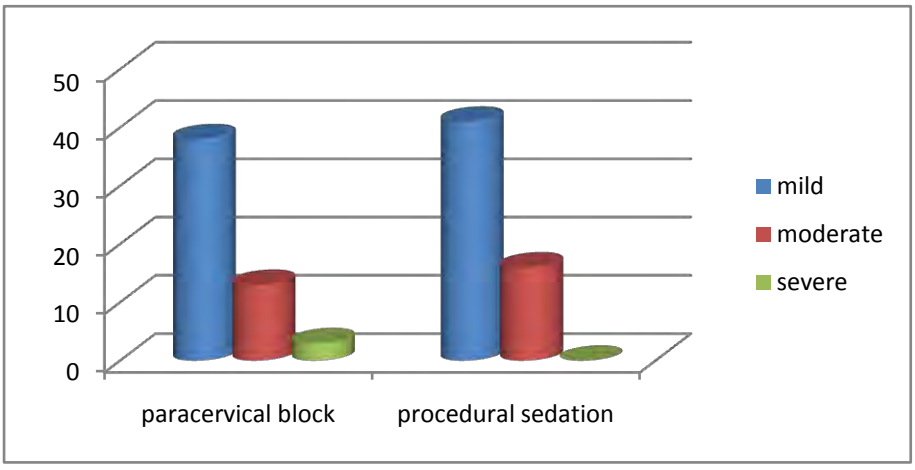
Figure 5: Ease of procedure between groups.



Blood loss

Severe blood loss was documented in 3 uterine evacuations in the PCB group and none in the procedural sedation group.

Figure 6: Estimated blood loss across the groups.



Unco- operative patients

There were 8 (7.21%) participants in total that were uncooperative. Of the 8 participants, 7 required extra analgesia. Of the 7 participants requiring extra analgesia, 4 (57%) got an extra dose of 5mg of midazolam, 2(28%) got an extra dose of 100mcg of fentanyl and 1(14.2%)

got both. Four of these participants were in the PCB group and 3 were in the procedural sedation group. OR 1.44 [95% CI 0.307-6.754]. This finding was not statistically significant.

Figure 7: Percentage of participants requiring extra analgesia across both groups.

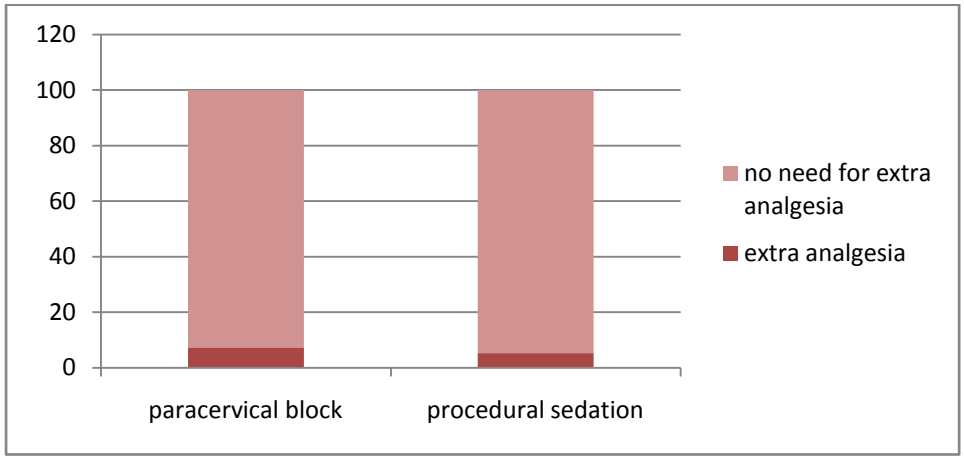
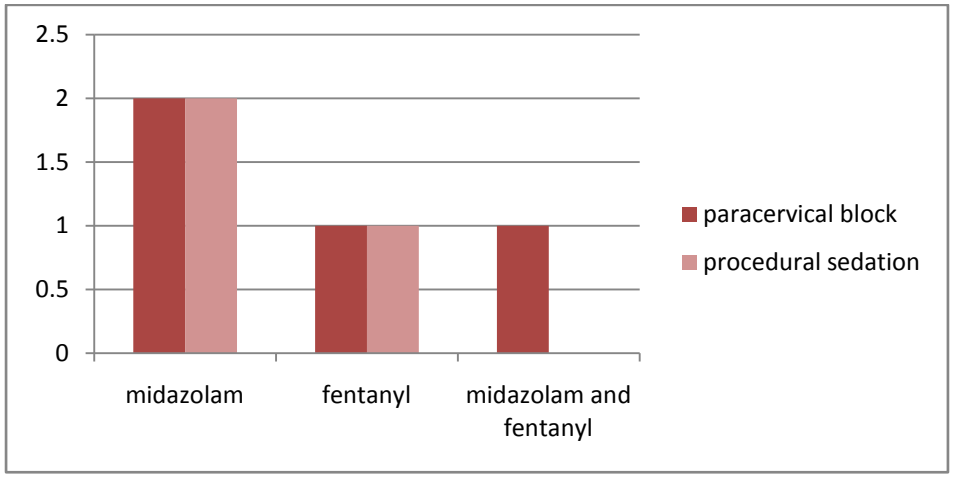


Figure8: Frequency of the type of extra analgesia used in each group.



101 (90.9%) of participants had a suction curettage compared to 10 (9.01%) participants that had a sharp curettage.

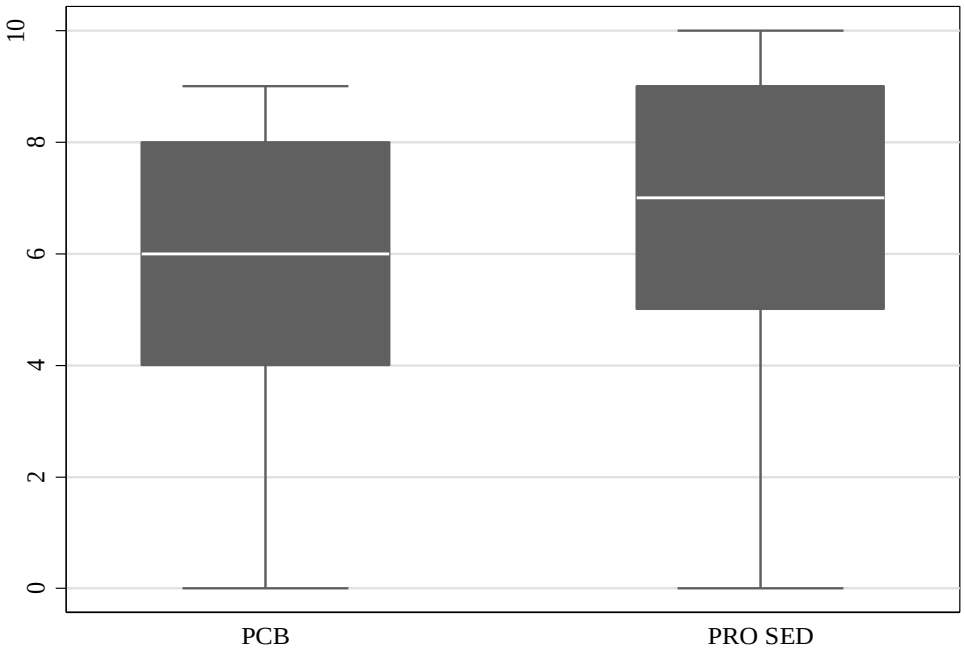
There was a 100% procedure completeness rate and no adverse effects across both groups.

