In partial fulfilment of the requirements for the Master of Medicine in Anaesthesia and Critical Care

A STUDY OF PAIN ASSESSMENT TOOLS AMONG WOMEN UNDERGOING MANUAL VACUUM ASPIRATION OF RETAINED PRODUCTS OF CONCEPTION AT THE UNIVERSITY TEACHING HOSPITAL
LUSAKA, ZAMBIA

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A STUDY OF PAIN ASSESSMENT TOOLS AMONG WOMEN UNDERGOING
MANUAL VACUUM THE UNIVERSITY TEACHING HOSPITAL (UTH)
LUSAKA, ZAMBIA

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DECLARATION

I hereby declare that this dissertation represents my own work, and it has not previously been submitted for a degree, diploma or other qualification at this or another University.

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CERTIFICATE OF APPROVAL

THIS DISSERTATION ENTITLED A STUDY OF PAIN TOOLS AMONG WOMEN UNDERGOING MANUAL VACUUM ASPIRATION OF RETAINED PRODUCTS OF CONCEPTION AT THE UNIVERSITY TEACHING HOSPITAL (UTH), LUSAKA, BY HAZEL MUMPHANSHA HAS BEEN APPROVED AS PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF DEGREE IN MASTER OF MEDICINE (ANAESTHESIA AND CRITICAL CARE) BY THE UNIVERSITY OF ZAMBIA, SCHOOL OF MEDICINE.

Head of Department: ....
Signature ....Date.......................................

Examiner I: ....
Signature...

Examiner II: ....
Signature: ....

DEDICATION

To my husband Brian & my sons Chembe and Yamba, You mean the world to me.

ACKNOWLEDGEMENTS

Firstly I want to thank God for bringing me thus far and making this research achievable.
 It is with sincere gratitude that I wish to thank the following individuals for their contribution towards the successful completion of this study:

1. Dr Dylan Bould my supervisor, for the guidance provided from the inception of this study, writing of the proposal and the final report. Thank you.
2. Dr Feruza, my co-supervisor of the study. For all your input.
3. Alan Kachuka who was my research assistant and spent hours collecting data
4. All the women who participated in this study. Here's to a step forward in pain assessment!

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ABBREVIATIONS

FPS	Faces Pain Scale
FPR – R	Faces Pain Scale - Revised
FCT	Full Cup Test
HM	Hazel Mumphansha
IASP	International Association the Study of Pain
LMIC	Low and Middle Income Countries
MVA	Manual Vacuum Aspiration
NRS	Numerical Rating Scale
PCA	Patient Controlled Analgesia
REC	Research Ethics Committee
RPOC	Retained products of conception
UTH	University Teaching Hospital
VAS	Visual Analogue Scale
VRS	Verbal Rating Scale
WHO	World Health Organisation

ABSTRACT

Background: Pain is subjective and its assessment is dependent on self-report. Evaluation of cause, type and severity helps in the selection of the appropriate therapeutic regimen and the assessment of the effectiveness of the therapy. To establish whether a particular pain intervention is effective or not, the best method for clinical research and practice is the use of simple pain assessment tools. The tool must be relevant to the setting understandable by the users and responsive to change in pain levels, taking into account tool content and patient factors. Limited reports regarding pain assessment in low income and low education settings exist. Pain assessment in these patients needs to be simple to understand and use, and requiring minimal or no word or number knowledge, yet demonstrate clinical usefulness and utility with current medications.

Methods: This was a cross sectional observational study involving women (n=138) undergoing manual vacuum aspiration of retained products of conception in the gynaecology admission ward at University Teaching Hospital, Lusaka, Zambia. Data was collected using a structured schedule. The first phase aimed to estimate the usefulness of Full Cup Test, Numerical Rating Scale and Faces Pain Scale-Revised in detecting pain. The second phase examined the usefulness of these tools in these patients in detecting change in pain in response to analgesia and the third phase aimed to validate a tool based on ease of understanding and completion and preference.

Results: The majority of women (53.6%) were aged between 21and 30 years and the majority (66.7%) had poor education (none or only primary education). The majority of women had severe pain during the procedure. All three tools were useful for detection of pain but however, the faces pain scale revised was the most discriminative. The mean Numerical Rating Scale, Full Cup Test and Faces Pain Scale-Revised scores were statistically correlated (0.67 - 0.94) but there was more correlation between the non-numerical tools. The Faces Pain Scale-Revised was the most preferred tool, was easiest to understand complete. It was able to detect changes in pain levels in relation to analgesia. It was the most acceptable tool for the study population.

The current guidelines for intra operative analgesia are inadequate with majority of patients dissatisfied with analgesia provided. None of the analgesic combinations appeared to give significant relief during the procedure. A combination of morphine, ibuprofen and

paracetamol gave statistically significant reduction in pain analgesia at 10 minutes and one hour after the manual vacuum aspiration while morphine was shown to have an analgesic effect intra operatively and at 10 minutes by the faces pain scale.

Conclusion: The revised faces pain scale (Faces Pain Scale-Revised) is most the most suitable tool for pain assessment in this population. It is clinically useful in both assessing and differentiating changes in pain and is easily understood and useful for patients with low education.

CHAPTER 1

1.0 BACKGROUND

Effective pain management requires careful assessment of both pain, and response to efforts employed to treat the pain. Multiple assessment tools have been developed to try to quantify how much pain a patient may be experiencing. As pain is subjective, pain assessment tools are therefore based on the patient's self- report. A variety of tools are used to assess pain, each having its own advantages and disadvantages. A scale that is clinically useful is one that is easy to understand and use and is responsive to change in pain levels, while at the same time maintaining validity (measurement does actually scale pain) across a variety of disease states and cultures (Cardno N, 2002).

Commonly used tools include the Verbal Rating Scale (VRS), the Numerical Rating Scale (NRS) and Visual Analogue Scale (VAS) (Chung et al 1997). Faces Pain scale (FPS), Full Cup test (FCT) and Colour Intensity Scales are also simple tools developed and adapted for patients with low education and reduced cognition. There are limited reports about pain assessment in populations from Low and Middle Income (LMIC) countries (Ergun U, 2007) where low levels of education are prevalent, such as Zambia. Pain assessment in patients with low levels of education needs to be simple to understand and use, and require minimal or no number or word knowledge (Ergun 2007). The verbal rating scale though simple, does not restrict patients to indicating a level giving rise to potential for a level of ambiguity. Severity of pain cannot be distinguished from frequency (Flaherty, 1996). The numerical rating scale is advantageous because of its simplicity in administration and requires no knowledge of English words. The potential for ambiguity of words is eliminated. Though the NRS continues to be popular among researchers, its disadvantage is that it becomes unreliable in patients who may not be able to differentiate between numbers, such as those with low education (Flaherty, 1996)

While a study in India (Nikhil M et al, 2012) in patients who lacked the ability to read or write showed that the visual analogue scale and the numerical rating scale can be used

interchangeably irrespective of literacy status several studies have shown that in fact, literacy levels play a vital role in choice of pain assessment tool. In Mexico a study comparing simple pain assessment tools determined that simple tools can be used in patients with low education but level of literacy i.e. ability to read and write plays a role in patient preference. While another study in Turkey (Ergun U, 2007) showed that patients with low education show preference for and have better understanding of tools requiring minimal or no word or number knowledge.

In sub-Saharan Africa, few studies have been done to validate pain assessment tools in patients with low education. A study in Nigeria (Soyanwo OA, 2000) compared the use of English and Yoruba versions of VAS, FPS and the NRS and confirmed the validity of using these single item pain tools in that population. A pilot study conducted in Uganda (Cartledge P et al, 2005) comparing the use of single item tools showed that the Revised Faces Pain Scale was easily understood and accepted in that population and that assessing pain in a culturally acceptable manner is important in combating pain. However this study was only done in cancer patients and did not include procedural or post operative pain assessment. A recent study in Kenya showed the validity of use of the VAS and the Faces Pain Scale and further noted that patients with a low education showed preference for the Faces Pain Scale. These highlight the fact that pain assessment tools must be tailored to the population context. This study included both children and adults and this may have had an impact on the translation of results.

Pain assessment during miscarriage or abortion is a critical aspect of patient care (Meckstroth K, 2009). The University Teaching Hospital handles all abortion referrals from 25 Lusaka district clinics. Lusaka has a population of 1,432,401, out of which 51% are women (ZDHS 2001 -2002). Of the female population, 22% are in the reproductive age group (ZDHS 2001 -2002). An estimated 430 abortions are admitted per month (Mupeta S, 2009).

The gynaecology department performs up to 10 to 20 MVAs per day, mostly for spontaneous incomplete abortion. (Chiko M, 2006). Incomplete abortion patients comprise 30 – 50% of all gynaecology admissions (Mupeta S, 2009) and are day case

surgeries with an average hospital stay of 6 to 12 hours. Therefore anaesthesia and analgesia choice is cardinal to allow continuous function of such a busy area. In UTH, no anaesthetic (local or general) or sedation is provided for this painful procedure. There is currently no routine pain assessment of these patients at UTH and therefore the pain pattern under the current guidelines remains unknown.

