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A PROSPECTIVE OBSERVATIONAL STUDY TO DETERMINE THE INCIDENCE AND EXTENT OF POSTOPERATIVE PAIN FOLLOWING UTERINE EVACUATIONS AND MANUAL VACUUM ASPIRATION – A PILOT STUDY.

Estie Mostert

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfillment of the requirements for the degree of Master of Medicine in the branch of Anaesthesia

Johannesburg, 2012

DECLARATION

I, Estie Mostert, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesia in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

E Mostert

21 September 2012

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ABSTRACT

BACKGROUND

Uterine evacuation (EVAC) and manual vacuum aspiration (MVA) are commonly performed minor gynaecological procedures, often being done on an out-patient basis. These procedures are associated with pain, but the severity and extent of the pain experienced, especially in the post-procedure period, is not well studied.

OBJECTIVES

The aim of this study was to determine whether patients who underwent EVAC and MVA procedures, experienced pain postoperatively; and if so, to quantify the degree of pain experienced. These patients were at Chris Hani Baragwanath Academic Hospital (CHBAH).

The objectives of this study were to determine whether patients (having undergone EVAC and MVA) experienced pain postoperatively, and to also determine the intensity of the pain. Additionally, to ascertain whether patient age, gestational age or the duration of the procedure, had any impact on the pain experienced.

METHOD

A sample of 53 patients were selected, presenting for EVAC and MVA at CHBAH. There were 26 patients in the EVAC group and 27 in the MVA group. Information was collected from patient interviews and their hospital files and subsequently recorded on data sheets. Data collected on each data sheet included: patient age, gestation, procedure (EVAC or MVA), reason for procedure, length/duration of procedure and analgesia received prior to and during the procedure.

Pain was assessed at intervals of 10 minutes, 40 minutes, 2 hours and 3 hours post-procedure. This was achieved using a ratio, which was determined from a visual analogue scale (VAS). Patients who had pain greater than 3/10 on the VAS score, received rescue analgesia in the form of diclofenac, 1mg/kg diluted in 250 ml of Ringer's lactate, over 30 minutes intravenously.

RESULTS

Patients in the MVA group experienced significantly more pain immediately postoperatively than the patients in the EVAC group. However, there were no significant differences found in pain experienced between the two groups at 40 minutes and thereafter.

CONCLUSION

Patients undergoing EVAC do experience pain, but if multimodal analgesia is provided, the pain experienced is not significant. Patients undergoing MVA experience significant pain post-procedure. It is recommended that improved analgesia protocols should be instituted.

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CHAPTER ONE - INTRODUCTION

Manual vacuum aspiration (MVA) and uterine evacuation (EVAC) are common minor gynaecological procedures performed worldwide. Indications include termination of pregnancy (TOP), management of miscarriage and molar pregnancy. MVA is usually done under conscious sedation, with or without local anaesthesia, when the gestational age is less than 14 weeks and the patient is haemodynamically stable (i.e. not requiring initial resuscitation). (1) EVAC procedures are usually done under general anaesthesia when the gestational age is more than 14 weeks and/or if any haemodynamic instability exists. (2)

Preventing postoperative pain is a very important aspect of the provision of anaesthetic care. Providing optimal pain relief postoperatively ensures patient satisfaction, reduces complications and reduces length of hospital stay. (3)

The definition of pain according to the “International Association for the Study for Pain” is:

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. (4)

This definition makes pain very difficult to measure.

Nevertheless, it is important to quantify pain for various reasons:

1. to give a sense of control to the patient
2. to ensure that adequate pain control measures and protocols are used

3. to prevent chronic pain from developing. (5)

The visual analogue scale (VAS) is a well-studied tool for measuring both acute and chronic pain. (5) **Figure 1.1**

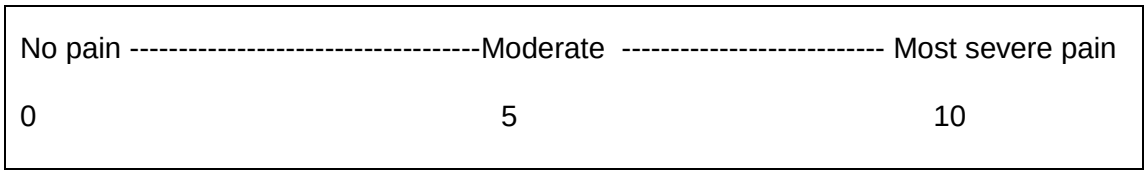

Figure 1.1 Visual analogue scale (6)

Even though the procedure is brief; lasting only 5–15 min, 97% of women experience pain during either EVAC or MVA. (1)

The pain experienced during EVAC and MVA is a combination of pain arising from cervical dilatation, and also arising from uterine contractions. Pain sensation is transmitted via sensory and sympathetic pathways from the posterolateral aspect of the cervix to the lateral spinothalamic tracts of the spinal cord. The various steps used during EVAC — such as clamping, traction and dilation of the cervical os, as well as curettage itself—can cause discomfort. (7)

Dalton et al found that anticipated pain negatively affected outcome regarding satisfaction and pain experienced during MVA. (8) Pain is worsened by anxiety, pre-procedure fearfulness and depression. (8)

Patients may have different reasons for requiring a procedure such as EVAC or MVA. Patients requesting a TOP may present with a different emotional burden when compared to patients presenting with a miscarriage following a desired pregnancy. (2) While this needs to be borne in mind, the nature of the procedure required is similar, and the question of postoperative pain is a valid concern in both situations.

Various modes of pain relief have been studied for short gynaecological procedures such as EVAC and MVA. Treatment modalities studied have ranged from pre-operative paracetamol and codeine suppositories, to intra-operative opioids for EVAC performed under general anaesthesia. (9) (10) (11).

The general practice for EVAC done under general anaesthesia at Chris Hani Baragwanath Academic Hospital (CHBAH), is to use a short acting opioid such as alfentanil during the procedure. Other drugs used for analgesia intra-operatively, include diclofenac and ketamine. Postoperatively, patients usually receive a combination of oral paracetamol and non-steroidal anti-inflammatory agents, eg. ibuprofen.

Various methods of providing analgesia for MVA have been studied. These include doing paracervical blocks and the use of simple analgesics (like diclofenac) with or without concious sedation. A randomized controlled trial has shown that the use of local anaesthesia for paracervical block is not associated with a reduction in pain levels for MVA. (1) (11)

The practice at CHBAH is to use a diclofenac 75 mg intramuscular injection (IMI) for MVA given 20 minutes pre-procedure.

1.1 Problem statement

While various studies have been done to determine the intraoperative efficacy of the use of various pain relief modalities for EVAC or MVA, no studies have been conducted investigating the degree of ***postoperative pain*** in these groups of patients. It is thus unclear whether the pain experienced during the procedure continues into the postoperative period or not, and if it does continue, to what magnitude.

1.2 Study aims and objectives

1.2.1 Aims

The aim of this study was to determine whether patients having undergone EVAC and MVA experienced pain postoperatively, and if so, to quantify the degree of pain experienced by these patients at CHBAH.

1.2.2 Objectives

- To determine whether patients having undergone EVAC experienced pain postoperatively.
- To determine whether patients having undergone MVA experienced pain postoperatively.

- To describe the intensity of postoperative pain experienced by patients having undergone EVAC.
- To describe the intensity of postoperative pain experienced by patients having undergone MVA.
- To review whether patient age, gestational age or duration of the procedure had any impact on the pain experienced.

1.3 Validity and reliability of data

To ensure validity and reliability of data, data was collected by the principal investigator. A translator was used for interviewing one of the patients.

1.4 Study design

This is a prospective observational study.

1.5. Ethical considerations

1.5.1 Ethical clearance

This study has been approved by the University of the Witwatersrand, Human Research Ethics Committee. (Appendix A)

1.5.2 Post-Graduate approval

The study has been approved by the Post-Graduate Committee of the University of the Witwatersrand, Faculty of Health Sciences.

1.5.3 Site approval

Permission to conduct this study has been granted by the Senior Clinical Executive at CHBAH. (Appendix B)

1.5.4 Patient consent

Patients that met the selection criteria were invited to participate in the study before having the procedure done. The aims of the study were explained as well as the risks and potential benefits. Patients received an information sheet containing all details of the planned study. (Appendix C)

The information sheet explained the reason for the study, the patient's involvement in the study, the right to refuse to participate without repercussions to their care, and the right to withdraw from the study at any time. A 24-hour contact number was supplied should they have required further information. The printed information was provided in English.

The researcher and a translator provided verbal information in a language that the patient could understand if they could not understand English, or were not able to read the document. Written consent was obtained from all patients agreeing to participate. (Appendix D)

1.5.5 Declaration of Helsinki

This study has been structured in accordance with the Declaration of Helsinki. (last updated October 2008)

1.6 Summary of methodology

After permissions from the relevant authorities were granted, participants were identified, either:

- in the gynaecology outpatient clinic awaiting MVA, or
- in the ward or theatre reception area, awaiting EVAC at CHBAH.

Participants matching the inclusion criteria were approached for inclusion into the study.

Written informed consent was obtained preoperatively from patients without exclusion criteria. The patients were made aware that their participation was voluntary, and that their results would be analysed by means of a numerical code system. All information that would link their identity to the trial results would remain separate and confidential.