There was no significant difference in the mean “pain during” value between the 2 groups (at a 5% level): t=-1.8495, p=0.0671. For the PCB group, the ‘’pain during ” mean and the standard deviation (SD) were 5.56 and 2.50 respectively, whilst for the Procedural sedation group, the mean and SD were 6.49 and 2.81 respectively, ie the average “pain during ” value was higher in then Procedural sedation group. There was no significant difference in the median or IQR between the 2 groups at the 10 minute and 2 hour pain scores.

Table 3: Pain scores at different time intervals between groups

VARIABLE	N	MINIMUM	MAXIMUM	MEAN	STANDARD DEVIATION	MEDIAN	25TH PERCENTILE	75TH PERCENTILE
PARACERVICAL BLOCK								
PAINDURING	**54**	**0**	**9**	**5.56**	**2.50**	**6**	**4**	**8**
PAIN10MIN	54	0	9	1.57	2.25	0	0	3
PAIN2HOURS	53	0	3	0.21	0.63	0	0	0
PROCEDURAL SEDATION								
PAINDURING	**57**	**0**	**10**	**6.49**	**2.81**	**7**	**5**	**9**
PAIN10MIN	57	0	6	1.63	2.02	0	0	3
PAIN2HOURS	57	0	3	0.37	0.84	0	0	0

Figure 9: The box plot below shows the median value, the IQR, and the minimum and maximum values for ‘’pain during ’’ for the 2 groups.



When we compared pain scores between those participants who had a uterine evacuation for either an incomplete miscarriage or a missed miscarriage, we found no significant difference in the mean or SD for the pain experienced during the procedure for either of the two types of miscarriages. There was no significant difference at the 10 minute or 2 hour pain score either. We further analysed the mean pain score during the procedure for each group (paracervical block and procedural sedation) within the different type of miscarriages (incomplete and missed miscarriages) and found no significant difference.

Similarly no significant difference was found when we compared pain scores at the different time intervals in those participants who had a 1st trimester and 2nd trimester miscarriage. This was also true when we analysed the mean pain score during the

procedure for each group (paracervical block and procedural sedation) for the different trimesters.

Table 4: Pain scores at the different time intervals for an incomplete and missed miscarriage.

VARIABLE	N	MINIMUM	MAXIMUM	MEAN	STANDARD DEVIATION	MEDIAN	25TH PERCENTILE	75TH PERCENTILE
INCOMPLETE MISCARRIAGE								
PAINDURING	72	0	10	5.90	2.87	6	4	8
PAIN10MIN	72	0	9	1.54	2.10	0	0	3
PAIN2HOURS	71	0	3	0.25	0.65	0	0	0
MISSED MISCARRIAGE								
PAINDURING	39	2	10	6.28	2.34	7	5	8
PAIN10MIN	39	0	7	1.72	2.19	0	0	3
PAIN2HOURS	39	0	3	0.36	0.90	0	0	0

Table 5: Sub group analysis- pain score during procedure for incomplete miscarriages

ANALGESIA	VARIABLE	N	MEAN	STANDARD DEVIATION
PARACERVICAL BLOCK	PAIN SCORE DURING	33	5.303	2.506
PROCEDURAL SEDATION	PAIN SCORE DURING	39	6.410	3.092

The difference in the mean pain scores during the procedure between the 2 groups was insignificant for those participants having an incomplete miscarriage, ie

-1.107 with the p value =0.659 and confidence interval of -2.423 to 0.209.

Table 6: sub group analyses- pain score during procedure for missed miscarriages

ANALGESIA	VARIABLE	N	MEAN	STANDARD DEVIATION
PARACERVICAL BLOCK	PAIN SCORE DURING	21	5.952	2.499
PROCEDURAL SEDATION	PAIN SCORE DURING	18	6.666	2.142

The difference in the mean pain scores during the procedure between the 2 groups were insignificant for those participants having a missed miscarriage, ie -0.714 with a p value of 0.743 and a confidence interval of -2.220 to 0.791.

Table 7: Pain scores at different time intervals in first and second trimester miscarriages.

VARIABLE	N	MINIMUM	MAXIMUM	MEAN	STANDARD DEVIATION.	MEDIAN	25TH PERCENTILE	75TH PERCENTILE
FIRST TRIMESTER								
PAINDURING	87	0	10	6.06	2.83	6	4	8
PAIN10MIN	87	0	9	1.62	2.27	0	0	3
PAIN2HOURS	86	0	3	0.28	0.76	0	0	0
SECOND TRIMESTER								
PAINDURING	24	2	10	5.96	2.18	5.5	5	7
PAIN10MIN	24	0	5	1.54	1.53	1.5	0	2.5
PAIN2HOURS	24	0	2	0.33	0.70	0	0	0

Table 8: subgroup analyses- pain score during procedure for 1st trimester miscarriages.

ANALGESIA	VARIABLE	N	MEAN	STANDARD DEVIATION
PARACERVICAL BLOCK	PAIN SCORE DURING	43	5.651	2.715
PROCEDURAL SEDATION	PAIN SCORE DURING	44	6.454	2.913

The difference in the mean pain scores during the procedure between the 2 groups were insignificant for those participants having a 1st trimester miscarriage, ie -0.803 with a p value =0.603 and a confidence interval of -2.003 to 0.396.

Table 9: subgroup analysis- pain score during the procedure for 2nd trimester miscarriages.

ANALGESIA	VARIABLE	N	MEAN	STANDARD DEVIATION
PARACERVICAL BLOCK	PAIN SCORE DURING	11	5.181	1.401
PROCEDURAL SEDATION	PAIN SCORE DURING	13	6.615	2.534

The difference in the mean pain scores during the procedure between the 2 groups were insignificant for those participants having a 2nd trimester miscarriage, ie -1.433 with a p value =0.820 and a confidence interval of -3.1487 to 0.281.

When pre operative blood pressure, post operative blood pressure, lowest oxygen saturation and highest pulse were compared across both groups, there was no significant difference seen in any of the variables.