A study in UTH showed that 75.3% of patients presenting for MVAs were unemployed with 47.3% having poor education – none or primary education (Chiko M, 2006). The best tool for pain assessment among these women is unknown. A standard pain assessment tool that is clinically useful and whose utility is demonstrable with current medications does not exist. A study to identify such a tool is thus, a crucial first step.

CHAPTER 2

2.0 LITERATURE REVIEW

To assess the efficacy of a pain strategy employed, pain must be assessed among that group of individuals. The pain tool used must be useful for that setting (Huang et al, 2012). No studies have been done locally on the use pain assessment tools for pain management services.

Fitzpatrick et al (1998) provided a framework which appears to be most comprehensive and easily applied in selection of pain assessment tools for a population. It takes into account factors of both patient and tool content. It was based on a review of 5621 articles that focused on patient based outcome measures and states that the pain assessment tool must be:

1. Appropriate – match the specific purpose of the study or clinical situation
2. Reliable – in terms of reproducibility and internal consistency
3. Valid – in that it measures patient's perception of pain
4. Responsive to change in pain that is of importance to the patient
5. Precise – accurate and discriminating between different pain scores
6. Interpretable – in that meaningful scores are produced
7. Acceptable to those completing it
8. Feasible – i.e. the degree of burden and effort involved in using it is acceptable.

Physiological factors such as heart rate and blood pressure are unreliable in assessment of pain as they also depend on several other factors (Buttner W et al, 2000). Cardiovascular and respiratory parameters are non-specific and prone to error. Their use in clinical practice is unproven and therefore not recommended as a sole modality (van Dijk et al, 2001).

In clinical practise and research, simple (single item) pain scales and multi- dimensional scales are used. Ease of use is an important criterion for choosing between pain rating scales and simple pain scales. The type of a pain assessment tool may limit its usefulness

in adequate pain assessment therefore preventing optimal treatment, especially of procedural pain (Ergun U, 2007)

Verbal rating scales, visual analogue scales, numerical rating scales, faces pain scales are the most commonly used (Jones K, 2007). These are all simple tools, each with its own advantages and disadvantages are based on self report

Single item pain measurement tools (simple) including VAS, NRS VRS and FPS-R have been validated for use in low income and low education contexts and in particular, the African context (Huang et al, 2012). However, evidence is lacking in the University Teaching Hospital as to whether these scales can be of use there.

Below are commonly used pain measurement tools.

VERBAL RATING SCALES- VRS

This kind of scale stratifies pain according to the level of severity by use of commonly used adjectives. These are "mild" "moderate" and "severe". This kind of scale is useful for audit measures and clinical practice (Cardno N, 2002). Verbal rating scales may be used in clinical research but their semi-quantitative nature makes them less suitable for this purpose as they lack precision to identify small changes in the patient's pain due to the limited number of responses (3) available.
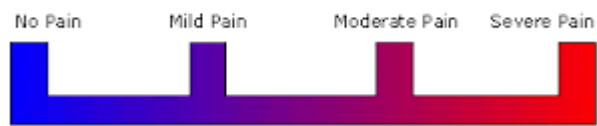
Figure 1

NUMERICAL RATING SCALE- NRS

These scales take two extremes of pain experience – "no pain" and "extreme pain" and assigns numbers to levels of pain in between. It is often assumed that each number represents a proportional increase in pain severity (Cardno N, 2002). Numerical rating scales are robust and give reproducible results. It is simple to administer and to understand. It is has been suggested that it be adopted as the universal assessment tool because of higher compliance rates, ease of use and good applicability (Hjermistad et al, 2011)

Numerical rating scales also generate ordinal data, often considered unsuitable for parametrical statistical techniques but in practice, this potential problem is frequently

overlooked and parametric analyses are used without significant methodological problems (Mathews J, 1990). A theoretical disadvantage is that use of specific points via digits reduces the capacity to detect subtle changes. In reality, variation within and among patients tends to mask this effect (Cardno N, 2002).

0-10 Numeric Pain Intensity Scale *

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

No pain — Moderate pain — Worst possible pain
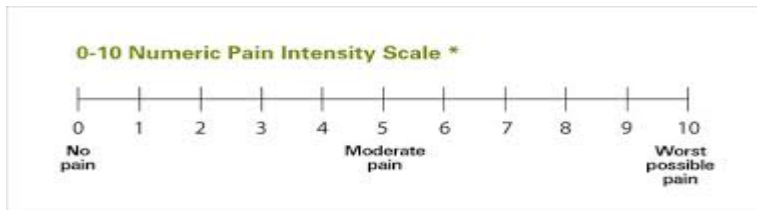
Figure2

VISUAL ANALOGUE SCALE - VAS

This scale is similar in concept to the numerical rating scale in that it also uses anchor points to represent pain extremes of pain. A standard length of line is used on which a subject marks their estimate of level of pain. The visual analogue scale has been used in clinical practice and successfully in research. The simple line marking gives robust and culturally independent data (Jensen M, 1992). It also yields continuous data making parametric analyses uncontroversial (Mathews J, 1990).

The visual analogue scale and numerical rating scale are thought to be superior to the verbal rating scale with the numerical rating scale having the highest sensitivity in showing even small changes in pain scores (Williamson A, 2005).

Visual Analog Scale (VAS)*

No pain — Pain as bad as it could possibly be

Figure 3

FACES PAIN SCALE-FPS

Another simple scale is the faces pain scale (Wong-Baker faces pain scale) (Wong D, Baker C, 1988), which was initially adapted for use in children but has now been validated for use in adults (Herr K.A, 1998). This scale has a series of faces ranging from a broadly smiling face to crying inconsolably. The faces pain scale – revised (FPS-R) (Herr K.A, 1998) is a validated tool for use in adults particularly with low education and

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language difficulties (Herr K.A, 1998). The FPS-R can be scored along the 0 – 10 metric as the numerical rating scale unlike the faces pain scale which scores 0 – 6 (Hick CL, 2001).

Faces Pain Scale - Revised
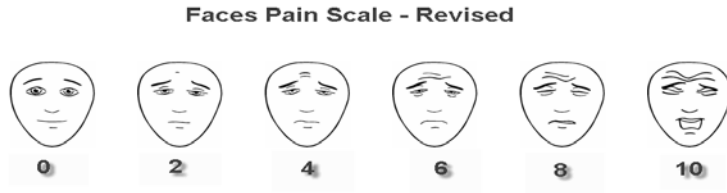
Figure 4

FULL CUP TEST

This is another simple pain scale adapted for use in populations with low education. This scale involves the use of a cup to depict pain. An empty cup (1) is synonymous with no pain while a full cup (3) is equivalent to worst pain. A line is drawn to show level of fullness of cup (2) as a measure of pain. This is also measured on a 0 – 10 metric. (a/b x 10)
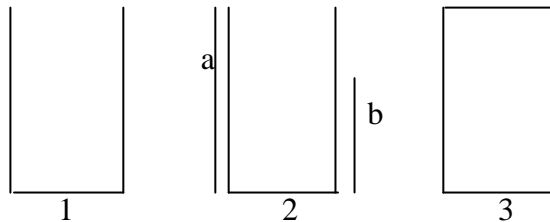
Figure 5

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MULTIDIMENSIONAL PAIN SCALES

These include the pain scales such as the McGill pain questionnaire and syndrome specific pain scales. These take into account many other factors that can be reported as pain including affect, distribution and evaluation (Melzak R, 1975). They may be clinically useful tools but are cumbersome and time consuming for the patient and clinician and patients often do not understand the words used. Explanation of the words used invalidates the measure (Cardno N, 2002).

Single item continuous rating scales are valuable tools for clinicians to ascertain pain. Studies comparing these tools have found similar accuracies and validity. This was measured by a computerised simulation study, randomly sampling 10,000 times

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repeatedly from simultaneous observations of VAS, NRS and VRS. It documented that the scales were able to detect differences in pain intensity but power to detect these differences was higher in the NRS and VAS. The values of the VAS and VRS also generally agreed well in the same patients (Hjermistad M.J, 2011). However, studies comparing these tools in low education populations are few.

In many clinical scenarios, the pain assessment tools may be all that is required. However, several researchers emphasise the importance of measuring pain relief associated with either a drug or an intervention. The easiest way being to assess the pain score before and after the intervention (Cardno N, 2002). This relationship can be used to validate a pain assessment tool.