Use of a medically knowledgeable translator was made if a language barrier was encountered, or if the patient requested that the information and consent forms be explained to them in a language of their choice.

The sample size was calculated assuming that a difference existed between the two groups of patients. The total sample calculated initially was 100 patients. The confidence interval of 9.3 would provide a confidence level of 95% for a population of 1000 patients.

In June 2011 the protocol for managing patients for MVAs at CHBAH was changed. These routine patients are no longer managed at CHBAH. All routine MVA patients are now being managed at primary level clinics. Only complicated cases are referred for management at CHBAH. This change in protocol has almost completely eliminated the number of patients presenting for MVA or EVAC.

At the time of the protocol change in June 2011, 53 patients had been enrolled in the study. There were 26 patients in the EVAC group and 27 in the MVA group. Information was collected from patient interviews and their hospital files, and recorded on a data sheet. (Appendix E).

Data collected on the data sheet included: patient age, gestation, procedure (EVAC or MVA), reason for procedure (TOP or miscarriage), length/duration of procedure, and also analgesia received prior to the procedure. The patient's name and hospital number were collected, but kept on a separate list to ensure confidentiality. This entire procedure was followed in case any patient decided to withdraw from the study.

Pain was assessed at intervals of 10 minutes, 40 minutes, 2 hours and 3 hours post-procedure. This was achieved using a ratio, which was determined from a VAS. (Appendix D) These results were captured on the data sheet. The intraoperative anaesthetic record was reviewed, and information regarding analgesia administered intraoperatively was noted. The duration of the procedure was included on the data sheet. Patients that had a pain score greater than 3/10 on the VAS score received rescue analgesia in the form of diclofenac 1mg/kg, diluted in 250 ml of Ringer's lactate, over 30 minutes IVI.

The study ended because of the change in protocol at CHBAH in June 2011. The new protocol caused the numbers of patients presenting for EVAC or MVA to reduce to near zero.

1.7 Significance of the study

1. The results of the study may guide anaesthetists to change currently accepted analgesia practice for patients presenting for EVAC.
2. The study results may guide primary health care providers performing MVAs to change protocols with regard to analgesia given to these patients.
3. The results may provide an estimate as to whether additional analgesia should be provided post-procedure for EVAC or MVA patients above the normally prescribed analgesia.

4. The study should encourage improvement of postoperative pain care in our hospitals.
5. The results of the study may lead to further research in the field of providing analgesia and management of postoperative pain for patients presenting for EVAC and MVA.

1.8 Limitations

1. Both TOP and post-miscarriage patients were included. This was done because these patients present as one group to the anaesthetist. However, this may have resulted in heterogeneity in the group.
2. Patients may have varying degrees of emotional strain owing to the nature of the circumstances in which they present. Emotion may alter the perception of pain, and thus create a bias.
3. Study period:

   Data was collected until the protocol change in June 2011. Data was collected at times convenient to the investigator, as per departmental roster allocations.
4. Surgeon and anaesthetist variation:

   EVAC is performed using a standardised technique taught at CHBAH. However, the EVACs were perfomed by different surgeons and anaesthetists, with different levels of experience and with differing surgical durations. The impact on the study will be discussed in chapter 5.

5. Contextuality:

   This study was done in the context of patients presenting for EVAC or MVA at CHBAH. Generalisation to other populations may be limited.

6. Retrospective review of data:

   Data collected from the anaesthetic chart was done retrospectively, as with all retrospectively collected data, the quality of the data collected is dependent on the quality of record keeping.

1.9 Research report outline

This research report will comprise the following chapters:

Chapter One: an introduction to the study, including the aim and objectives of the study, and a brief summary of the methodology used.

Chapter Two: a literature review pertaining to the topics raised by the study.

Chapter Three: a detailed description of the methodology used for the study.

Chapter Four: the results of the study.

Chapter Five: an interpretation of the results of the study, and a discussion of the issues raised by the results.

Chapter Six: a summary of the study, and conclusions drawn from the study.

CHAPTER 2 - LITERATURE REVIEW

In this chapter different literature applicable to the two procedures will be reviewed and discussed. Pain management for the two procedures will be reviewed.

2.1 Introduction

MVA and EVAC are common minor gynaecological procedures performed worldwide.

Early pregnancy failure occurs in 14 – 19% of recognised pregnancies. (3) No statistics on the incidence of miscarriages for South Africa could be found. Statistics on legal TOP in 2003 looking at 60 countries, found that the incidence of abortions for large countries like the United States were more than a million for 2003. (12)

The same study found TOP rates for South Africa in 1997 to be 0.6%. (12). The reported number of TOPs for 2010 were 68 736. (13)

2.2 Description of EVAC

EVACs were first performed in the late 19th century. EVAC is a procedure done under general anaesthetic, where the contents of the uterus are

removed following, for example, a miscarriage. The products of conception are removed from the uterus with a curette. (14)

2.2.1 Indications

EVACs are commonly performed to resolve abnormal uterine bleeding, to remove retained products of conception after miscarriage, or for TOP and for management of molar pregnancies. (1)

EVACs done under general anaesthesia are usually done when the gestational age is more than 14 weeks. (2) (4)

2.2.2 Contra-indications

A relative contra-indication for performing an EVAC under general anaesthesia would be, for example if the patient is considered as having a full stomach for whatever reason. In this case the procedure could still be performed, but rather under regional anaesthesia. (15)

2.2.3 Technique

EVACs are performed under general anaesthesia. General anaesthesia usually comprises the administration of a combination of propofol, alfentanil and anaesthetic vapour (such as isoflurane or halothane and nitrous oxide or air in oxygen). (16)

The patient lies in the dorsal lithotomy position. An iodine solution is used to clean the perineum and vagina. A bimanual examination is performed to study the adnexa and to determine the size, shape, consistency, and position of the uterus. A full bladder may interfere with the determination of the uterine position, so catheterization of the bladder may be necessary. Knowing the position of the uterus minimizes the chance of perforation of the uterus. (15)

The vagina is retracted with a weighted vaginal speculum in order to visualize the cervix. The surgeon performs the uterine curettage by first dilating the cevical os if needed, then clamping the anterior lip of the cervix. This aligns the cervix and the uterus in the same axis to decrease the risk of perforating the uterus. A uterine sound is used to measure the depth of the uterine cavity. (15)

The products of conception are removed using a series of sharp curettes of different sizes that are inserted through the cervical os. The surgeon then uses these to scrape the walls of the uterine cavity. (15)

2.2.4 Complications

A review of 14 903 cases of surgical TOP found the most common complications to be retention of products (2%), bleeding from clamping the cervix (2%), infection (< 1%) and perforation of the uterus (0.05%). (17)

Other complications mentioned by the World Health Organization are trauma to the cervix, and also anaesthetic complications such as cardiorespiratory depression and toxicity of local anaesthetics. (2)

2.3 Description of MVA

The use of vacuum aspiration to remove uterine contents was pioneered in 1958 by Drs Yuantai Wu and Xianzhen Wu in China, but their paper was only translated into English 50 years later. (18) Dorothea Kerslake introduced the method into the United Kingdom in 1967, and also published a study in the United States. Harvey Karnen refined the technique in the early 1970's, and developed a soft, flexible cannula that reduced the risk of perforating the uterus. (18)

MVA uses aspiration to remove the contents of the uterus through the cervix. It is a method of induced abortion as well as a therapeutic procedure used after miscarriage. (18)

2.3.1 Indications

Indications for performing a MVA include TOP and management of miscarriage. MVA under conscious sedation, with or without local anaesthesia, is usually done when the gestational age is less than 14 weeks

and the patient is haemodynamically stable (i.e. not requiring initial resuscitation). (1)

2.3.2 Contra-indications

Contra-indications to performing a MVA occur when the gestational age is more than 13 weeks, or where haemodynamic instability is present. (2)

2.3.3 Technique

MVA can be performed under conscious sedation, with or without a paracervical block using local anaesthesia. Normally, patients receive intramuscular diclofenac before the procedure for prevention of pain. (1) MVA is performed by inserting a cannula with a hollow suction tip, connected to a syringe, into the cervical os. A vacuum then extracts the products of conception, as the suction tip is rotated gently around the uterus. (19)

2.3.4 Complications

Complications that can arise from MVA, include bleeding from the uterine tissue or cervix, retained products and trauma to the cervix and uterus. The risk of perforating the uterus from MVA is minimal. (2) (17)

2.4 Pain

Management of perioperative pain is an important part of patient care for the anaesthesiologist. Pain is an individual acute sensation and requires specific care as it results in suffering, systemic complications, prolonged treatment and increased hospitalization costs. (3)

The subjective character of pain, and the complexity of the emotion that is evoked, make its reliable measurement by health care professionals a key factor in its successful management. (20)

2.4.1 Causes of pain from EVAC and MVA

Even though MVA or EVAC are brief procedures lasting 5–10 min, 97% of women experience pain during the procedure. (1)

The pain of EVAC and MVA is a combination of pain due to cervical dilatation, and of pain due to uterine contractions. The cervix and lower uterine segment are innervated by parasympathetic fibers from S2 to S4, which form ganglia lateral to the cervix and enter along with the uterine blood vessels. (7)

The fundus is innervated by two groups of nerve fibres:

- sympathetic fibres from T10 to L1 via the inferior hypogastric nerve, which enter the uterus at the uterosacral ligaments, and
- ovarian plexuses which enter at the cornua. (7)

Pain sensation transmits via somatic sensory and sympathetic pathways from the posterolateral aspect of the cervix to the lateral spinothalamic tracts of the spinal cord. (7)

Pain after TOP is usually described as abdominal cramps, similar to those experienced during dysmenorrhoea. It has been postulated that this kind of pain may be related to prostaglandin release, which produces painful contractions of the myosalpinx and the myometrium. (21) Non-steroidal anti-inflammatories have been shown to be more effective than paracetamol in controlling this type of pain. (21)

2.4.2 Standard procedure for management of pain from EVAC

Short acting opioids, such as alfentanil, are the most effective intraoperative analgesic to use for a short procedure such as EVAC. Use of a short acting opioid decreases the incidence and severity of side-effects, ensuring that patients recover quicker, yet still ensuring postoperative analgesia. Side effects of opioids may include nausea and vomiting, pruritis, respiratory depression and sedation. (9)

In a study comparing medical versus surgical TOP, 242 women who underwent surgical TOP, were given either diclofenac 100 mg rectally, or paracetamol 1000 mg rectally, in theatre following the procedure. (22)

However, a further 96 (39.7%) women required additional analgesia, with 91 (37.6%) women requesting oral analgesia and 5 (2.1%) requesting parenteral opioids. (22) Using only simple analgesics like paracetamol and diclofenac for EVAC may not be enough to ensure optimal postoperative analgesia. (11)

A Swedish study completed in patients undergoing EVAC under general anaesthesia with propofol and fentanyl, found no beneficial effect of administering paracetamol 1 g rectally at the end of surgery. The majority of patients still experienced mild to moderate pain. (21)

One study investigating patients undergoing EVAC due to second trimester abortion, found 34% of patients still experienced severe pain. The study does not mention at which times postoperatively this pain was reported. No mention is made of which analgesia was given. (23)

Standard procedure at CHBAH for EVAC, is to use alfentanil intraoperatively for pain relief and a combination of paracetamol and ibuprofen orally postoperatively. Additional combinations of ketamine and diclofenac, may also be used.

2.4.3 Standard procedure for management of MVA

In a study looking at MVA for first trimester pregnancy loss, patients were given 100 mg diclofenac rectally, and then randomly received either

remifentanil and midazolam, or remifentanil and propofol during the procedure. (24)

In this study low pain scores and high acceptability of MVA by all women were found, regardless of the technique used for the administration of analgesia. None of the women needed additional postoperative pain relief and all were discharged within three hours following the procedure. (24)

Gazvani et al investigated ibuprofen and tramadol as adjuncts to pain relief in manual vacuum aspirations done under local anaesthesia. In this study, there was no significant difference in effect between the two drugs immediately postoperatively. They found that ibuprofen was more effective than tramadol in reducing pain 30 minutes following the procedure. (25)

Literature from South Africa is limited. One study done at King Edward VIII Hospital in Durban examined pain relief for patients undergoing TOP under MVA. In this study, diclofenac intramuscularly was prescribed 30 minutes prior to the MVA. It was found that a significant number of patients still experienced pain during and after the procedure. (19)

Standard procedure at CHBAH for MVA is to give diclofenac 75 mg IMI 20 minutes prior to the procedure.

2.4.4 Pain measurement tools

The sensory or discriminative component of pain has been quantified primarily through psychophysical methods that attempt to establish a threshold for pain and through rating scale methods. The measured variable is generally the severity or intensity of pain. (20)

A range of interpretations of pain have led to the development of various measurement tools that address different components of pain.
Most of the commonly used methods to measure pain can be viewed as rating scales, including:

- The Verbal Descriptor / Rater Scale,
- The Numerical Rating Scale and
- The Visual Analogue Scale (VAS). (20)

The Verbal Descriptor Scale was devised by Keele in 1948, and is based on words numerically ranked such as ‘none’, ‘slight’, ‘mild’, ‘moderate’ or ‘severe’. This was used to assess responses to analgesia over a 24 hour period. (20)

Downie described the numerical rating scale in 1978 as either a horizontal or vertical line with ‘0’, indicating no pain, located at the bottom or one extremity and ‘10’, indicating severe pain at the top or the other. Currently there are multiple versions of this scale. (20)

The VAS was first developed over 70 years ago, and is possibly the most widely used assessment tool in the measurement of pain. During its early years, the VAS was popular for measuring subjective phenomena. Two of the leading advocates of this method were Clarke and Spear in 1964, and Huskisson in 1974. The latter used a VAS to measure intensity of pain. (20)

The VAS is a simple and frequently used method for evaluting variations in pain intensity. (24) The VAS consists of a 10 cm line anchored by two extremes of pain with the left side representing 'no pain' and the other end representing 'unbearable pain'. Patients are asked to make a mark on the line that represents their level of perceived pain intensity. (5) (20) **Figure 2.1**

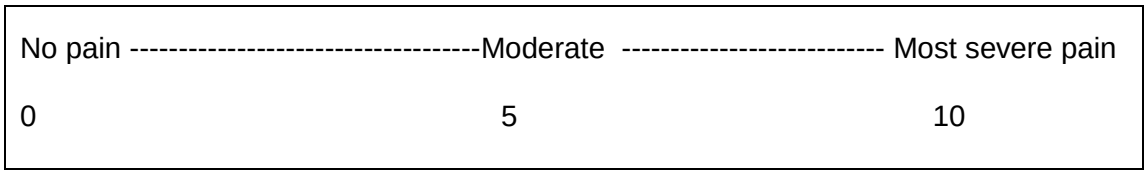

Figure 2.1 Visual analogue scale (6)

The VAS is recommended as a research tool, based on its methodological qualities of reliability, validity, sensitivity and appropriateness for a day surgery population. It is also one of the most widely used assessment tools for postoperative pain. (20)

In the Departments of Anaesthesiology at Johns Hopkins Bayview Medical Center, Baltimore and Vanderbilt Medical Center, Nashville, research was done to determine whether the VAS can be used to accurately measure pain

in the immediate postoperative period in order to compare the effect of different analgesic regimens. (26)

The study concluded that the VAS seems to be a valid measure of pain in the immediate postoperative period. It is easily understood, but has some limitations. Any single VAS measurement should be considered as accurate ± 20 mm. In using the VAS for treatment decisions or for the measurement of the effect of pharmacological interventions, one needs to be aware of this imprecision. (26) Another limitation of the VAS is that it only measures pain intensity, or the sensory aspects of pain. (6)

The use of the VAS as a pain measurement tool benefits the respondent, as it uses few words and, therefore, vocabulary is less of an issue. Provided that clear instructions are given to respondents, it is reasonably simple to complete. (20)

Using the VAS to determine the amount of pain experienced was found to be easy and brief to administer and score, and it is a good method of expressing pain severity. Because is has the properties of a ratio scale, it has a true zero point and, thus, differences between VAS measurements can be interpreted as meaningful percentages. The VAS has a continous frequency distribution, which allows statistical tests to be conducted on average pain levels. (20)

The VAS was found to be methodologically sound, conceptually simple, easy to administer and unobtrusive to the respondent. The VAS seems to be most suitable for measuring intensity of pain after day surgery. (20)

The VAS is a well studied method for measuring both acute and chronic pain, and its usefulness has been validated by several investigators. (5) (26)

The purpose of this study, is to investigate the intensity of pain in the postoperative period in the two groups of patients. This makes the VAS ideal to use as a measuring tool of pain in this study.

CHAPTER 3 – METHODOLOGY

In this chapter the methodology that was followed will be outlined and discussed.

3.1 Study design

This study was a prospective observational study.

Prospective: The patients were followed forward in time until the required data was collected.

Observational: The data was collected without any intention of intervention in the gynaecological and anaesthetic management of the participants. Rescue analgesia was provided in line with ward protocols.

The study design chosen will provide an appropriate method to determine whether patients presenting for EVAC and MVA, experience postoperative pain and also the extent of the pain. This study design will compare these.

3.2 Study site

The study was conducted in the gynaecology theatre reception and recovery room, as well as the MVA procedure recovery room in the maternity wing of

CHBAH, in Soweto, Johannesburg. CHBAH is a 2800 - bed tertiary hospital providing care for a population in the low-income bracket.

3.3 Study population

The study population consisted of women presenting for EVAC or MVA following TOP or incomplete miscarriage (ICA) at CHBAH.

Before the protocol change in June 2011, MVAs were usually done when the gestational age was less than 14 weeks and the patients were haemodynamically stable (i.e. not requiring initial resuscitation). EVACs were done under general anaesthesia for patients who were more than 14 weeks gestational age or if any haemodynamic instability existed.

3.4 Study period

Data collection was done over the period March 2009 to June 2011. The majority of data being collected March to May 2011.

3.5 Ethical considerations

This study has been approved by the University of the Witwatersrand, Human Research Ethics Committee. (Appendix A)

The study has been approved by the Post-Graduate Committee of the University of the Witwatersrand, Faculty of Health Sciences.

Permission to conduct this study has been granted by the Senior Clinical Executive at CHBAH. (Appendix B)

This study has been structured in accordance with the Declaration of Helsinki (last updated October 2000).