Table 10: Pre/ post operative blood pressures, lowest oxygen saturation and highest pulse in both groups

VARIABLE	N	MINIMUM	MAXIMUM	MEAN	STANDARD DEVIATION	MEDIAN	25TH PERCENTILE	75TH PERCENTILE
PARACERVICAL BLOCK								
PRESBP	54	86	220	123.57	21.85	118.5	110	133
PREDBP	54	40	122	67.96	15.01	69	58	77
POSTSBP	54	84	222	118.59	21.81	118	105	128
POSTDBP	54	44	150	69.57	17.70	67.5	59	76
LOW O2	54	72	100	96.31	5.66	98	96	100
H PULSE	54	61	152	91.22	18.62	89.5	80	95
PROCEDURAL SEDATION								
PRESBP	57	89	192	119.67	19.87	118	104	129
PREDBP	57	40	100	63.68	12.03	63	54	73
POSTSBP	57	79	153	119.46	16.78	118	109	128
POSTDBP	57	40	101	67.42	12.02	68	61	73
LOW O2	57	75	100	96.25	4.69	98	95	99
H PULSE	57	67	138	93.07	15.21	91	82	100

DISCUSSION

Procedural sedation is a highly effective and safe method of analgesia for uterine evacuation when used correctly as recommended by the World Health Organisation.

Paracervical block is an effective alternate analgesia for women requiring a uterine evacuation for the management of incomplete/missed miscarriages, with pain scores comparable to that experienced with procedural sedation.

Approximately eighty percent of miscarriages were 1st trimester and twenty percent were 2nd trimester. About two thirds were incomplete miscarriages and one third missed miscarriages. The trimester and type of miscarriage did not have an effect on pain experienced. One would have expected the participants who had a 2nd trimester miscarriage to experience more pain since they had a larger sized uterus. A difference may have been demonstrated if sample sizes were larger. It was not surprising to find no significant difference in pain scores between the participants who had an incomplete and missed miscarriage since all participants who had a missed miscarriage received pre procedural misoprostol for cervical ripening. This reduced the number of participants needing cervical dilatation to a minimum and subsequently the pain experienced with cervical stretching during dilatation.

PCB is as safe as procedural sedation. As seen in the study were no adverse effects were witnessed in both groups and were prolonged procedure length was less likely in the PCB group.

The reason for the 3 participants in the PCB group experiencing severe blood loss compared with none in the procedural sedation group is not well understood. It could possibly due to

an increase in duration and difficulty of those specific uterine evacuations, but only 1 of those 3 participants had a procedure length > 15 minutes together with difficulty being documented. The other 2 were easy to perform and took < 15 minutes. In addition we have already demonstrated that it was less likely to have a prolonged uterine evacuation in the PCB group. The only plausible cause is that the severe blood loss was attributed to the participants' specific clinical presentation (example: exact gestational age and amount of retained products), information which was not recorded on the data collection sheet.

The frequency of difficult procedure and need for extra analgesia were higher in the paracervical group. It was interesting to find that extra analgesia was needed in the paracervical block group since we demonstrated similar (slightly lower) mean and SD for intra procedural pain scores. Extra analgesia was more likely given for increased levels of restlessness and anxiety where the sedation effects of midazolam and/or fentanyl were required.

Interestingly the 10 sharp curettages done were all done by the same clinician, showing operator preference. This clinician was reminded of the strong clinical evidence favoring suction over sharp curettage.

We were surprised to have found no difference in the lowest oxygen saturation between the two groups. The lowest oxygen saturation ranged from 75% to 100% and 72% to 100% in the control group and the intervention group respectively. We had expected a lower average value in the procedural sedation group since we know that benzodiapines cause respiratory depression. On retrospective enquiry, it was found that the C24 staff prophylactically (before a drop in oxygen saturation) and throughout the procedure administered 40% face mask oxygen to all participants in the procedural sedation group.

This was done because of past experience; patients who received procedural sedation almost always had a significant drop in oxygen saturation. This was not done in the PCB group. We believe a significant drop in oxygen saturation may have been demonstrated in the procedural sedation group if oxygen was not given prophylactically, but only when needed. The lack of demonstrating this information was an oversight in methodology. However it would have been difficult to stop giving prophylactic oxygen since this is standard practice in the facility.

The highest pulse rate was recorded for each patient. In the intervention group the results ranged from 61/min to 152/min. In the control group the highest pulse rate ranged from 67/min to 138/min.

The time differences from the administration of the analgesia to the time of the start of the procedure were not analysed because the time intervals in both groups were minimal and thought not to affect the main outcome of the study. The mean time difference in the paracervical block group was 05.33 mins. The mean time difference in the procedural sedation group was 05.22mins.

Limitations

We were unable to determine the exact time of discharge of the participants due to logistic issues. Firstly a minimum of 6 hrs post procedure stay is standard protocol for any patient having uterine evacuation. Secondly numerous staff members and 12 hourly nursing shifts resulted in a break in communication when it came to documenting the time of discharge on the data sheets. Lastly a large proportion of the participants used public transport and

therefore those who had their uterine evacuations after 16:00 waited until the following morning before they were formally discharged. The general opinion from the C 24 staff was that the participants in the paracervical group where mobile, eating and drinking and fit to go home earlier in comparison to those participants in the procedural sedation group. This can be explained by the fact that Paracervical block has no sedation effects. Further studies documenting the exact time of discharge and post procedural vital checks are required to confirm these findings.

Patient demographics, socio economic status, history (previous gynaecological history especially) and details on clinical presentation (gestational age and amount of retained production of conception) are all factors that could affect the participants perceived pain and were not explored.

Due to time and practical constraints it was decided not to include nurse and doctor experiences. However this information was volunteered informally and will be a meaningful inclusion in future studies of this nature. An interesting point volunteered was that most patients who refused to participate did so because of the fear of an injection into their cervix or/and that they preferred to be sleepy and unaware (sedated) during the procedure. This suggests possible bias and refusal of participant to be in the study was the perceived pain which may have been felt when PCB was done. Low dose midazolam (1mg ivi) prior to administering the PCB is definitely a consideration for future investigation.

Possible bias that could have influenced pain scores was proficiency bias, since fewer uterine evacuations in the PCB group were performed by interns. The main reason for this was that registrars were more experienced in administrating the PCB. Performance bias could have also taken place, since participants were aware of which group they were

allocated to and this could have heightened their perceived pain. This could be overcome by blinding the participant and the nurse recording the pain score.

Paracervical block with 1% lidocaine provided comparable pain relief when compared to procedural sedation with midazolam/fentanyl for the surgical management of incomplete and missed miscarriages. This data suggests that a multi centre, randomised, double blind trial should be undertaken. There are distinct advantages to exploring alternatives to procedural sedation for managing patients undergoing uterine evacuation for incomplete or missed miscarriage.