Martin S Angst and colleagues, (1999) undertook a study to investigate the relationship between Visual Analogue Scale pain intensity and pain relief score changes during analgesia in which two analgesic drugs (methadone and hydromorphone) were studied. This study involved adults participants who had chronic non-malignant pain treated with methadone and chronic malignant pain treated with hydromorphone. Pain before and after was plotted on a similar 100mm VAS. Results showed a systematic relationship between pain intensity and pain relief scores with a conclusion that pain assessments scales can quantify analgesic drug action and that this relationship can be used to validate a tool.

A study in Ankara, Turkey, (Ergun U, 2007) compared the use of a Visual Analogue Scale (VAS) with a Full Cup Test (FCT) to assess pain in adult patients with average age of 42 years with low education (mean number of years of education = 9 years) and concluded that the (FCT) was easier to understand and respond to, measured by the average number of times required to explain each scale to the participants. The average number of times required to explain the VAS was approximately two times more than the FCT. It was also easier to complete in comparison to the VAS and was in fact useful in assessing and differentiating changes in pain in patients with low education, therefore validating a pain tool for that population. This study shows that education level plays a role in the selection of appropriate pain tools for populations.

In another study (Klopper H, 2005), at a South African teaching hospital, a comparison was done to assess the accuracy of the pain scored by patients using the VAS comparison to that scored for them by the surgical nurses who were also asked to assess the patient and score their pain on a VAS. The study involved patients undergoing elective surgery including orthopaedic, gynaecological, plastic, vascular and trauma related surgery. The patients in this study were awake enough for verbal communication and in pain. It was found that in 23 out of 36 assessments, the nurses underestimated the pain score level indicated by the patient. This attests to the fact that standardised assessment tools must be employed during treatment of pain in order to remove bias. In addition, a pattern was shown noted which showed differences in pain perception related to ethnic differences. Mixed race women were noted to tolerate pain more than white women while among the black population, the levels of tolerating pain varied. This study demonstrates that pain is often under-appreciated by health care providers and that, in LMIC pain management is therefore often inadequate. At the same time, the study showed that ethnic differences should be considered in efforts to assess pain.

A study in Kenya compared the use of the numerical rating scale and the faces pain scale – revised (FPS-R). The two scales were adapted in Swahili and administered to patients with age range 8 – 89 years including medical, surgical and paediatric in- patients in order to test their validity in that population. This was done by cognitive interviewing to examine how participants understood, processed and responded to the pain scales. The study however did not include the full cup test which has been validated in low education settings and did not disaggregate the data by age. The study demonstrated usefulness and acceptability of both scales in that both easily understood and participants were able to accurately describe what progression of the faces on the scale meant as well as progression of 0 to 10 on the NRS. It also showed preference for the FPS–R which was more easily understood measured by ability to describe what progression on the faces meant i.e. 93% compared to 73% for the NRS. This was attributed to the low education levels in Kenya whose literacy rates stand at 61.5% of the participants and thus difficulties with numeracy (Huang K.T, 2012). This may have implications on the pain

scales chosen for use among populations with low education levels and also on the movement towards adoption of an international standard pain assessment tool, NRS being the leading candidate for universal adoption (Ferreira-Vallente M.A, 2011).

A study of 95 patients (Ferraz et al, 1998) was done in Brazil in which three different pain scales were compared to evaluate the reliability of VAS, VRS and NRS in literate and illiterate patients indicated that the NRS had higher reliability using Cronbachs alpha which ranged from 0.65 to 0.86 in both groups. On the contrary, a study in Mexico (Clark p, 2003) compared the use of 2 commonly used scales, the VAS and VRS. Patients who preferred the VRS found it easier to understand and were more comfortable using words than numbers. It also showed that both scales were valid measures pain intensity because they could both be used to assess pain. The study showed that choice however, depends on setting, clinician's goal and patient's level of education. The more educated population preferred the VAS while those with low education VRS. Patient preference is cardinal to patient – physician communication.

Reliability of a pain assessment tool in a particular population is important. A study in Brazil to determine the reliability of selected pain assessment tools (Ferraz et al, 1990) was done including the VRS, NRS, FPS-R and the Iowa Pain Thermometer (IPT). In patients admitted to acute care services, a majority of patients were able to use all tools. However, in the more educated population – more than primary education the NRS was the preferred tool while the FPS-R was the preferred tool in those with less education and had either no education or primary education only.

CHAPTER 3

3.1 STATEMENT OF THE PROBLEM

Until recently, many MVAs in UTH have been performed without any analgesia but with patients expected to cooperate despite pain. Even though protocols for analgesia have been placed in the department (appendix 5), personal observation has revealed that no standard pain assessment is done preoperatively. There is also no reassessment to establish if efforts to relieve the pain have been successful. Coupled with this is the fact that, there is a paucity of data pertaining as to what the best pain scales for low income, low education contexts such as in UTH are. Simple scales are used in clinical practice and research. In the UTH in Zambia, standard application of pain scoring tools among women undergoing MVAs does not exist. No validated, simple tool that is acceptable and clinically useful in this population is currently in use as should be the standard of practice. The best tool for this purpose is unknown.

3.2 RATIONALE

The turnover of patients in the gynaecology emergency room in UTH requiring manual vacuum aspirations stands at 30 – 50% (Mupeta S, 2009). It is a procedure that is characterised by distress and pain on the part of the patient. The pain in these women is not assessed by any of the attending medical personnel including nurses, doctors and clinical officers. This may well be because there is no standard assessment tool employed in the UTH. As such, the pattern of pain surrounding this procedure is unknown and relevant data as to whether the current guidelines are effective cannot be obtained.

The majority of women in reproductive age in Zambia have an education of primary level. The percentage of women presenting to UTH with poor education i.e. no or primary education (0-7 years) stands at 47.3% (Chiko et al, 2006). It is therefore imperative that a standardised pain scoring tool be established in order to ascertain whether or not procedural pain is adequately alleviated during MVA of RPOCs.

3.3 RESEARCH QUESTION:

Which simple pain scale –Numerical Rating Scale, Faces Pain Scale–Revised or Full Cup Test, can be best used to assess pain and efforts to alleviate it, in women undergoing manual vacuum aspiration of retained products of conception in U.T.H

3.4 OBJECTIVES

3.4.1 General Objective:

To explore the use various pain assessment tools in patients undergoing manual vacuum aspiration of retained products of conception in University Teaching Hospital.

3.4.2 Specific objectives

1. To determine pattern of pain (mild/moderate/severe) in women undergoing MVA
2. To establish a relationship between pain scores and analgesia as a measure of validity of tools
3. To ascertain if educational background plays a role in the acceptability of a pain assessment tool
4. To assess ease of understanding and completion of various pain scales to determine usefulness
5. To determine the most suitable pain assessment tool for women undergoing MVA

CHAPTER 4

4.1 METHODS:

Study design:

This was a prospective observational cross sectional study

Setting

The study was conducted at the University Teaching Hospital, gynaecology department, ward CO3.

Study population:

The study involved all women presenting to the gynaecology emergency ward requiring manual vacuum aspiration of retained products of conception who met the inclusion criteria

Sampling:

138 participants were enrolled. This was chosen to include variations that may have occurred in numbers of MVAs performed per day, in education levels, in institutional availability of drugs, which could be erratic, and prescription of analgesia.

Study process

Prior to beginning enrolment of patients, an assistant was trained by the primary investigator (HM) in the use of the tools, administration of and completion of the questionnaire. Patients were enrolled consecutively as they presented to the gynaecology emergency room theatre. Participants were fully informed via an information sheet, consent to participate was sought and confidentiality was respected (Appendix 1 and 2). Participants were then asked to fill in a questionnaire (appendix 3) at various times. (i) These were immediately after procedure to score their worst pain during the procedure, (ii) they were asked for their current pain at 10 minutes after and (iii) they were asked for their current pain 1 hour after the procedure. Patients were then asked which tool they most preferred and which was easiest to understand and complete.

Understanding was ascertained by how easily the patient understood the tool and how many times the tool was explained before the patient was able to complete the tool.

The investigators then gathered information from the patient and file as to whether analgesia had been given, timing of the analgesia and type.

Information was plotted onto an information sheet (appendix 4) then later input into a Microsoft excel sheet.