3.6 Definitions

1. EVAC / Dilation and curettage: The procedure of dilating the cervix and removing products of conception from the uterus with a curette. (14)
2. MVA: Aspiration of the content of the uterus using a soft, flexible suction tip/canulla connected to a syringe or vacuum source. (18)
3. Pain: an unpleasant sensory and emotional experience associated with actual or potential tissue damage. (4)
4. Postoperative period: The time period after a surgical procedure. In this study, the time immediately up to three hours after EVAC or MVA. (27)
5. VAS: The VAS is a simple and often used method for evaluting variations in pain intensity. (24) The VAS consists of a 10 cm line anchored by two extremes of pain with the left side representing ‘no pain’ and the other end representing ‘unbearable pain’. Patients are

asked to make a mark on the line that represents their level of perceived pain intensity. (5) (20)

3.7 Sample population and sampling method

The sample size was calculated assuming that a difference existed between the two groups of patients. The total sample calculated initially was 100 patients. The confidence interval of 9.3 would provide a confidence level of 95% for a population of 1000 patients.

In June 2011 the protocol for managing patients for MVA's at CHBAH was changed. These patients are no longer routinely managed at CHBAH. All routine MVA patients are now being managed at primary level clinics. Only complicated cases are referred for management at CHBAH. This change in protocol has almost completely eliminated the numbers of patients presenting for MVA and EVAC at CHBAH.

The study consisted of a total of 53 patients. These patients were included in the study before the protocol change in June 2011. There were 26 patients in the EVAC group and 27 in the MVA group. This affected the power of the study and will be further discussed in Chapter 4 and 5.

Consecutive convenience sampling was used. At CHBAH there is one theatre for gynaecological emergencies including EVAC, and one procedure room for patients requiring MVA. Patients for EVAC were approached in the

ward or theatre reception area awaiting EVAC for inclusion in the study. Patients for MVA were approached in the MVA procedure waiting room for inclusion in the study.

The inclusion process stopped when there were a total of 53 patients as a result of the change in protocol at CHBAH. Due to the sample size constraint, this was deemed a pilot study.

3.8 Inclusion criteria

ASA I and II patients presenting for EVAC or MVA at CHBAH were approached for inclusion in the study.

3.9 Exclusion criteria

The following patients were excluded from the study:

1. Patients younger than eighteen years or otherwise unable to give Informed consent.
2. Patients other than ASA I or II.
3. Patients that were haemodynamically unstable preoperatively, in other words, patients that required preoperative resuscitation with intravenous fluids and/or vasopressors.
4. Patients with a conta-indication to diclofenac.

3.10 Data collection

Patients that met the selection criteria were invited to participate in the study before having the procedure. The aims of the study were explained, as well as the risks and potential benefits. Patients received an information sheet containing all details of the planned study. (Appendix C)

The information sheet explained the reason for the study, the patient's involvement in the study, the right to refuse to participate without repercussions to their care, and the right to withdraw from the study at any time. A 24-hour contact number was supplied should they have required further information. The printed information was provided in English.

The researcher and a translator provided verbal information in a language that the patient could understand if they could not understand English, or were not able to read the document. Written consent was obtained from all patients agreeing to participate. (Appendix D).

Data was then collected from the patient history and hospital file, and post-procedure from the anaesthetic record, and then recorded on the data sheet. (Appendix E)

Patients' names and hospital numbers were kept seperate from the data collection sheets, and were encoded by a numerical coding system. This code was only known to the investigator. All information that would link a

patient identity to the study was kept seperate and confidential.

Patients were allowed to withdraw from the study at any time and no patient was coerced into participation in the study.

3.10.1 Patient information

Data collected was entered onto a seperate data sheet for each patient, and also onto a spreadsheet.

The following data was collected:

1. Patient age

   The patient's age was recorded in years.

2. Gestation

   The gestational age was recorded in weeks.

3. Type of procedure

   The type of procedure the patient was undergoing was recorded, whether EVAC or MVA.

4. Reason for the procedure

   The reason for the patient presenting for either EVAC or MVA was noted.

5. Analgesia received

   Any analgesia the patient received was recorded: this included pre-procedure, during the procedure and post-procedure.

6. Duration of the procedure

The duration of the procedure was recorded in minutes.

7. VAS score

   The VAS score was recorded at different intervals post-procedure: 10 minutes, 40 minutes, 2 hours and 3 hours. This was recorded as a ratio.

8. Rescue analgesia

   If the patient had a VAS score greater than 3/10, rescue analgesia was offered in the form of diclofenac 1mg/kg, diluted in 250 ml Ringer's lactate, over 30 minutes IVI.

3.10.2 Procedure in theatre or MVA room

The standard technique for conducting EVAC under general anaesthesia or doing MVA in the procedure room at CHBAH was followed. The technique and drugs used during the procedure were at the discretion of the specific anaesthetic registrar allocated to the gynacological emergency theatre for the day.

Before the protocol change in June 2011, MVA's were done in the MVA room in the gynaecology departement. Uncomplicated cases (TOP patients) were managed by a trained professional nursing sister. Complicated cases were done by the attending gynaecology registrar.

After completion of the procedure, pain scores were assessed using a VAS.

The VAS used was administered by the investigator. Patients were followed up post-procedure in the recovery rooms or post-procedure ward. Patients that had a VAS greater than 3/10 received rescue analgesia.

Normal protocol for post-procedure analgesia at this hospital is paracetamol 1g orally and ibuprofen 400 mg orally 8 hourly for 3 – 5 days post-procedure for both groups of patients.

3.11 Data analysis

The collected data was entered into a Microsoft Exel ® spreadsheet and analysed with Statistica ® version 10.0. Data were presented as means and standard deviation, or frequencies and percentages for continuous and categorical variables respectively. A Mann Whitney test was used for comparison of continuous variables (not normally distributed) between the two groups. For comparison of categorical variables between the groups a Chi square or Fisher exact test (when necessary) was performed. Differences between the two study groups and the level of pain overall (no pain, ≤ 3 and >3) was calculated using a Mantel & Haenzel Chi Square test. Bonferroni correction for two by two comparisons was used. A p-value < 0.05 was considered significant.

CHAPTER 4 - RESULTS

4.1 Sample and patient refusal

A total of 59 patients were approached to participate in the study, of which four patients refused to participate. The patients did not state a specific reason for refusal. Two patients were younger than 18 years of age. A total of 53 patients were used in this study. There were 26 patients in the EVAC group and 27 patients in the MVA group.

4.2 Results related to characteristics of patients that underwent EVAC and MVA

4.2.1 Age of patients

The mean overall age of patients presenting for EVAC or MVA was 25.9 years, with a standard deviation (SD) of 4.7. In the EVAC group the youngest patient was 20 years and the oldest 32 years. The mean being 25.5 years and SD 3.1. The youngest patient included in this study in the MVA group was 18 years and the oldest 40 years. The mean was 26.3, SD 5.8.

See **Table 4.1.**

4.2.2 Gestational age

The mean gestational age for both groups was 12.9 weeks with SD of 4.2. In the EVAC group the minimum gestational age was 13 weeks, the maximum

gestational age was 21 weeks. In this group the mean gestational age was 16.3 weeks, SD of 2.2. In the MVA group the minimum gestational age was 2 weeks and maximum 14 weeks, the mean was 9.6 weeks and SD 2.9.

(Table 4.1)

Table 4.1 Characteristics of patients that underwent EVAC and MVA

Characteristics	**EVAC**	**MVA**	**P value**
	Mean±SD	**Mean±SD**	
N	26	27	
Patient Age (years)	25.5 ± 3.1	26.3 ± 5.8	0.83
Gestational age (w)	16.3 ± 2.2	9.6 ± 2.9	< 0.0001
Length of procedure (Minutes)	26.5 ± 8.5	6.2 ± 2.8	< 0.0001
	Frequency (n, %)	**Frequency (n, %)**	
Amount of analgesic drugs received 0 1 2	 2 (7.6%) 11 (42.3%) 13 (50%)	 0 (%) 27 (100%) 0 (%)	 <0.0001
VAS 10	0.8 ± 2.2	4.7 ± 3.5	0.0002
Vas 40	0.8 ± 1.6	1.5 ± 1.6	0.07
VAS 2hr	0.1 ± 0.4	0.1 ± 0.4	0.66
VAS 3hr	0.1 ± 0.6	0.07 ± 0.2	0.49
Pain (overall)	0.6 ± 0.7	1.4 ± 0.8	0.0007

4.2.3 Duration of procedure

In the EVAC group, the shortest duration of the procedure was 15 minutes and the longest 50 minutes, the mean time was 26.5 minutes, SD 8.5 minutes. In the MVA group, the longest duration of the procedure was 15 minutes and the shortest 2 minutes. The mean duration of a MVA was 6.2 minutes, SD 2.8 minutes. **(Table 4.1)**

4.2.4 Amount of analgesic drugs received

50% of patients (13/26) that underwent an EVAC received two different drugs for analgesia, 11 patients received one drug only, and two patients in this group received no analgesia. Of these two patients, one patient had a VAS of 1/10 at 2 hours. The other patient reported no pain over the study period. Patients undergoing MVA all received one drug only, diclofenac 75 mg IMI 20 minutes pre-procedure. **(Table 4.1)**