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ADDENDA

1. Participant Information leaflet
2. Consent
3. Paracervical block- Step by Step instruction
4. Verbal Pain Score
5. Data Collection Sheet
6. Tables and figures

A STUDY COMPARING THE EFFICACY OF PARACEVICAL BLOCK TO PROCEDURAL SEDATION IN THE SURGICAL MANAGEMENT OF INCOMPLETE/MISSED MISCARRIAGES.

HREC NO: 521/2012

Participant Information Leaflet

We are inviting you to take part in our study/investigation that looks at different ways to provide pain relief during the treatment of a miscarriage. The following are answers to your possible questions. If any of your questions are not answered, please feel free to ask the doctor who is attending to you.

What is a miscarriage?

A miscarriage is when a pregnancy fails to progress beyond 24 weeks (the first two thirds of the pregnancy). It is called a miscarriage when the fetus (baby growing inside the womb) is 500g or less. Often we do not know the exact cause of miscarriages, but we do know it is common. We also know that many women go on to have a successful outcome (live baby) in following pregnancies. Most miscarriages cause vaginal bleeding because the mouth of the womb starts to open up. Part of the womb is made up of muscle which contracts (squeezes) during a miscarriage to try and push out the fetus and placenta. Therefore you may get lower abdominal/stomach pain. If the fetus and the whole placenta are pushed out we call this a complete miscarriage. When some products of pregnancy (fetus and placenta) are still in the womb, we then call that an incomplete miscarriage. Sometimes all the products of pregnancy are still in the womb, but the fetus has no heartbeat and the mouth of the womb is closed, we call this a missed miscarriage. The heartbeat of the fetus can first be seen by

the doctor using the ultrasound scanning machine (a special machine that allows us to see inside the womb) at 6 – 8 weeks (1 ½ - 2 months) of the pregnancy.

If a patient has a missed or incomplete miscarriage they will need the doctor to remove the products of pregnancy, to stop the bleeding, and to make sure they don't become ill with an infection (pain and fever). If the mouth of the womb is opened and there are still products of pregnancy inside it may allow infection to enter and grow which can make a patient very sick.

How does the doctor remove the pregnancy products?

There are 3 choices.

1. Wait for the products to come out on their own. This can lead to the problems of bleeding and infection mentioned above and may require you to come in and out of hospital many times.
2. The doctor can give you medication which will help the mouth of the womb to open and makes the womb muscle contract/squeeze stronger. Once again the problem of bleeding and infection may occur.
3. The doctor can do a womb scrape/suction (uterine evacuation). This method does not require you to follow up, unless a problem arises. A small plastic pipe which has an opening at either end is used. The plastic pipe is connected to a suction system and the products of pregnancy are removed. The womb scrape is often very quick. Usually it takes about 10-15 minutes. All the equipment used is specially cleaned (sterile) to decrease your chance of getting an infection. Once the womb scrape is done and you are well, there is no need for you to return to the doctor. If needed

you may get a course of antibiotics to take home with you to prevent you from getting an infection.

What pain relief medication do I get?

This question brings us to the study we are doing. We are trying to find out if there is better medication than the one we are currently using. We are currently using two medications; Midazolam and Fentanyl. They are in liquid form and are given directly into the blood stream using a drip. These medications make you relaxed and drowsy. They are also strong painkillers. They can sometimes make you forget exactly what happened. You will feel drowsy for a while after the womb scrape.

The pain relief medication that we are looking at for our study is called a paracervical block. What this means is that we use a numbing medication (local anaesthetic - lidocaine), and inject it around the nerves found near the mouth of the womb. These nerves are fibres that allow us to feel pain. If we numb these nerves, we hope to numb the pain. The paracervical block has been used before for womb scrapings and has been shown to be a good painkiller but we want to find out more information on it, especially focusing on our community and patients. When we use the paracervical block, you will not feel sleepy or drowsy.

If I agree, which medication do I get?

It depends on which month you have the procedure. The doctor will inform you which medication is being used.

Am I helping?

Yes. If you agree, you are helping our investigation. The more patients we have in our study, the better the information we obtain. We hope that in the future this information will help other patients that need a womb scrape.

Do I get paid?

No, unfortunately you don't get paid.

Is it harmful?

No. All these medications have been tested and used in clinical practice many times previously and we know that they are safe when used properly. All our doctors are properly trained and can intervene if anything should go wrong.

If I agree, what must I do?

You will be asked to rate/ score your pain on a number scale, with 0 being no pain and 10 being the worst pain you have felt. This will happen once during the womb scrape and twice afterwards.

Will my name be kept a secret?

There is a record of all patients seen in C24 (gynaecology emergency room) and the doctors will make notes as usual. The information about your experience with the pain relief medication will be used, but you will be given a number, so that your name will be a secret. Only the principal investigator of the study will know which number is yours. The principal investigator cannot let anyone else know this information. So yes, your name will be kept secret.

If I don't agree, what will happen?

You will receive the current pain relief medication (Midazolam/Fentanyl) that is being used.

If anything goes wrong who do I contact?

Below are the names and telephone numbers of the doctors involved in the study.

Principal Investigator

Dr M Naiker

Registrar

UCT Department of Obstetrics and Gynaecology

Tel: 021 402 6464/ cell: 0824139244

Supervisors:

Dr GA Petro

Chief Specialist and Head of Obstetrics and Gynaecology Metro West

New Somerset Hospital, Green point

Tel: 021 402 6324

Dr A Reed

Chief Specialist Anaesthesiologist

Metro West Anaesthetic service

New Somerset Hospital, Green point

Tel: 0214026418

Contact details of doctor not involved in study:

Dr P Archary

Registrar

UCT Department of Obstetrics and Gynaecology

Tel: 021 4043536/ 021 4046020

Chairman of the Research Ethics Committee of the Faculty of Health Sciences of UCT:

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A STUDY COMPARING THE EFFICACY OF PARACERVICAL BLOCK TO PROCEDURAL SEDATION IN THE SURGICAL MANAGEMENT OF INCOMPLETE/MISSED MISCARRIAGES.

HREC NO: 521/2012

CONSENT FORM

I have read the participant information leaflet, or it has been read to me. I have had the opportunity to ask questions about the study and any questions that I have asked have been answered to my satisfaction. I understand that paracervical block may be given for pain relief for uterine evacuation.

I understand that clinical data will be collected for research purposes. Confidentiality will be maintained and I will not be identifiable.

I agree to take part in this research study and understand that my participation is entirely voluntary and I may withdraw at any time. Declining to participate will not affect my medical care. The study poses no risk to me. I understand that I may not benefit directly from study.

I have been given the contact details of persons who are involved in the study and who I may contact to answer questions, if I so choose. I will be provided with a copy of the informed consent form.