Figure 6: study process

Flow chart

```
┌─────────────────┐
│ Training of     │
│ assistant       │
└─────────────────┘
         │
         ▼
┌─────────────────┐
│ Enrolment       │
└─────────────────┘
         │
         ▼
┌──────────────────────────────────────────────┐
│ Administration of questionnaire immediately, at│
│ 10 minute and 1hour                            │
└──────────────────────────────────────────────┘
         │
         ▼
┌──────────────────────────────────────────────┐
│ Completion of questionnaire by investigator    │
│ (primary or assistant)                         │
└──────────────────────────────────────────────┘
         │
         ▼
┌──────────────────────────────────────────────┐
│ Entry into Microsoft Excel sheet               │
│                                                │
└──────────────────────────────────────────────┘
```
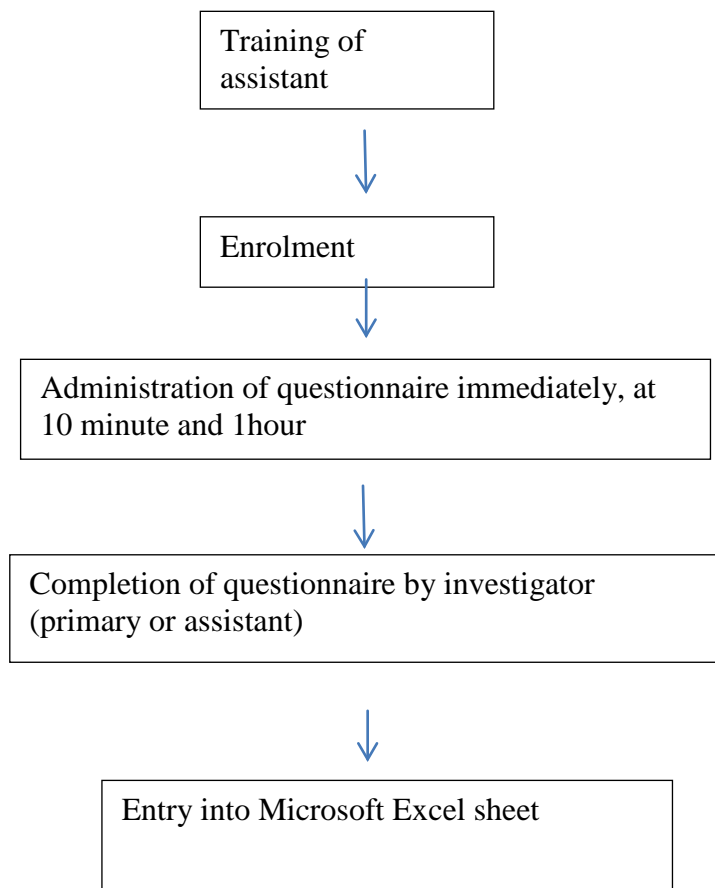
Data collection:

The data was collected by use of various pain scales. (Appendix 3) Three (3) different types were administered after the procedure via a questionnaire. Data was collected by the primary investigator (HM) and a trained assistant who participated in the study.

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4.2 OUTCOMES:

4.2.1 Primary outcome

The proportion of women that easily understood and completed a pain assessment tool.

4.2.2 Secondary outcomes

    a. Pattern of pain (mild, moderate or severe) intra-operatively, at 10 minutes and 1 hour after operation.

    b. Indication as to whether the current guidelines (appendix 5) were being followed by use of investigator answered questionnaire.

    c. Correlation between educational background and ease of use of particular tools.

    d. Association between analgesic intervention and pain score as an indicator of validity.

4.3 INCLUSION AND EXCLUSION CRITERIA

4.3.1 Inclusion criteria

    Women undergoing an MVA, aged 16 years and above. Younger mothers were not included as this was not ethical. Young girls below the age of 16 are not considered consenting partners and considered defiled and are therefore treated as police cases. This study chose not to cross those boundaries

4.3.2 Exclusion criteria

    All women with septic abortions

    All women with missed abortions

    All women with shock requiring immediate MVA

Shock being defined as:

    BP < 90/60

    CRT > 4 seconds

    Urine output <0.5mls/kg/hr

        Altered GCS

These were excluded from the study this population of patients were too unstable to participate in the study.

4.4 DATA ANALYSIS

4.4.1 Sample size calculation

Sample size was based on the expected proportion of pain in women undergoing MVA (Mupeta S, 2009).

Expected proportion with variable of interest = 90% (Mupeta 2009) i.e. to experience pain.

Therefore, proportion expected to have negative result = 10 % = 0.10

Desired precision (total width) of confidence interval = +/- 0.05 = 0.1

Confidence level for interval = 95%

Therefore sample size = 138

4.4.2 Analysis

Data was stored in a data bank that was created and statistical package SPSS Version 20 (IBM Armonk, US) was used to analyse it. Categorical variables were expressed as percentages or proportions, while a Chi square test was used to analyse dichotomous variables. Graphs of pain scores for each tool at the variable timings were plotted and graphs of pain scores for each tool in the presence of analgesia were plotted. Descriptive analysis was also done and appropriate charts produced. Multivariable logistic regression was performed to assess individual independent variable in relation to pain relief for all pain tools. All significant variables were included in the model. Spearman's correlation for measure of agreement between the scales was done. Tables presenting scores and correlation were drawn to show statistical relevance.

All tests were set at 95% confidence interval (CI) and a p value < 0.05 was considered statistically significant.

4.6 ETHICAL CONSIDERATION

Permission was obtained from University Teaching Hospital management to carry out the study in the institution. Ethical clearance was given by ERES Converge IRB (Ref. No. 2015-Feb-009). Informed consent was obtained from participants and confidentiality was kept for all participants. Participants could withdraw from the study at any point without prejudice against further care. There were no risks due to participation in this study on the part of the participant. Participation was entirely voluntary and there will be no payment or incentive for participation

CHAPTER 5

5.0 RESULTS

5.1 DEMOGRAPHICS

A total number of 138 women were enrolled in the study. The age range of recruits was from 16 to 45 years. Majority of patients were aged 21 to 30 years accounting for 53.6%. . 20.3% were aged below 21 years while 0.7% were aged above 40 years.

Many of the women in the study had low education with 21% having no education while 45.7% had some primary education. This accounted for a total of 66.7% of women with poor education. 20.3% had secondary education while only 13% had attained any tertiary education.

Below is a table depicting the demographic data collected for this study.

Table 1: Demographic characteristics

n=138	n	%
Age		
<21	28	20.3
21 – 30	74	53.6
31 – 40	35	25.4
>40	1	0.7
Education		
No Education	29	21.0
Primary	63	45.7
Secondary	28	20.3
Tertiary	18	13.0

5.2 PATTERN OF PAIN

Intensity of pain was defined as mild, moderate or severe pain. The pattern of pain was studied in the periods (i) intra operatively (retrospective report immediately after the procedure), (ii) ten minutes after the procedure and (iii) one hour after the procedure. Retrospective report was used for intraoperative pain as it was inhumane to question the patient while she was undergoing a painful procedure. All three pain tools were used to elicit the pattern of pain at these three timings. Below are graphs representing the results of pain patterns with use of the various pain tools.

On all tools, the pattern of pain was shown to be severe pain during the procedure, moderate pain at 10 minutes and mild to no pain 1hour after the procedure.