4.2.5 Reason for EVAC or MVA

In the EVAC group 14 patients (54%) underwent the procedure for TOP. Nine patients (35%) underwent EVAC following ICA, and 3 (11%) following intrauterine fetal deaths (IUFD). **(Figure 4.1)**

In the MVA group 23 patients (85%) underwent the procedure for TOP and only 4 (15%) following ICA. The p value was 0.02. **(Figure 4.2)**

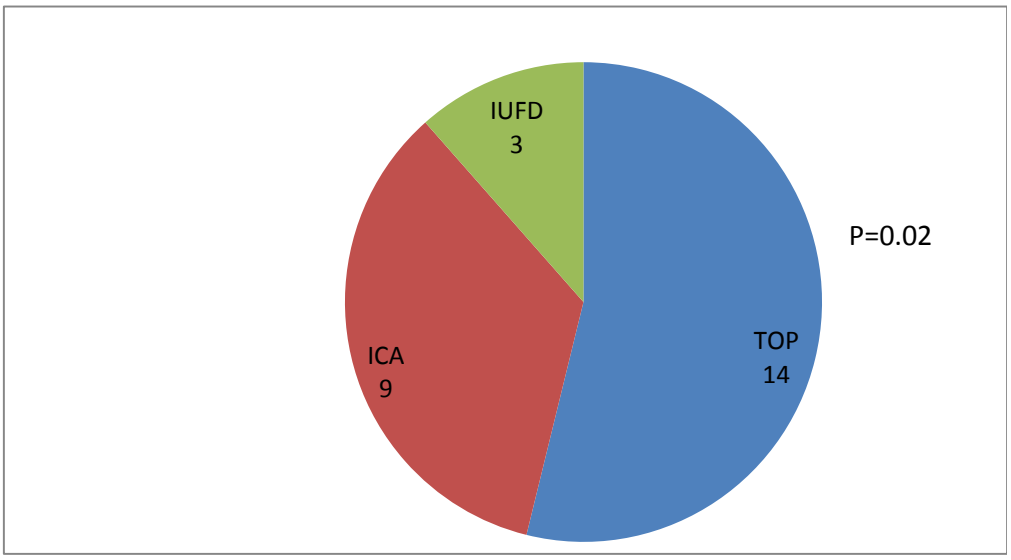

Figure 4.1 Reason for procedure – EVAC group

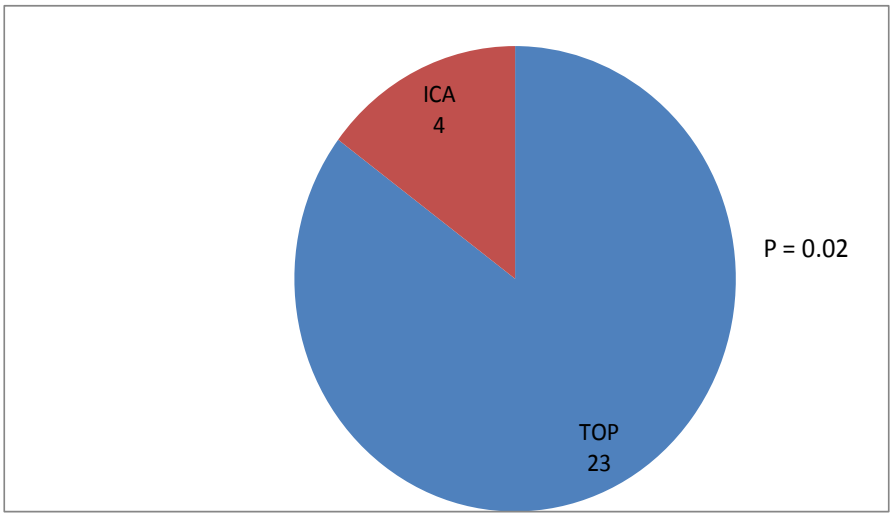

Figure 4.2 Reason for procedure – MVA group

4.3 Results related to the objectives

4.3.1 To determine whether patients undergoing EVAC experience pain postoperatively, and to describe the intensity of postoperative pain experienced

In the EVAC group 26 patients participated: **(Table 4.1)**

4.3.1.1 Pain at 10 minutes in the EVAC group

At 10 minutes, 20 patients (76.92%) had a VAS score of 0/10. One patient (3.85%) had 10/10 pain. Two patients (7.69%) had a score of 1/10, another two had pain 3/10 and one patient (3.85%) had pain 5/10. **(Figure 4.3)**

The mean VAS at 10 minutes was 0.8, SD 2.2. **(Table 4.1)**

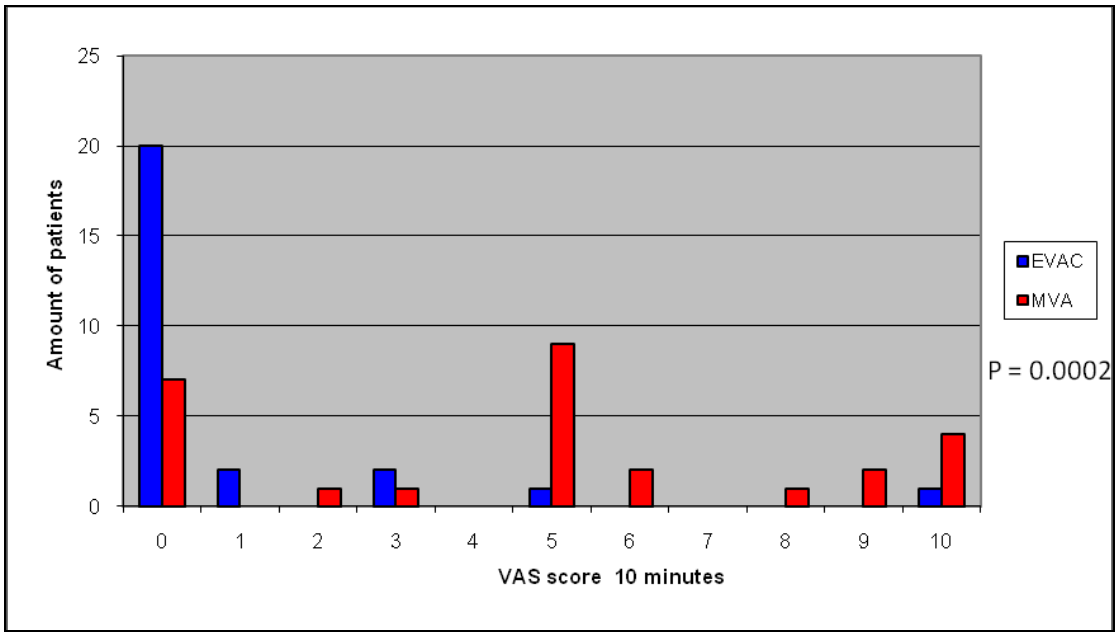

Figure 4.3 VAS at 10 minutes

4.3.1.2 Pain at 40 minutes in the EVAC group

At 40 minutes 18 patients (69.23%) had 0/10 pain. The highest pain score at 40 minutes was 5/10, (2 patients – 7.69%). Three patients had a VAS score of 1/10 (11.54%), one patient (3.85%) had 2/10 pain and two patients (7.69%) had a VAS score of 4/10. **(Figure 4.4)** The mean VAS at 40 minutes was 0.8, SD 1.6. **(Table 4.1)**

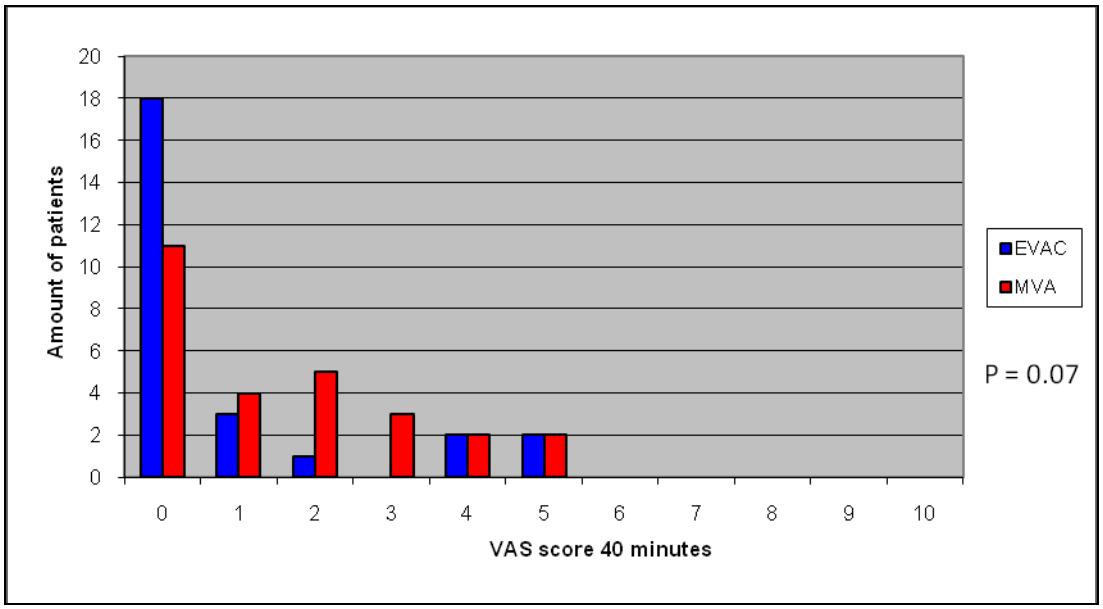

Figure 4.4 VAS at 40 minutes

4.3.1.3 Pain at 2 and 3 hours in the EVAC group

At 2 and 3 hours the majority of patients had no pain (84% and 92% respectively). The highest pain scores at those times were 2/10 (one patient), at 2 hours and 3/10 (one patient) at 3 hours. **(Figure 4.5 and 4.6)** The mean VAS at 2 hours was 0.1, SD 0.4, and at 3 hours the mean VAS was 0.19, SD 0.6. **(Table 4.1)**

Two patients received no analgesia – their VAS scores were 0/10 except for one score at 3 hours of 1/10 for one of these patients.