PARTICIPANT'S NAME SIGNATURE

_____ _____

INVESTIGATOR'S NAME SIGNATURE

_____ _____

WITNESS'S NAME SIGNATURE

_____ _____

DATE ____/____/____

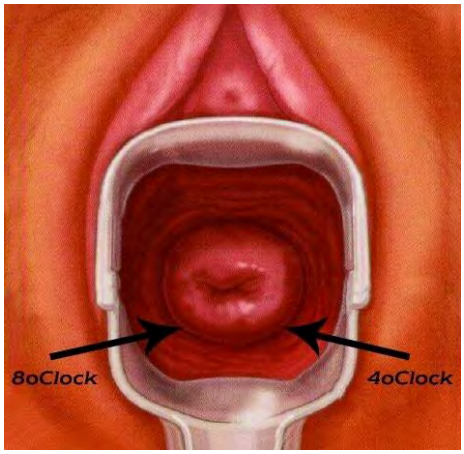
ADMINISTRATION OF A PARACERVICAL BLOCK

THE PATIENT IS CLEANED AND DRAPED IN LITHOTOMY

A SPECULUM IS PASSED TO VISUALISE THE CERVIX

GRASP THE ANTERIOR LIP OF THE CERVIX WITH A VELSELLUM, TO GENTLY MANIPULATE THE CERVIX.

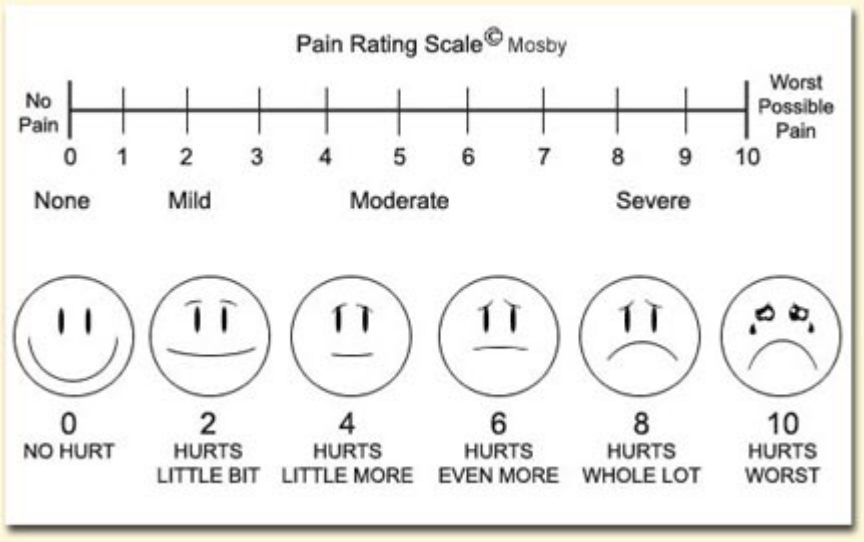
THE 4 0' CLOCK AND 8 0' CLOCK POSITION ON THE CERVIX MUST BE IDENTIFIED, AS DEPICTED BELOW



5MLS OF LIDOCAINE IS INJECTED INTO THESE 2 SITES, AT A DEPTH OF 3-7mm ON THE CERVIX. REMEMBER TO DRAW BACK BEFORE INJECTING TO ENSURE THAT ONE IS NOT IN A VESSEL.

WAIT 5 MINUTES TO ALLOW BLOCK TO WORK.

VERBAL PAIN SCALE



A STUDY COMPARING THE EFFICACY OF PARACERVICAL BLOCK TO PROCEDURAL SEDATION IN THE SURGICAL MANAGEMENT OF INCOMPLETE MISCARRIAGES

DATA COLLECTION FORM – ANALGESIA FOR EVACUATIONS

STUDY ID ☐ DATE:

TYPE OF ABORTION: SPONTANEOUS INCOMPLETE / MISSED
TRIMESTER: ☐ 1ST ☐ 2ND

SURGEON: INTERN/MEDICAL OFFICER REGISTRAR
PATIENT WEIGHT: _____KG

PRE –OP MISPROSTOL
PRIMARY MEDICATION AND DOSE
FENTANYL _____MCG
MIDAZOLAM _____MG
LIDOCAINE _____ %/MLS

TIME OF ADMINISTRATION: ____H____

TIME OF START OF SURGERY: ____H____

VITAL SIGNS: PRE-OP BP _____/_____
POST-OP BP _____/_____
HIGHEST PULSE _____
LOWEST O_2 SAT _____

SURGERY: CERVICAL DILATATION NECESSARY ☐ YES ☐ NO

LENGTH OF PROCEDURE ☐ <10MIN ☐ 10-15MIN ☐ >15MIN

EASE OF PROCEDURE ☐ EASY ☐ DIFFICULT

BLOOD LOSS ☐ MILD ☐ MODERATE ☐ SEVERE

CURETTAGE ☐ SUCTION ☐ SHARP

SATISFACTION WITH ANALGESIA
WAS PT CO-OPERATIVE ☐ YES ☐ NO
COMPLETENESS OF PROCEDURE ☐ YES ☐ NO
NEED FOR ADDITIONAL ANALGESIA ☐ YES ☐ NO
(IF YES, WHAT USED) _____

ADVERSE EVENTS:_____

PAIN SCORES

Using the 10 point Pain Scale depicted below, score patients pain perceived at the following times.