Graph 1: Pattern of pain using the Numerical Rating Scale
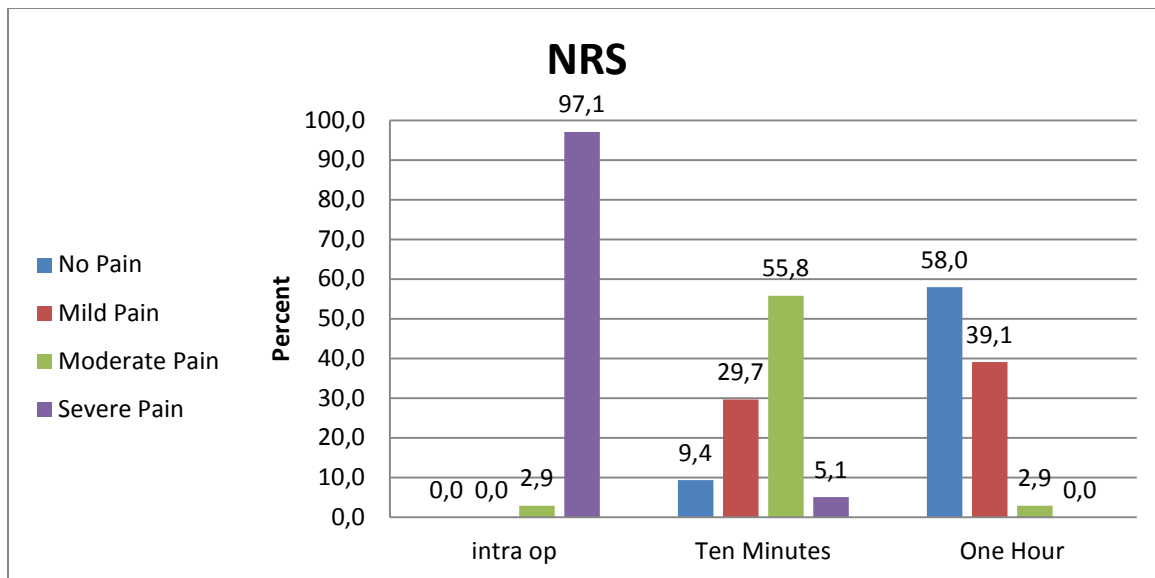
Graph 2: Pattern of pain using Full Cup Test
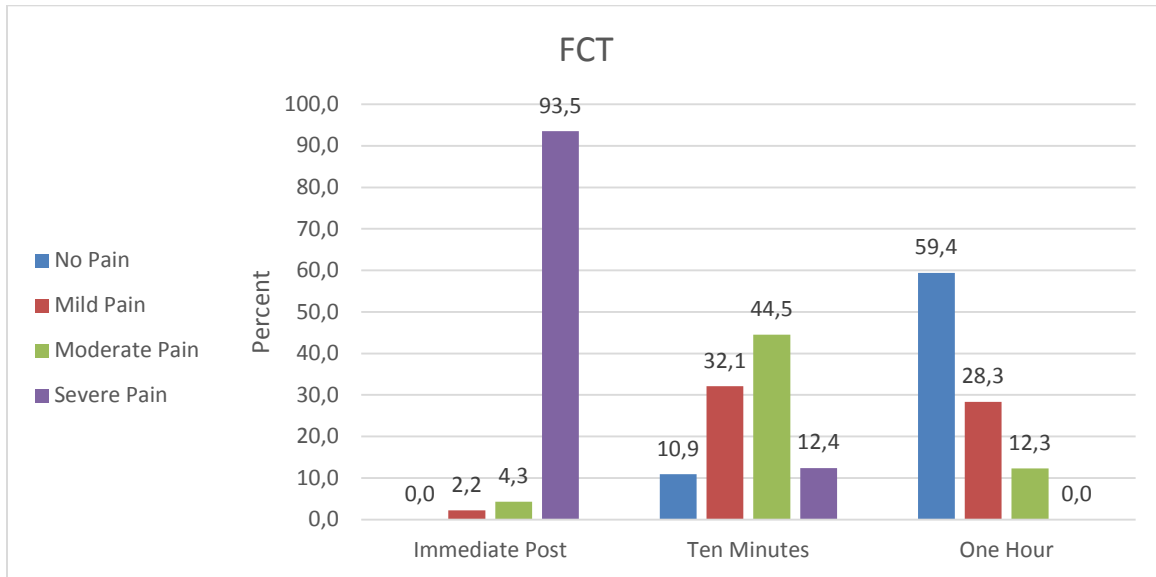
Graph 3: Pattern of pain using Faces pain scale
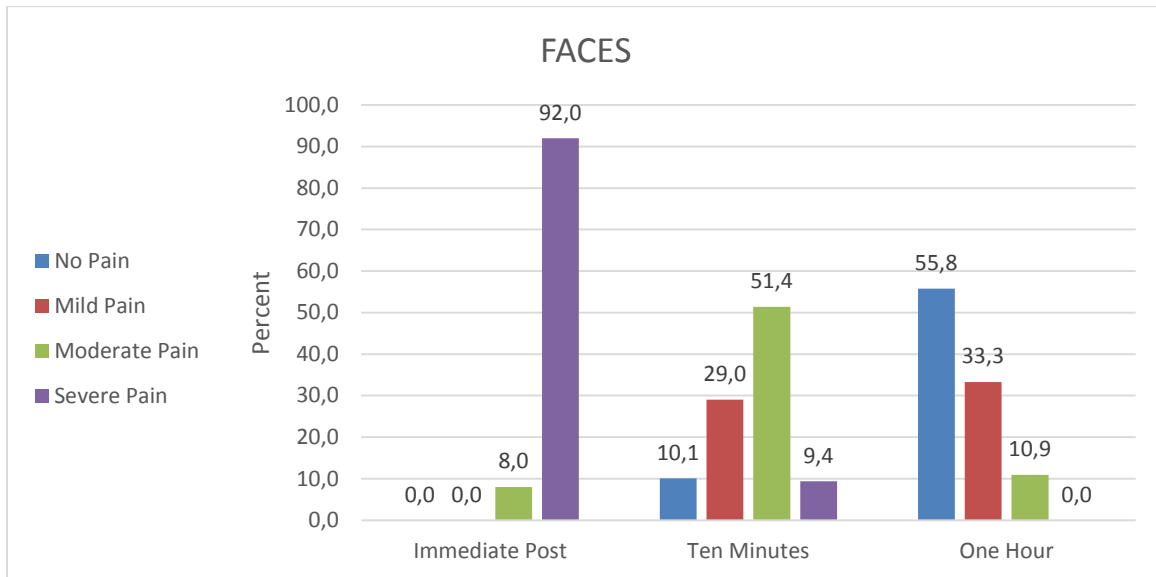
5.3 PAIN SCORES

Pain scores were categorized as mild moderate and severe. This can deduced from each of the pain tools.

NRS: 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, 7-10 = severe pain

FPS-R: 0 = no pain, 2 = mild pain, 4/6 = moderate pain, 8/10 = severe pain

FCT: 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, 7-10 = severe pain

Taken from Jones et al, 2007
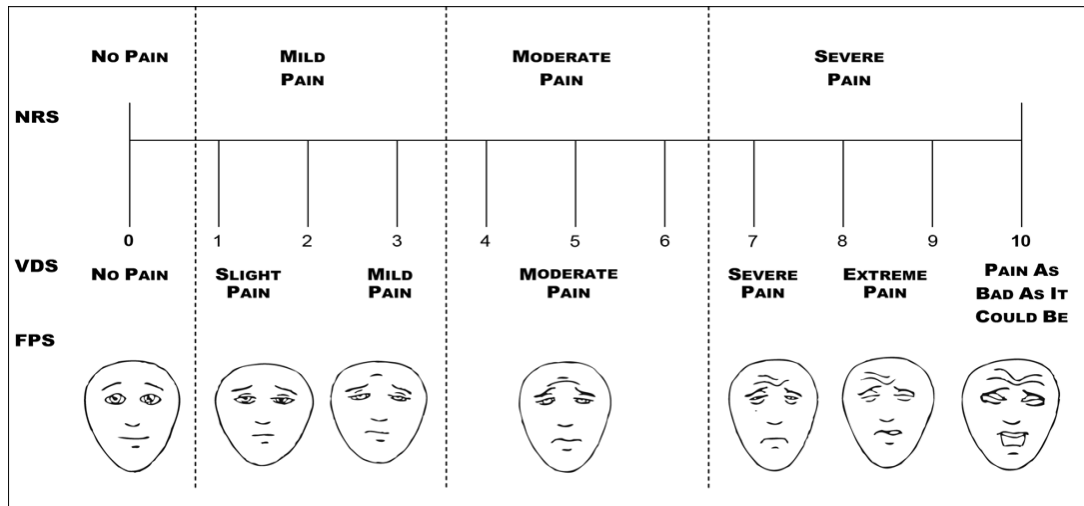
Figure 7

Recruits received several drug combinations for analgesia and all drugs were included in the multivariable regression. However there were only four combinations that had numbers that were used more than 3 times. These were:

1. All analgesics – morphine, ibuprofen, paracetamol n=54
2. Ibuprofen and paracetamol n=37
3. Morphine and paracetamol n=21
4. Paracetamol only n=16

All other combinations accounted for only 8 i.e. morphine only = 2, ibuprofen only = 3, morphine and ibuprofen = 3, no analgesia = 2.

Standard doses were used for all patients as follows:

I.   Morphine 30 mg orally

II.   Ibuprofen 400mg orally

III.   Paracetamol 1g orally.

According to the protocol, the patient should receive all three at least. The MVA preemptive analgesia protocol (appendix 12) also states that 20mg oral morphine be given. However 30mg is given routinely, in contrast to the published protocol.

There was no other official MVA preemptive analgesia protocol present in the University Teaching Hospital.

Table 2 shows that a combination of all three analgesic drugs only gave statistically significant pain relief at 10 minutes ($p<0.05$) and 1hour ($p<0.05$) after the operation but gave no pain relief during the operation.

TABLE 2: PAIN SCORES IN PATIENTS WHO TOOK COMBINATION OF ALL ANALGESICS

n=138	None n(%)	Mild n(%)	Moderate n(%)	Severe n(%)	Statistics x^2	P
All Analgesia	NRS (intra op)				2.23	0.136
Yes			3(75.0)	51(38.1)		
No			1(25.0)	83(61.9)		
	FCT (intra op)				1.32	0.516
Yes		2(66.7)	3(50.0)	49(38.0)		
No		1(33.3)	3(50.0)	80(62.0)		
	FPS-R (intra op)				0.20	0.654
Yes			5(45.5)	49(38.6)		
No			6(54.5)	78(61.4)		
All Analgesia	NRS (10 minutes)				15.18	0.002
Yes	10(76.9)	21(51.2)	21(27.3)	2(28.6)		
No	3(23.1)	20(48.8)	56(72.2)	5(71.4)		
	FCT (10 minutes)				10.87	0.012
Yes	8(53.3)	23(52.3)	20(32.8)	2(11.8)		
No	7(46.7)	21(47.7)	41(67.2)	15(88.2)		
	FPS-R (10 Minutes)				17.66	0.001
Yes	9(64.3)	22(55.0)	23(32.4)	0(0.0)		
No	5(35.7)	18(45.0)	48(67.6)	13(100.0		
All Analgesia	NRS (1 Hour)				11.75	0.003
Yes	41(51.3)	12(22.2)	1(25.0)			
No	39(48.8)	42(77.8)	3(75.0)			
All Analgesia	FCT (1 Hour)				13.36	0.001
Yes	42(51.2)	10(25.6)	2(11.8)			
No	40(48.8)	29(74.4)	15(88.2)			
All Analgesia	FPS-R (1 Hour)				14.23	0.001
Yes	40(51.9)	13(28.3)	1(6.7)			
No	37(48.1)	33(71.7)	14(93.3)			

Each drug was assessed separately to ascertain its effect on severe pain using each tool intra op and at 10 minutes. The results showed that using the FPS-R, morphine had some statistical effect intra op (p=0.047) while the NRS and FCT did not show this.