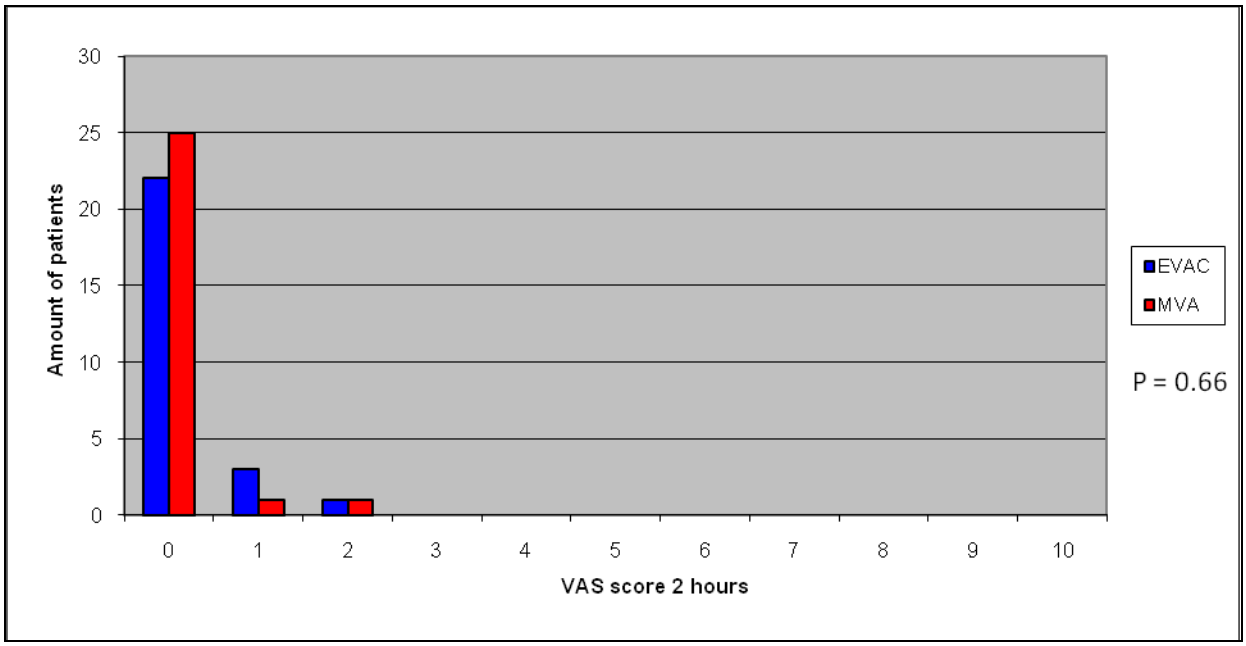

Figure 4.5 VAS at 2 hours

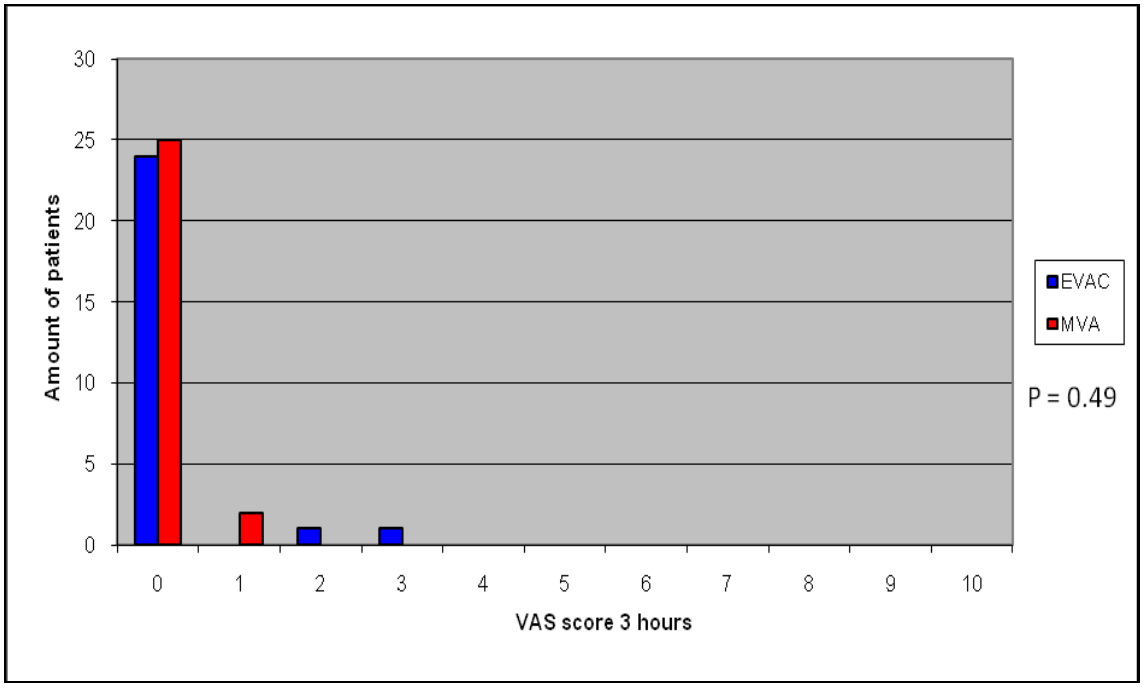

Figure 4.6 VAS at 3 hours

4.3.1.4 Pain overall during study period in EVAC group

Twelve patients (46.15%) had no pain overall during the investigative period, 10 patients (38.46%) had pain less than or equal to 3/10, and 4 patients (15.38%) had pain greater than 3/10. The p-value was < 0.017 between patients that had pain ≤ 3 vs pain > 3 and between no pain and pain > 3. The overall p-value was 0.0007. **(Figure 4.7)**

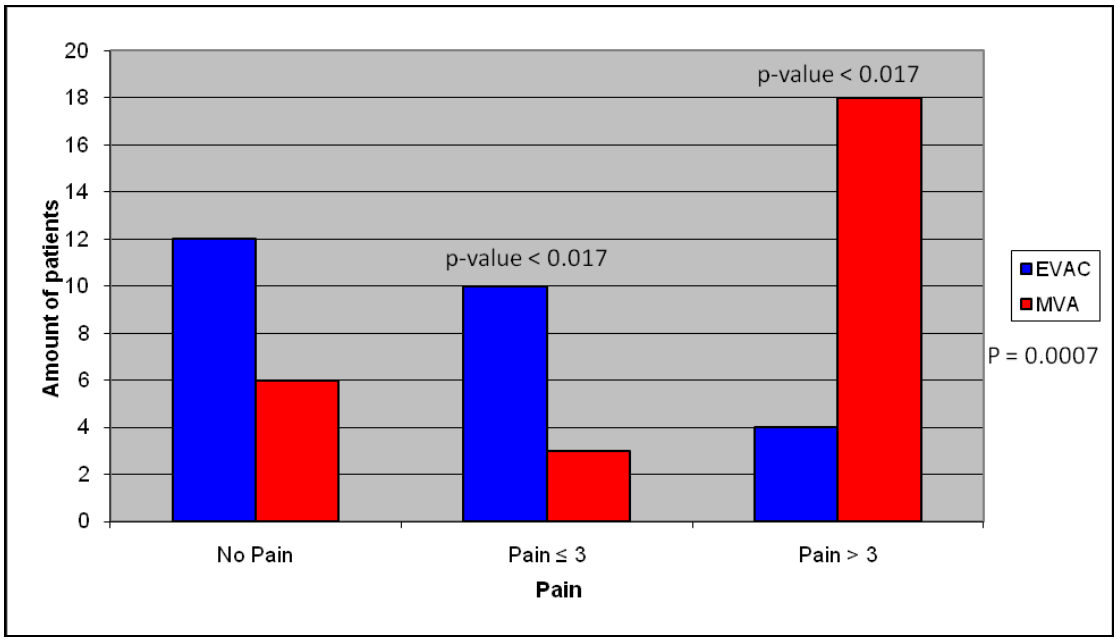

Figure 4.7 Pain over total study period

Three patients (11.54%) required rescue analgesia (in the form of diclofenac 75 mg diluted in 250 ml Ringer's lactate, IVI) in the uterine evacuation group.

No patients in the MVA group received rescue analgesia. This will be discussed in chapter 5.

4.3.2 To determine whether patients undergoing MVA experience pain postoperatively, and to describe the intensity of postoperative pain experienced.