- DURING EVACUATION

- 1O MINUTES AFTER EVACUATION

- 2 HOURS POST PROCEDURE

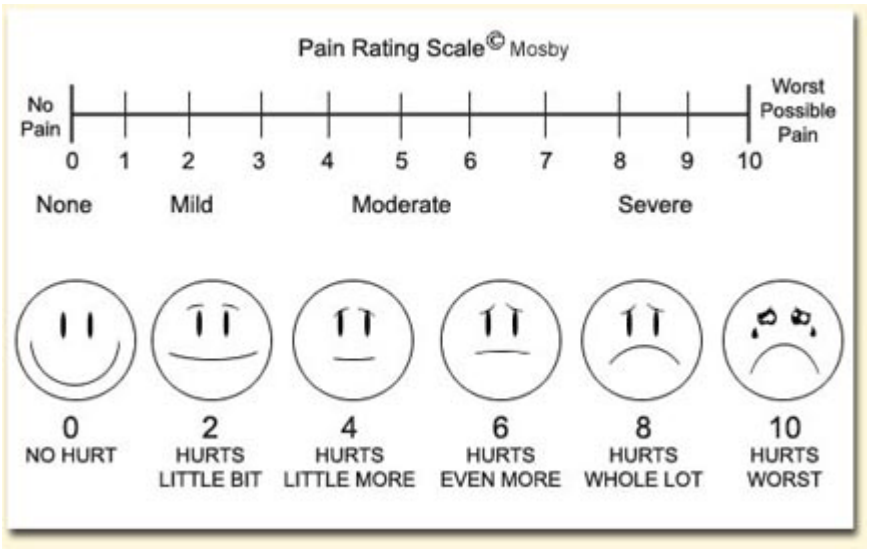


Figure 1: flow diagram of study participants and reason for non recruitment

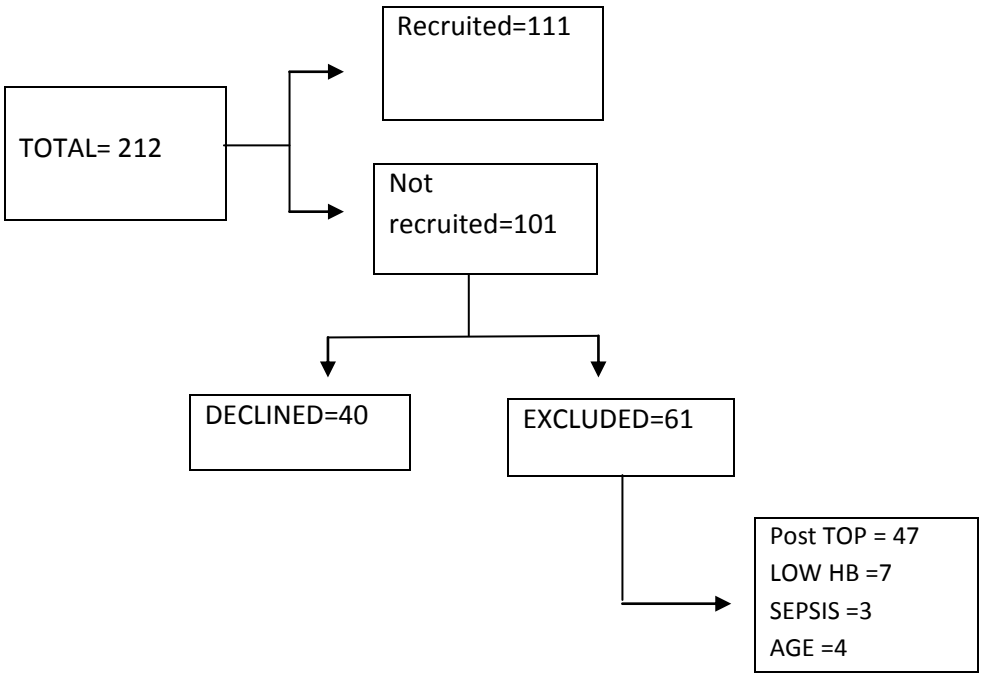


Table 1: Depicts percentage of participants per group.

GROUP	FREQUENCY	PERCENTAGE
PARACERVICAL BLOCK	54	48.65
PROCEDURAL SEDATION	57	51.35
TOTAL	111	100

Table 2: Percentage of different types of miscarriages

TYPE	FREQUENCY	PERCENTAGE
INCOMPLETE	72	64.86
MISSED	39	35.14
TOTAL	111	100

Figure 2: Percentage of 1st and 2nd trimester of total recruited participants.

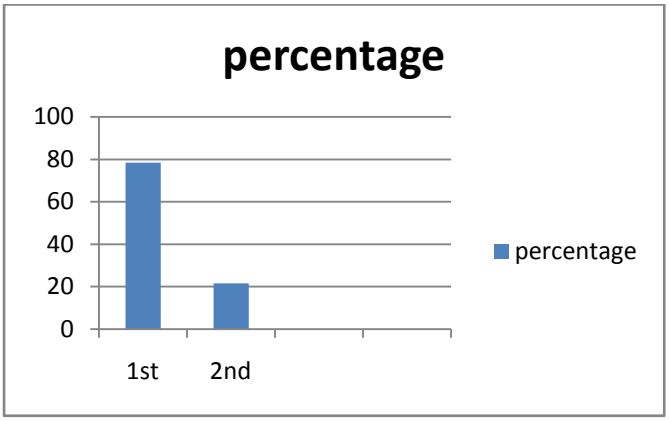


Figure 3: Percentage of uterine evacuations performed by intern/registrars across the 2 groups.

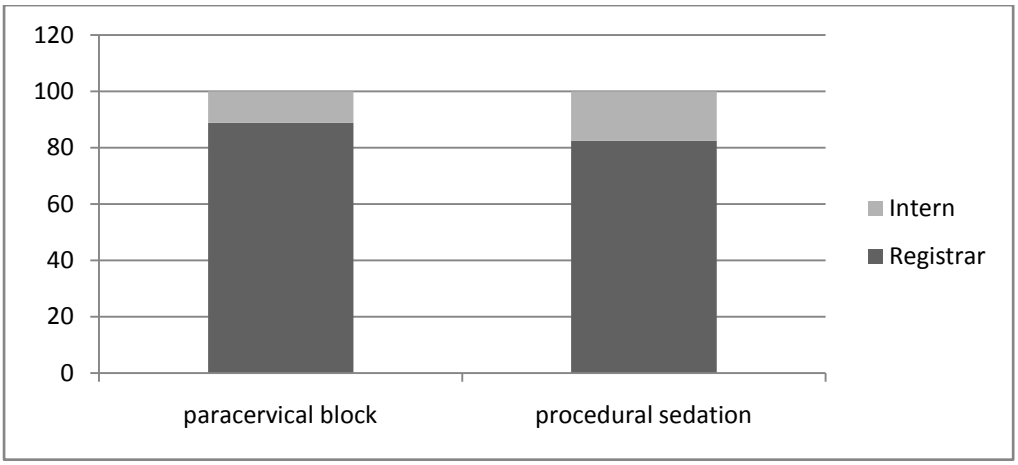


Figure 4: Frequency of procedure length between groups.

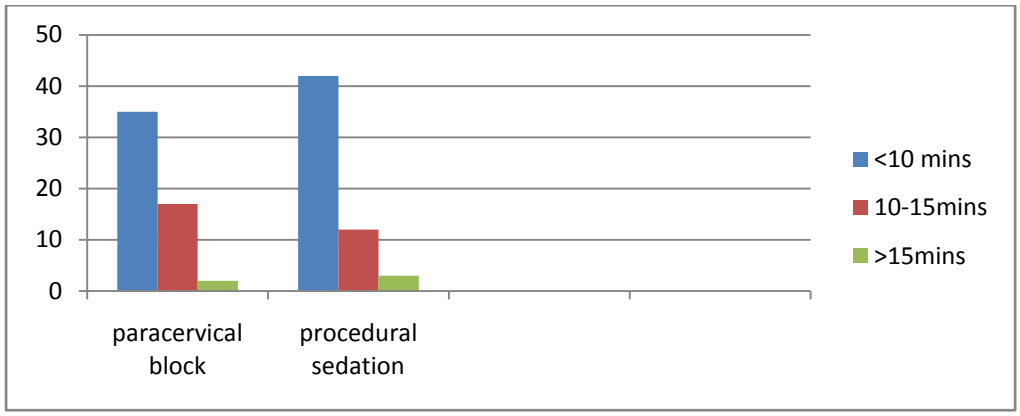


Figure 5: Ease of procedure between groups.