At 10 minutes, the FCT and FPS – R were able to show statistical analgesic significance (p=0.001, p=0.004). This was again not the case with the NRS.

TABLE 3: LOGISTIC REGRESSION FOR SEVERE PAIN INTRA OPERATIVELY

	P	Odds	95%CI
NRS intra-Op			
Paracetamol	0.116	8.500	0.590, 122.489
Ibuprofen	0.997	0.000	-
Morphine	0.997	0.000	-
FCT intra-Op			
Paracetamol	0.586	1.880	0.194, 18.249
Ibuprofen	0.549	0.602	0.114, 3.166
Morphine	0.495	0.166	0.020, 1.371
Faces intra-Op			
Paracetamol	0.999	0.000	-
Ibuprofen	0.184	2.400	0.660, 8.726
Morphine	0.047	0.120	0.015, 0.973

TABLE 4: LOGISTIC REGRESSION FOR SEVERE PAIN AT 10 MINUTES

	P	Odds	95%CI
NRS at 10 Minutes			
Paracetamol	0.557	0.502	0.050, 5.013
Ibuprofen	0.607	0.658	0.134, 3.243
Morphine	0.402	0.516	0.110, 2.418
FCT at 10 Minutes			
Paracetamol	0.884	1.187	0.118, 11.968
Ibuprofen	0.754	1.214	0.361, 4.085
Morphine	0.001	0.071	0.016, 0.327
Faces at 10 Minutes			
Paracetamol	0.879	1.203	0.112, 12.935
Ibuprofen	0.267	0.486	0.137, 1.727
Morphine	0.004	0.047	0.006, 0.375

5.4 EDUCATIONAL ROLE IN PREFERENCE AND EASE OF USE OF TOOLS

This study also sought to ascertain if education played a role in the preference of tool choice by patients and also ease of use of tool and ease of understanding. There was statistically no significant association between education background and preference for tools, ease of use and understanding. The table below shows statistics of educational role on pain tools. It shows that the majority preferred the use of the non numerical pain tools and found them easier to understand and complete. The recruits in the lower education bracket in fact counted for the larger percentage that preferred and found the non numerical simple tools easier to understand and complete even though there was no statistical association.

TABLE 5: EDUCATIONAL LEVEL INFLUENCE ON PREFERENCE AND EASE

	NRS	FACES	FCT	Statistics	
	n (%)	n (%)	n (%)	x^2	P
Education	Preferences			10.40	0.109
No Education	0(0.0)	23(79.3)	6(20.7)		
Primary	3(4.8)	31(49.2)	29(46.0)		
Secondary	0(0.0)	15(53.6)	13(46.4)		
Tertiary	0(0.0)	11(61.1)	7(38.9)		
Education	Ease to Understand			9.51	0.147
No Education	0(0.0)	23(79.3)	6(20.7)		
Primary	3(4.8)	33(52.4)	27(42.9)		
Secondary	0(0.0)	15(53.6)	13(46.4)		
Tertiary	0(0.0)	10(55.6)	8(44.4)		
Education	Ease to Complete			4.20	0.650
No Education	0(0.0)	14(48.3)	15(51.7)		
Primary	1(1.6)	20(31.7)	42(66.7)		
Secondary	0(0.0)	8(28.6)	20(71.4)		
Tertiary	0(0.0)	6(33.3)	12(66.7)		

5.5 EXPLANATION OF TOOLS

The number of times that the tool was explained was used as a way to assess the feasibility and ability to understand the tools for the particular population. It was noted that educational background did not play a statistically significant role with regards to the number of times that the FCT and FPS-R were explained. However the p value for the NRS is very close to 0.05, so while not statistically significant, it shows a trend and may be significant if n were larger. The majority of patients with low education had the FCT and FPS-R explained once before use while a larger number of women had the NRS explained twice or more before use.

TABLE 6: EXPLANATION OF TOOLS

	Once n (%)	>/=Twice n(%)	Statistics x²	P
Education	NRS Explained		7.79	0.051
No Education	6(20.7)	23(70.3)		
Primary	14(23.3)	46(76.7)		
Secondary	13(46.4)	15(53.6)		
Tertiary	8(44.4)	10(55.6)		
Education	FCT Explained		0.64	0.888
No Education	24(82.8)	5(19.2)		
Primary	50(83.3)	10(16.7)		
Secondary	25(89.3)	3(10.7)		
Tertiary	15(83.3)	3(16.7)		
Education	FACES Explained		0.64	0.887
No Education	28(21.5)	1(25.0)		
Primary	57(43.8)	2(50.0)		
Secondary	27(20.8)	1(25.0)		
Tertiary	18(13.8)	0(0.0)		

TABLE 7: FREQUENCIES OF EASE OF UNDERSTANDING AND COMPLETION

n=138	N	%
Ease to Understand		
NRS	3	2.2
FACES	81	58.7
FCT	54	39.1
Completion		
NRS	1	0.7
FACES	48	34.8
FCT	89	64.5

Above is a comparison of numbers on the ease of understanding and ability to complete a tool. All patients were able to understand and complete all three tools. It is of note that the non

numerical tools were easier to understand and complete. 58.7% found the FPS-R easiest to understand while 64.5% found the FCT easiest to complete.

The above results indeed show that the cohort preferred the non numerical pain tools and in fact showed 57.9% preference for the FPS-R, 39.8% preferred the FCT while only 2% preferred the NRS with the women in the poor education bracket accounting for the majority that preferred the non numerical tools. Similarly, the most participants found it easy to understand and complete the non-numerical tools

5.6 REVISED FACES PAIN SCALE (FPS-R) VALIDATION

As can be seen from the results, the FPS-R, according to preference, ease of understanding and completion is the most appropriate tool for assessment of pain among women undergoing MVA of RPOCs.

Further evaluation to validate this tool is shown below

The box plot below shows the pattern of pain experienced by women undergoing manual vacuum aspiration of RPOCs. It can be noted using the FPS-R which is the most preferred, easiest understood, and easiest to complete tool among this population, the pain was noted to be severe intra operatively, moderate at 10 minutes and zero to mild at 1 hour after the procedure.
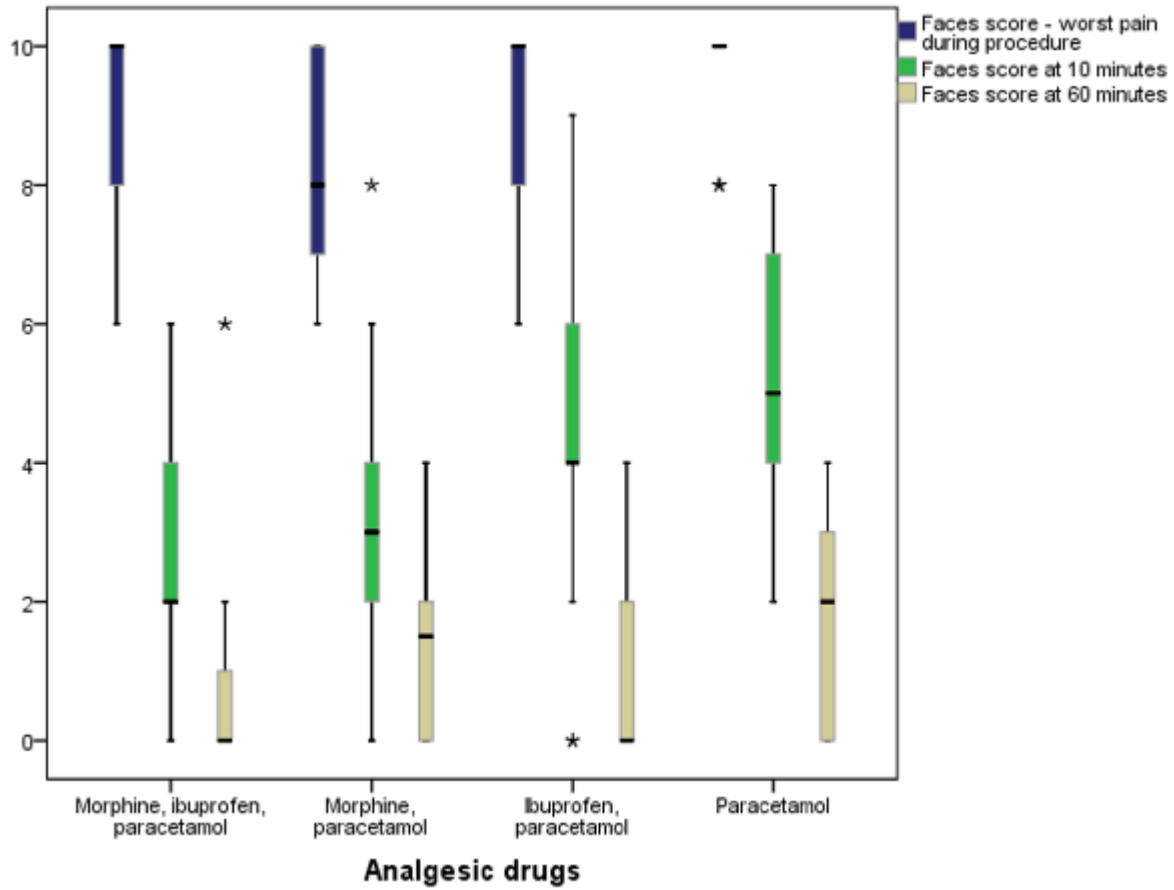
5.7 CORRELATION OF TOOLS