The MVA group had 27 patients: **(Table 4.1)**

4.3.2.1 Pain at 10 minutes in the MVA group

Seven patients (25.93%) had a VAS score of 0/10, two patients had a VAS score of 3/10 and less, while 14 patients (51.85%) had pain ranging from 5/10 to 9/10. Four patients (14.81%) had 10/10 pain. **(Figure 4.3)** The mean VAS at 10 minutes was 4.7,SD of 3.5. **(Table 4.1)**

4.3.2.2 Pain at 40 minutes in the MVA group

At 40 minutes 11 (40.7%) patients had no pain and 12 (44.44%) patients had pain equal or less than 3/10. Four patients (14.82%) had pain greater than 3/10. **(Figure 4.4)** At 40 minutes the mean VAS was 1.5 with a SD of 1.6. **(Table 4.1)**

4.3.2.3 Pain at 2 and 3 hours in the MVA group

At 2 and 3 hours 25 patients (92%) having undergone MVA did not have any pain and the other two patients had pain scores of 1/10 or 2/10. **(Figure 4.5 and 4.6)** The mean VAS at 2 hours was 0.1, SD 0.4 and at 3 hours the mean VAS was 0.07, with a SD 0.2. **(Table 4.1)**

4.3.2.4 Pain overall during study period in MVA group

Overall, 18 (66.6%) of patients in the MVA group had pain greater than 3/10, three out of 27 (11.1%) had pain less than or equal to 3/10, and 6 (22.2%) had no pain at all during the study period. **(Figure 4.7)**

4.4 Summary of results

In this chapter the results of the study were presented. Patients in the MVA group experienced significantly more pain immediately postoperatively than the EVAC group. However, there were no significant differences found in pain experienced between the two groups at 40 minutes and after that.

Due to the small sample size, an analysis of whether patient age, gestational age and duration of procedure had an effect on the pain experienced, was not feasible.

Due to the sample size constraint, the statistical findings are not considered to be statistically proven. This study was therefore deemed a pilot study.

CHAPTER FIVE – DISCUSSION

Chapter 5 includes an interpretation of the results of the study, and a discussion of the issues raised by the results. Chapter 5 also includes a discussion of the study in terms of potential limitations of the study, implications for clinical practice and further research.

5.1 Patient refusal

Four patients refused to participate. The reasons for their refusal were not clearly stated. This could possibly have been because of the possible emotional strain of having to undergo either a MVA or EVAC for the various presenting reasons.

5.2 Results pertaining to the objectives of the study

5.2.1 Pain in the EVAC and MVA patients

Results from this study showed that there was a significant difference in VAS scores between the two groups at 10 minutes. 20/26 (76.9%) of patients in the EVAC group had no pain at 10 minutes, compared to the MVA group where only 7/27 (25.9%) had no pain at 10 minutes.

Two of the 26 patients in the EVAC group had pain greater than 3/10 at 10 minutes compared to the MVA group where 18/27 patients had pain greater than 3/10 at 10 minutes. In the EVAC group four of the 26 patients had pain equal to or less than 3/10, whereas in the MVA group two of the 27 patients had pain equal to or less than 3/10 at 10 minutes.

Patients in the MVA group experienced significantly more pain immediately postoperatively (at 10 minutes) than the EVAC group. However, there were no significant differences found in pain experienced between the two groups at 40 minutes. At two and three hours no difference in pain experienced could be shown between the two groups. This is possibly because of the small sample size that was used.

Two patients in the EVAC group received no analgesia. Despite this they reported no significant pain. The reason for these patients not reporting significant pain is not clear. The literature describes the pain from an EVAC as abdominal cramps, similar to those experienced during dysmenorrhoea. (21)

Patients may not regard this type of pain as being significant. These particular patients could have had a higher pain threshold, or the lack of pain could be due to under reporting of pain by patients in general. In one cross-sectional study from South Africa investigating second trimester abortions, 7% of the patients reported no pain after EVAC, although the exact timing of the interview is not stated. (23)

The results from the EVAC group is in keeping with current literature that looked at intra-operative pain in this group of patients. The literature does not report significant pain immediately postoperatively. (23)

Very few studies investigated pain in MVA patients. Literature found, showed that patients that underwent MVA and reported no postoperative pain, had all received opioids and sedation during the MVA procedure. (11)

5.3 Results relating to characteristics of patients

5.3.1 Age of patients

There was no significant difference in the ages of patients between the two groups.

5.3.2 Gestational age

There was a difference in the gestational ages between the two groups. The reason for this being, that MVA can only be done if the gestational age is less than 14 weeks, and EVACs are usually done after 14 weeks gestational age. There was no clear indication that increased gestational age increased the amount of pain experienced. For example, three patients in the EVAC group had a gestational age of 20 weeks and above. All of them had pain scores of 0/10 throughout the entire study period.

5.3.3 Duration of procedure

There was a difference in duration of procedure between the two groups. An EVAC is usually a longer procedure, as the anaesthetic time has to be taken into consideration. A longer duration of procedure did not equate to an increase in pain experienced. The highest pain scores were recorded in the MVA group.

5.3.4 Reason for procedure

There was a difference between the two groups in the reason for presenting for either EVAC or MVA, most patients (85%) presenting for MVA were due to TOP.

This correlated with the earlier gestational age of patients presenting for MVA. Patients for TOP generally present earlier (usually before 12 weeks) than patients with ICA (usually between 8 and 16 weeks). Pregnancy can be conclusively diagnosed at 4 to 6 weeks (28).

Patients with unwanted pregnancies typically want to have a TOP as soon as possible. By law, a TOP has to be done before 12 weeks gestational age without any specific reason necessary. Between 13 and 20 weeks gestation, there has to be a medical, psychological or economical reason for TOP. (29).

ICA usually occurs between 6 and 16 weeks, typically making a large proportion of these patients present too late for the 14 week MVA cut-off date. Performing an EVAC has been found to be safer than MVA after 12 – 14 weeks gestation. (2) (23)

5.3.5 Analgesia received in the EVAC group

The anaesthesia and analgesia given for EVACs in this study was not standardised. Drugs and doses used varied, and was at the discretion of the attending anaesthetist. Despite this, there were no significant differences in pain scores between the patients in the EVAC group.

The different drugs used included: alfentanil, diclofenac, fentanyl, ketamine and sufentanil. Opioids were used alone or in conjunction with simple analgesics or ketamine. There was no significant difference in the pain scores of these patients. The use of intravenous paracetamol for EVAC patients is not part of the current practice protocol at CHBAH.

5.4 Limitations

5.4.1 Study period

Data was collected by convenience sampling. The majority of data was collected during April and May 2011, when it was possible according to departemental rostering. The first few patients however, were assessed more sporadically. This method of sampling is not as robust as other methods, which necessarily introduces a potential for selection bias.

5.4.2 Protocol change and small sample size

The protocol change in June 2011 effectively ended the study period as only complicated patients are now referred to CHBAH for MVA and also for EVAC. The number of patients presenting to CHBAH for MVA or EVAC is now significantly less than before. This caused the sample size to be small.

It was deemed that the power of this study was insufficient because of the small sample size. This study was therefore underpowered to show differences in pain at 40 minutes, 2 hours and 3 hours. Despite the study being underpowered, a difference in pain experienced was shown between the EVAC and MVA group at 10 minutes.

A future study using a larger sample size and therefore increased power, should be done to conclusively detect differences in pain experienced between the two groups at 40 minutes, 2 hours and 3 hours postoperatively.

5.4.3 Rescue analgesia

Three of the 26 patients (11.54%) required rescue analgesia (in the form of diclofenac 75 mg, diluted in 250 ml Ringer's lactate over 30 minutes IVI) in the EVAC group. Two of these patients reported a VAS score of 4/10 at 40 minutes and one patient had a VAS score of 5/10 at 40 minutes. At 2 and 3 hours, these three patients reported no significant pain (equal or less than 3/10).

One other patient reported pain of 5/10 at 40 minutes. This patient however was already receiving diclofenac 75 mg in 1 litre of Ringer's lactate IVI, started during anaesthesia. On follow up at 2 and 3 hours, this patient had VAS scores of 0/10 and 0/10.

In the MVA group no patient received rescue analgesia, despite the finding that 18/27 patients had pain greater than 3/10 at 10 minutes. The reason for this, according to the current practice at the time of the study, was that these patients received diclofenac 75 mg IMI before the MVA. This was given only 10 – 20 minutes prior to having the MVA, and the diclofenac had not yet reached maximal effect.

At 30 – 40 minutes after the MVA, only 4/27 patients had significant pain. Rescue analgesia was stipulated in the study protocol to be diclofenac 75 mg IVI or IMI. As these patients had already received a dose only 1 hour before, a repeat dose could not be given. This presented a limitation of this study, as effective pain control could not be obtained immediately. However, at 2 and 3 hours no patients from the MVA group had significant pain (VAS scores 0/10 and 1/10).

5.4.4 Analgesia received in the MVA group

Before performing a MVA at the time of the study, current protocol for analgesia was diclofenac 75 mg IMI. Using diclofenac IMI for analgesia in MVA is not incorrect, but the pharmacokinetics and pharmacodinamics have to be understood to make the use of this drug effective as an analgesic at the time of the procedure. The diclofenac should be given 30 – 40 minutes before the MVA to have enough time to reach maximal effect before the procedure is done.