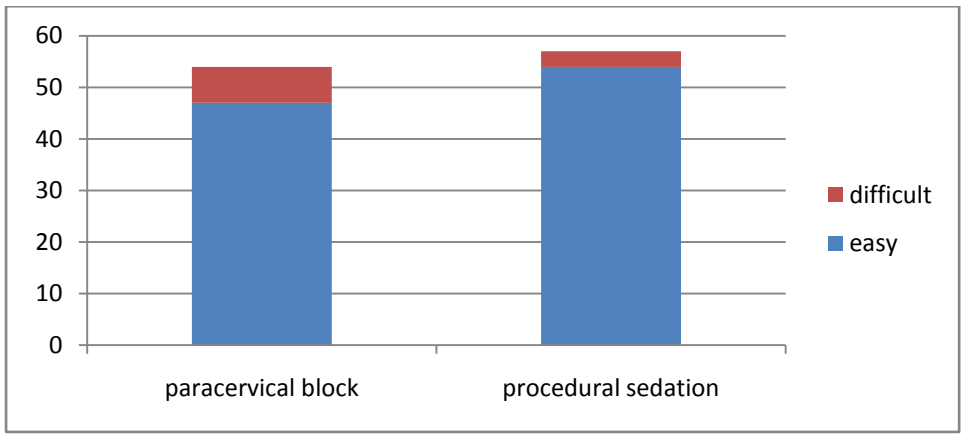


Figure 6: Estimated blood loss across the groups.

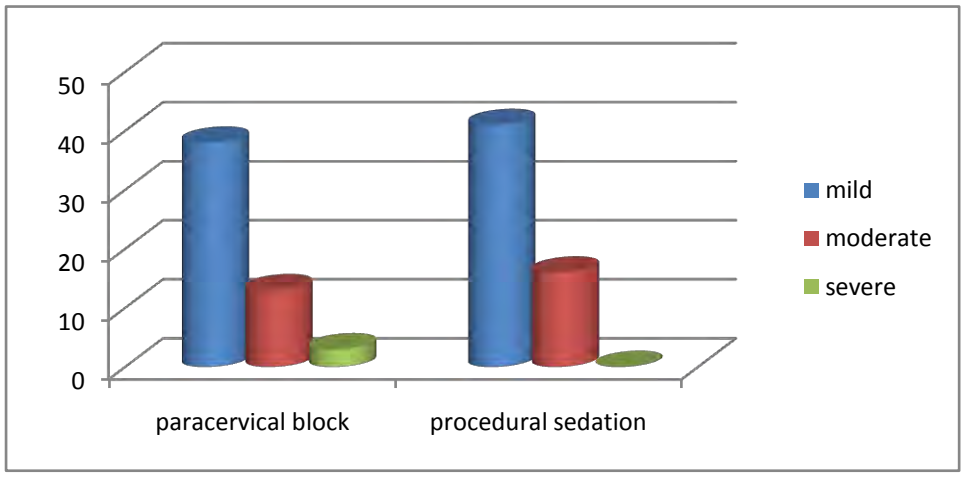


Figure 7: Percentage of participants requiring extra analgesia across both groups.

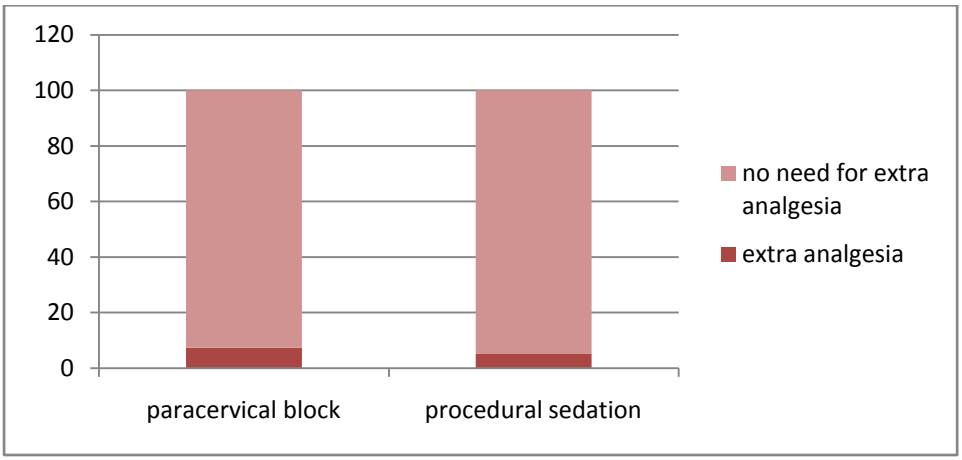


Figure 8: Frequency of the type of extra analgesia used in each group.

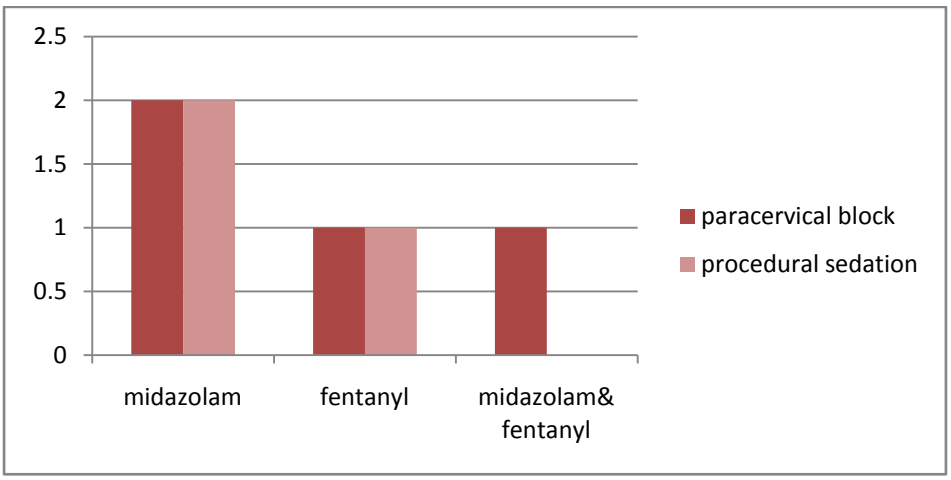


Table 3: Pain at different time intervals between groups.