The results below show that the pain scores intra operatively, at ten minutes and one hour after the operation between FPS-R, FCT and NRS did not differ significantly and were highly correlated. There was greater correlation between the non-numerical tools.

TABLE 8: CORRELATIONS OF PAIN SCORES INTRA OPERATIVELY

			NRS-0	FCT-0	Faces-0
Spearman's rho	NRS-0	Correlation Coefficient	1.000	.889**	.882**
		Sig. (2-tailed)	.	.000	.000
		N	138	138	138
	FCT-0	Correlation Coefficient	.889**	1.000	.781**
		Sig. (2-tailed)	.000	.	.000
		N	138	138	138
	Faces-0	Correlation Coefficient	.882**	.781**	1.000
		Sig. (2-tailed)	.000	.000	.
		N	138	138	138

TABLE 9: CORRELATIONSOF PAIN SCORES AT 10 MINUTES

			NRS-10	FCT-10	Faces-10
Spearman's rho	NRS-10	Correlation Coefficient	1.000	.676**	.744**
		Sig. (2-tailed)	.	.000	.000
		N	138	138	138
	FCT-10	Correlation Coefficient	.676**	1.000	.844**
		Sig. (2-tailed)	.000	.	.000
		N	138	138	138
	Faces-10	Correlation Coefficient	.744**	.844**	1.000
		Sig. (2-tailed)	.000	.000	.
		N	138	138	138

TABLE 10: CORRELATIONS AT 1 HOUR

			NRS-60	FCT-60	Faces
Spearman's rho	NRS-60	Correlation Coefficient	1.000	.902[**]	.893[**]
		Sig. (2-tailed)	.	.000	.000
		N	138	138	138
	FCT-60	Correlation Coefficient	.902[**]	1.000	.943[**]
		Sig. (2-tailed)	.000	.	.000
		N	138	138	138
	Faces	Correlation Coefficient	.893[**]	.943[**]	1.000
		Sig. (2-tailed)	.000	.000	.
		N	138	138	138

CHAPTER 6

6.0 DISCUSSION

Pain assessment in women undergoing evacuation of retained product of conception becomes very cardinal in the setting where no anaesthetic or sedative is used during the procedure. The choice of the assessment tool in a low education setting such as Zambia is also of importance.

This study was undertaken to validate a pain assessment tool that is clinically useful for women undergoing MVA of RPOCs in the University Teaching Hospital. The visual analogue scale, verbal rating scale and revised faces pain scale were explored. We also sought to determine the pattern of pain surrounding the procedure, the adequacy of the current analgesia protocol for such an intensely painful procedure and whether efforts to alleviate it were clinically significant.

Demography

A total number of 138 participants were enrolled for this study. The majority of patients were aged between 21 and 30 years. . This group accounted for 53.6. 25.4% were aged between 31 to 40years. Those aged over 40 years were 0.7%% while 20.3% were aged less than 21 years.

The majority had poor education (up to primary education). 21 % had no education at all. 45.7% had primary education while 20.3% and 13% had secondary and tertiary education respectively. Therefore 66.7% had poor education. This result shows a marked increase in poor education when compared to a study done by Chiko et al (2006) in which 47.3% of women who presented to UTH for MVAs had poor education. This is significant because it a highlights high level of low literacy and therefore a need for a tool that is tailored to a population of women whose majority have poor education.

Severity of pain

Evacuation of retained products of conception can be performed by in a treatment room without using general anaesthesia and an operating theatre. A study by Filshie et al (1971) showed that without premedication, 29% of patients undergoing evacuation of the uterus experienced severe pain. Another study (Filshie et al) showed that with premedication of intravenous pethidine or papavaretum and diazepam, evacuation of the uterus can be performed with acceptable pain. However, the average hospital stay was 2.3 days. It can be postulated that one of the reasons that

sedation or general anaesthesia is not used in UTH is in an effort to reduce hospital stay in a hospital that is burdened with shortages both in medications and staff. The average hospital stay in UTH following an MVA is six to eight hours. It is possible that in an effort to reduce hospital stay the analgesia for this procedure in UTH has taken a minor role.

The majority of women in this study experienced severe pain during the procedure. Using the various tools, the frequencies of severe pain were similar with more than 90% of women in all instances experiencing severe pain. These results show a higher percentage compared to pain scored by patients who received diazepam and pethidine IV (Filshie et al, 1997). This implies that administration of oral morphine, ibuprofen and paracetamol is a regimen that is not sufficient for procedural pain. More importantly, Filshie et al did not administer standard pain assessment tools and therefore did not give evidence that patients in fact had acceptable pain and could not quantify how much pain the patients actually experienced. This is the importance of administering a pain assessment tool which has highlighted in this study that though MVAs can be performed without an anaesthetic, pain can be severe.

It can be noted that a combination of all three drugs gave statistically significant analgesia at 10 minutes and 1 hour after the operation. While this is a failing regimen for procedural pain it is effective for post-operative pain.

The timing between intake of analgesia and the procedure was not indicated. This is because the times that the patients were given analgesia was not indicated in the patient records by the health care providers. The onset of action and peak for the analgesics vary and is also dependent on route of administration. Therefore it would have been useful to relate intake to onset of action and effect if timings had been recorded. However, it is noteworthy to point out that the trend showed severe pain regardless of timing, showing that the analgesia is inadequate.

Ability to discriminate

This study sought to validate a tool by its ability to detect differences in pain scores with different interventions. All three pain tools were useful for this. The pain scores were correlated at the different timings. This result is similar to a study in Nigeria by Soyannwo et al that showed that single item tools can be validated for use in low education settings. However, only the FPS-R was able to pick out changes in pain with relation to morphine alone both intra operatively and

at 10 minutes. This lends weight to the fact the FPS – R may have indeed been more discriminating.

A study in Mexico (Clark P, 2003) also showed similar results in that all pain tools could be used in that population but the choice of the best tool was dependent on the preference and choice by patient.

The margin of error (type 1) was set at the standard 0.05. It would have been more conservative to use a margin of 0.01 however, a much larger sample size would have been necessary. A margin of error of 5% is acceptable and makes the conclusion that the FPS-R was more discriminative than the other tools valid. This finding was not only statistically significant but clinically significant because the ability of the FPS-R to identify a change in pain score has clinical relevance as this shows that morphine may be useful for procedural pain and exploration into increased doses or adjuncts should be done.

Educational role and acceptability

There was no statistical association between educational background and preference for tools. However, the cohort preferred the non numerical pain tools and in fact showed 57.9% preference for the FPS-R, 39.8% preferred the FCT while only 2% preferred the NRS. These results are comparable with a study done in Kenya by Huang et al, 2012 that showed majority of the population with low education preferring the FPS-R to the NRS.

Similarly, the majority of patients enrolled in this study found it easier to understand and complete the non - numerical pain tools. 58.7% found the FPS-R easiest understand while 39.1% found the FCT easiest to complete. Only 2.2% felt the NRS was the easiest to understand. These results are comparable to a study in Turkey (Ergun U, 2007) in which the patients with low education, found the non numerical FCT easier to understand and complete compared to the VAS and another done in Mexico that showed that patients with low education found non numerical pain scales easier to understand and complete. 34.8% found the FPS-R easiest to complete.