The main reason for using diclofenac as analgesia in MVA was that these procedures were performed on an out patient basis, with patients usually only staying for an hour, provided that there were no complications like bleeding. For this study patients were asked to stay for three hours after the MVA to complete the study period.

The usual short period of observation post-procedure, limits the use of other drugs, such as opioids and sedative agents, for MVA. These drugs potentially have more side effects, including respiratory depression. Intravenous paracetamol is also not available for use in the MVA room.

Another factor determining the protocol for analgesia provided for MVA, was that the MVA room had very limited recources in terms of monitoring and resuscitation equipment. Oxygen and suction points were also limited. Consequently, no sedation or opioids could safely be administered to these patients.

MVAs were mainly performed by trained professional nurses, and only complicated cases were done by the gynaecology registrar. The training and scope of practice of these nurses does not include the use of sedation agents and opioids for day case procedures, which falls more in to the scope of practice of the anaesthetist.

Before June 2011, the MVA service at CHBAH was provided by the gynaecology department. Since then, MVAs are done at local clinics, where the analgesia provided may be even more limited.

Since this was an observational study of current practice, this limitation revealed a flaw in current practice of the analgesia management of MVA patients. This limitation questions whether any significant difference would

have been found between VAS scores at 10 minutes in both groups, had the MVA group received adequate analgesia early.

5.4.5 Contextuality

This study was done in the context of patients presenting for EVAC and MVA at CHBAH. CHBAH is a tertiary state hospital that serves a predominantly low-income black population from Soweto and surrounding areas in Johannesburg. It may not be possible to generalise the results of this study to other population groups.

5.5 Recommendations

The following should be implemented to minimize the amount of pain experienced in MVA patients :

1. Increasing the time period between the patient receiving IMI diclofenac and performing the MVA, to at least 30 – 40 minutes.
2. Consider the addition of paracetamol 1 g orally as added analgesic before the MVA is done.

This combination may decrease the amount of pain experienced, and is a cheap method of providing analgesia.

Recommendations for EVAC patients:

1. The use of multimodal analgesia has been shown to be the most effective method of ensuring good intra-operative and postoperative pain control in the EVAC group. This practice should be continued.

5.6 Importance of this study

This study has importantly demonstrated the following:

1. Proven that patients undergoing MVA **DO** experience significant pain requiring analgesia.
2. A change in local practice of analgesia provided for MVA patients is necessary.
3. Shown that patients undergoing EVAC do experience pain, but mostly not significant pain, which is easily managed with short acting opioids and simple analgesics.

5.6.1 Areas for future studies

This study highlighted areas where further research may be done with regards to pain management in the EVAC and MVA groups.

This study should perhaps be viewed as a pilot study. A study with a larger sample size should be done to determine whether any differences in experienced pain exist between the two groups at 40 minutes and beyond.

This study showed that the limited analgesia provided during and post-procedure in the MVA group, led to these patients experiencing significant pain immediately post-procedure. Future studies may investigate whether improved analgesia is being offered since the service was moved to primary level institutions.

Another area for future study should investigate patient satisfaction with both procedures and analgesia received. Questions asked should include whether patients would be prepared to undergo a MVA again. Patients who had received both MVA and EVAC procedures, could be asked which was the better experience.

CHAPTER 6 – SUMMARY AND CONCLUSIONS

6.1 Summary

In the previous chapter the results of the study were discussed. Patients that underwent EVAC experienced significantly less pain immediately post-operatively than the MVA patients. The study was underpowered and therefore could not show significant differences in pain between the two groups at 40 minutes, 2 and 3 hours.

There were differences between the two groups pertaining to reasons for the procedure, duration of the procedure and gestational age.

This study highlighted the limitations in analgesia provided to patients presenting for MVA.

6.2 Conclusions

This study demonstrated that EVAC patients do not experience significant pain postoperatively because current management, using multimodal analgesia, is effective in controlling pain in this group of patients.

The care provided to MVA patients needs revising in terms of choice and timing of analgesia administration. This service was previously offered at CHBAH and is currently offered at local clinics. The analgesia provided and

the satisfaction of patients undergoing MVAs in the local clinics should be investigated, and is a potential area for future research.

The results of this study have provided useful information which can be applied directly in the clinical setting, hopefully improving the care given to patients presenting for EVAC and MVA at CHBAH in the future.

APPENDICES

Appendix A Ethics approval certificate

Appendix B Permission from Hospital Senior Executive

Appendix C Patient information sheet

Appendix D Informed consent form

Appendix E Data collection sheet

APPENDIX A Ethics approval certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mostert

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M071103**
PROJECT	Postoperative Pain in Uterine Evaluations and Manual Vacuum aspiration: A Pain Audit
INVESTIGATORS	Dr E Mostert
DEPARTMENT	Department of Anaesthesia
DATE CONSIDERED	07.11.30
DECISION OF THE COMMITTEE*	APPROVED UNCONDITIONALLY

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application

DATE 08.01.16 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones, A Dhai, M Vorster, C Feldman, A Woodiwiss)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr PR Penfold

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX B Permission from Hospital Senior Executive

FORM HREC (2005 - MEDICAL)

2

HEAD / RESEARCH COORDINATOR OF DEPARTMENT / INSTITUTE IN WHICH STUDY WILL BE CONDUCTED (where applicable)

X [illegible] (Director: Clinical Services) (No additional drugs will be provided for research other than routine stock provided for in the Department of O&G.

or, if not applicable,

NAME, CONTACT DETAILS AND SIGNATURE OF COMPANY REPRESENTATIVE:

Name: A C LUNDGREN

Signature: [signature]

Date: 6-8-2007

~~**Company:**~~ HOD, Dept. of Anaesthesia, CHBH

Tel No: 0825574605

Fax No: 011 9331843

Email: chris.lundgren@wits.ac.za

MSWord/Iain0015/HERCMedAF

APPENDIX C Patient information sheet

INFORMATION FOR STUDY PARTICIPANTS

Good morning. My name is Dr Mostert. I am a doctor in the Department of Anaesthesia of this hospital. I would appreciate it if you could help me with a study I am doing, and would like to invite you to first listen to the information I have about the study, and then you can decide whether you would like to participate or not.

The procedure you are going to have is clean out your womb and to stop any bleeding.

This will either be done while you are awake or you will go theatre for a general aneasthetic (where you will be made asleep). Your doctor will decide which of the 2 procedures you will be having.

You will receive pain medication while the procedure is done.

The purpose of the study I am doing is to find out whether patients like yourself, having this procedure, experience any pain, and how much, after the procedure is done. This will help us, as doctors, to make sure we help patients not to have any pain during and after these procedures.

There will be no risks involved for yourself if you decide to take part in the study, as I will only be assessing if you have pain at all after you had the

procedure. If you do experiece the discomfort of pain after the procedure, pain medication will be given to you.

The potential benefit of your participation in the study would be that you would be monitored for pain and would not be left in pain after the procedure.

If you agree to take part in the study, then I can assess the degree of pain after the procedure is done. This will be done at different times: 10 minutes, 40 minutes, 2 hours and 3 hours after the procedure.

To help you in telling me if you have pain and how bad the pain is, I will use a pain scale, called a visual analogue scale. This is tell me how you experience pain. This is what the scale looks like:

Visual analogue scale

No pain ----------Moderate ---------- Most severe pain
0 5 10

If you agree to partake in the study some of your information need to be used, but your name and hospital number would be kept seperate from the rest of the information. The information will be collected according to a secret code that will only I will know. If you consent to take part, your age, how far you were pregnant and all the medication you receive for pain and what type of procedure you have had will need to be used for the study. All your information will be kept confidential.

If you decide not to participate in the study the procedure will continue and it will not affect the standard of care that you will receive.

Your participation in this study is entirely voluntary. If you decide to participate in the study, but change your mind at a later stage, we will remove all your information from the study.

This clinical study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC), and written approval has been granted by that committee.

Before you decide whether you will participate or not, do you have any questions ?

If you want to contact me at a later stage about anything you are not sure of regarding the study, I am available at 076 421 0277.

Thank you

APPENDIX D Informed Consent Form

I, _____, agree to participate in the study that Dr Mostert has explained to me.

I understand that after I have had my womb cleared out the doctor will be asking me if I am having any pain and how bad it is or not. I understand that this will be done at a few different times after the procedure. I understand that if I am in pain I will be given something for the pain.

I understand that some of my information will be used for the study: my age, how far pregnant I had been, any pain medication that I receive, the amount of pain I feel and the type of procedure I have had.

I understand that all my information will be given a special code so that no one will be able to trace it back to me. I understand that my name and hospital number will be kept separate from my information, and will be locked away.

I understand that my participation is entirely voluntary and that I can pull out at any time.

Signed at _____ on_____

_____

SIGNATURE

APPENDIX E Data Collection Sheet

Patient data sheet

Age:

Gestation:

Type of procedure:

Reason for procedure:

Analgesia received preoperatively:

Analgesia received intraoperatively:

Analgesia received postoperatively:

Visual analogue score:	Actual time and ratio score:
During recovery (10 minutes)	_____
40 min	_____
2 hours	_____
3 hours	_____

Rescue analgesia received:

Visual analogue scale

No pain ----------Moderate ---------- Most severe pain
0 5 10

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