VARIABLE	N	MIN	MAX	MEAN	STD DEV.	MEDIAN	25TH PERCENTILE	75TH PERCENTILE
PARACERVICAL BLOCK								
PAINDURING	**54**	**0**	**9**	**5.56**	**2.50**	**6**	**4**	**8**
PAIN10MIN	54	0	9	1.57	2.25	0	0	3
PAIN2HOURS	53	0	3	0.21	0.63	0	0	0
PROCEDURAL SEDATION								
PAINDURING	**57**	**0**	**10**	**6.49**	**2.81**	**7**	**5**	**9**
PAIN10MIN	57	0	6	1.63	2.02	0	0	3
PAIN2HOURS	57	0	3	0.37	0.84	0	0	0

Figure 9: box plot shows the median value, the IQR, and the minimum and maximum values for ‘’pain during ’’ for the 2 groups.

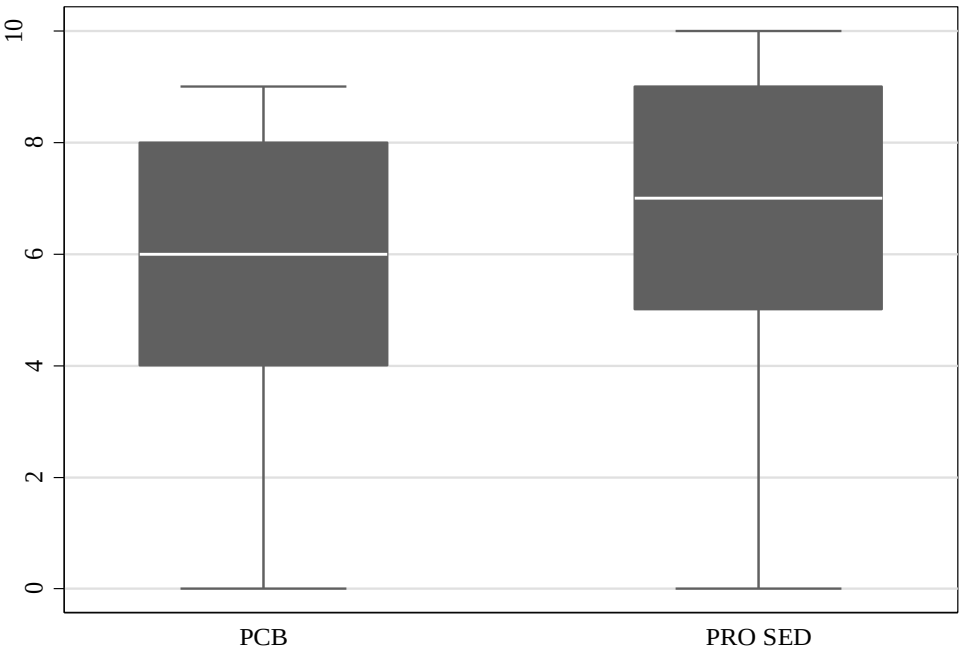


Table 4: Pain scores at the different time intervals in an incomplete and missed miscarriage.

VARIABLE	N	MINIMUM	MAXIMUM	MEAN	STANDARD DEVIATION	MEDIAN	25TH PERCENTILE	75TH PERCENTILE
INCOMPLETE								
PAINDURING	72	0	10	5.90	2.87	6	4	8
PAIN10MIN	72	0	9	1.54	2.10	0	0	3
PAIN2HOURS	71	0	3	0.25	0.65	0	0	0
MISSED								
PAINDURING	39	2	10	6.28	2.34	7	5	8
PAIN10MIN	39	0	7	1.72	2.19	0	0	3
PAIN2HOURS	39	0	3	0.36	0.90	0	0	0

Table 5: Subgroup analysis- pain score during procedure for incomplete miscarriages

ANALGESIA	VARIABLE	N	MEAN	STANDARD DEVIATION
PARACERVICAL BLOCK	PAIN SCORE DURING	33	5.303	2.506
PROCEDURAL SEDATION	PAIN SCORE DURING	39	6.410	3.092

Table 6: subgroup analysis- pain score during procedure for missed miscarriages

ANALGESIA	VARIABLE	N	MEAN	STANDARD DEVIATION
PARACERVICAL BLOCK	PAIN SCORE DURING	21	5.952	2.499
PROCEDURAL SEDATION	PAIN SCORE DURING	18	6.666	2.142

Table 7: Pain scores at different time intervals in first and second trimester miscarriages.

VARIABLE	N	MINIMUM	MAXIMUM	MEAN	STANDARD DEVIATION	MEDIAN	25TH PERCENTILE	75TH PERCENTILE
FIRST TRIMESTER								
PAINDURING	87	0	10	6.06	2.83	6	4	8
PAIN10MIN	87	0	9	1.62	2.27	0	0	3
PAIN2HOURS	86	0	3	0.28	0.76	0	0	0
SECOND TRIMESTER								
PAINDURING	24	2	10	5.96	2.18	5.5	5	7
PAIN10MIN	24	0	5	1.54	1.53	1.5	0	2.5
PAIN2HOURS	24	0	2	0.33	0.70	0	0	0

Table 8: subgroup analysis- pain score during procedure for 1st trimester miscarriages.

ANALGESIA	VARIABLE	N	MEAN	STANDARD DEVIATION
PARACERVICAL BLOCK	PAIN SCORE DURING	43	5.651	2.715
PROCEDURAL SEDATION	PAIN SCORE DURING	44	6.454	2.913

Table 9: subgroup analysis- pain score during the procedure for 2nd trimester miscarriages.

ANALGESIA	VARIABLE	N	MEAN	STANDARD DEVIATION
PARACERVICAL BLOCK	PAIN SCORE DURING	11	5.181	1.401
PROCEDURAL SEDATION	PAIN SCORE DURING	13	6.615	2.534

Table 10: Pre/ post operative blood pressures and lowest oxygen saturation over both groups

VARIABLE	N	MIN	MAX	MEAN	STANDARD DEVIATION	MEDIAN	25TH PERCENTILE	75TH PERCENTILE
PARACERVICAL BLOCK								
PRESBP	54	86	220	123.57	21.85	118.5	110	133
PREDBP	54	40	122	67.96	15.01	69	58	77
POSTSBP	54	84	222	118.59	21.81	118	105	128
POSTDBP	54	44	150	69.57	17.70	67.5	59	76
LOW O2	54	72	100	96.31	5.66	98	96	100
H PULSE	54	61	152	91.22	18.62	89.5	80	95
PROCEDURAL SEDATION								
PRESBP	57	89	192	119.67	19.87	118	104	129
PREDBP	57	40	100	63.68	12.03	63	54	73
POSTSBP	57	79	153	119.46	16.78	118	109	128
POSTDBP	57	40	101	67.42	12.02	68	61	73
LOW O2	57	75	100	96.25	4.69	98	95	99
H PULSE	57	67	138	93.07	15.21	91	82	100