Several studies have compared comprehension levels and completion rates of tools in an effort to validate tools for those populations. Ibukunle et al compared comprehension levels and completion rates of the VAS and the FCT patients undergoing dental extraction in Nigeria. It showed that both tools were valid tools for that population by their ability to understand and

complete the tool. In this study, even though all tools were completed, the FPS-R required the least explanation to the patients before they could understand and complete the tool. Therefore unlike the Nigerian study, a single best tool can be picked out for this population

Validation of FPS-R

The FPS-R was in fact the most preferred tool, required the least explanation and was easiest to understand while a representative population found it the easiest to complete. Therefore it can thus be accepted as the pain rating tool of choice for women undergoing MVA of RPOCs at the UTH in Lusaka. It gave reproducible results and consistency was evident. A study done in Ankara to validate the FCT for that population showed a correlation of scores between the VAS and the FCT with analgesic intervention. In this study there was significant correlation between pain scores of the FPS-R and other tools. The correlation was higher between the FPS-R and the FCT (0.84 -0.94) at 10 minutes and after an hour compared to the correlation between the FPS-R and the NRS (0.74, 0.89). This may be because the non numerical tools were the more preferred and acceptable tools in the study. The tools were administered in the order NRS – FCT – FPS-R. It has already been shown that the majority found the NRS difficult to understand and complete. It can be inferred therefore that the lower correlation may be due to progressive ease of use of tools as one completed firstly the NRS, followed by the FCT and finally the FPS-R

A study in India (Mudgulakar N, 2012) that sought to assess the agreement between pain tools, i.e. the VAS and the NRS among people with low education showed that the tools were useful with correlation of 0.79 - 0.91, while study in Nigeria (Odai et al, 2015), that validated the use of the VAS and the FCT for that population showed that the scores of the two tools were statistically correlated and reliable with a Cronbachs alpha 0.85.

In this study, FFPS-R was able to discriminate pain scores at different timings and with use of different drug combinations giving meaningful and interpretable results. The mean NRS, FCT and FPS-R scores at the different timing were similar and highly correlated.

Fitzpatrick et al (1998) described the most comprehensive tool. Using that outline, as described in the literature review of this study, the FPS-R is acceptable as it matched the purpose of the study and the clinical aspect, it is valid as it was able to describe pain at various timings and

relation to intervention. It is a reliable tool as it gives reproducible results but internal consistency was not measured as it a one-dimensional tool. All three tools were responsive to changes to changes in pain and were able to discriminate between pain scores. However, the FPS-R was the most valid and acceptable as it was most preferred and easiest to understand and a representative number found it easiest to complete. Feasibility was not delved into but in the study it can be postulated that it is the most feasible as it required the least explanation before patients could understand it and complete it. It therefore met the 8 criteria outlined in the framework by Fitzpatrick et al for selection of a pain assessment tool for a population.

6.1 STRENGTHS AND LIMITATIONS

The strengths of this study are that it is the first of its kind in the University Teaching Hospital and the FPS-R can in fact be adapted in other areas that require pain assessment in adults. This study can also pave the way for interventional studies with regards to pain relief in women undergoing evacuation of retained products of conception

A limitation was that memory of procedural pain may have been inadequate as this study relied on the patient recall of pain. However this is the only way to assess pain during the procedure as it would be inhumane to ask the women to fill out the scales during a very painful procedure and it would be impossible to know when to ask the patient at the moment of maximal discomfort.

Another limitation was that the pain tools were administered at the same time and this may have influenced completion and correlation. However, the tools had to be administered at the same time to a discern pain intensity and analgesic effect of drugs at similar times.

CHAPTER 7

7.1 CONCLUSIONS

The revised faces pain scale is the most suitable pain assessment tool among these women as it is the most acceptable, gives statistically relevant information while maintaining clinical relevance in both assessing pain and changes in pain with relation to intervention. It is also useful for assessing pain in patients with low education. The full cup test may also be used in similar settings with reliable results. The findings of this study can be extrapolated in other low resource and low education populations similar to that in this study. The current guidelines for pain relief during MVA of RPOCs are inadequate. The majority of patients experience severe pain during the procedure. The pain management service for women undergoing MVA must be revised and the FPS-R will reliably give information as to whether the new interventions will be satisfactory. The results of this study will allow for evidence based practice tailored to patient satisfaction.

7.2 RECOMMENDATIONS

1. To the UTH department of gynaecology: The revised faces pain scale (FPS-R) must be adopted for standardised assessment of pain in women undergoing MVA of RPOCs.
2. To the UTH Pain Team: The pain management protocol for women undergoing MVAs must be revised. The FPS-R will be valuable in aiding this transition.
3. To the UTH management and Ministry of Health: The FPS-R must be explored for use in other clinical areas for assessment not only in the University Teaching Hospital but also in district and rural health centres where the levels of education are low
4. To the UTH, Ministry of Health and Directorate of Research and Graduate studies: A follow up study employing the use sub anaesthetic doses of Ketamine during MVA should be done as it potentiates opioids, is analgesic itself and has an amnesic effect

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Consent form

I…………………………………………………………………………..
of……………………………………………………………………… having read the information sheet/having had the information sheet read to me, and having been availed with all information about this study, do hereby accept to enroll myself in this research and agree to participate voluntarily at no cost to myself.
I understand that I can opt out if I feel the need to, without discrimination or withholding of treatment meant for my wellbeing.

Signature/thumb print of
patient…………………………………………………………………….

Signature/thumb print of
witness……………………………………………………………………

Date ……………………………………………………………………

Appendix 1

PATIENT ID #   :
INVESTIGATOR   **:** Hazel Mumphansha
SUPERVISORS   : Dr D. Bould
                                       : Dr. Ferusa Ismailova

INTRODUCTION

I, Hazel Mumphansha, a Master of Medicine (MMED) in Anaesthesia and Critical Care student in the School of Medicine at the University of Zambia hereby request you to participate in a research study of pain assessment tools among women undergoing manual vacuum aspiration of retained products of conception at UTH. You will be one among several women participating in this study. The purpose of this study is to note which simple pain scale, among three different pain tools, can be best used to assess pain in this population of women, to assess whether or not the current analgesia protocols are consistently adhered to and optimal and to develop a pain assessment scale that is useful for this particular population. My role in this study is to administer the questionnaire to you and further analyze the information I will collect to come up with the most suitable pain tool for this setting.

PURPOSE

Optimal pain management can only be given if pain patterns in a particular cohort are known. To establish this, pain needs to be assessed with a valid, useful and sensitive tool that is standard across everyone and which can be an indication as to whether current pain management being followed is adequate. The outcome of the study will be identification of a simple tool that is useful for ascertaining the severity of pain among these women, pain pattern, and it will also highlight the effectiveness of the current pain protocol and try to bring out its pitfalls.

STUDY PROCEEDURES

A questionnaire will be administered in which you will be asked to answer honestly and objectively score pain experienced by you during the procedure, 10 minutes after and 1 hour after. You will also be asked on analgesia offered to you

Three (3) different pain tools will be used and you will be required to answer each as accurately as possible. Each session will last between five (5) to ten(10) minutes

The questionnaire will be administered in CO3 by your bedside by myself(HM) or a trained research assistant.

RISKS

There are no risks to you. You may find the assessments repetitive. Kindly bear with me as it is vital that for the study to repeat the questions. Your cooperation will be greatly appreciated.

COSTS OF PARTICIPATION

There will be no cost on your part for participating in this study. You will not be paid to participate in it either. However your participation will aid in revolutionizing pain management in women having similar procedures through pain assessment.

CONFIDENTIALITY

The information collected in the study will be kept confidential. However the research assistants will be able to inspect your medical records to have access to information pertaining to the study. Your name will not be used in any information about you is published, and neither will your name be used by the government if it uses the information from this study to implement pain assessment tools for pain management.

PARTICIPATION/WITHDRAWAL

Your participation in this study is completely voluntary and you are free to withdraw your consent to participate at any time, without prejudice against further care you may receive in this institution.

You are free not to answer any question that you deem uncomfortable.

Persons to contact for questions/problems

If you are not clear about anything before and after enrolling in this study please contact Dr Hazel Mumphansha or ERES converge IRB on the following:

Dr Hazel Mumphansha,   ERES Converge IRB office
University of Zambia   33 Joseph Mwilwa Road
Department of Anaesthesia and Critical Care   Rhodes Park
P/B RW1X   Lusaka
Lusaka   Zambia
Zambia   Email to eresconverge@yahoo.co.uk
Phone +260 969 239620   Phone +260 955 155633
+260 955 155634

Appendix 2

Surrogate consent form

I…………………………………………………………………………..
of………………………………………………………………… having read the
information sheet/having had the information sheet read to me, and having been availed with all
information about this study, do hereby accept to enrol my relative in this research and agree, on
her behalf, to participate voluntarily at no cost to myself or my relative.
I understand that I can opt out, on her behalf, if I feel the need to, without discrimination or
withholding of treatment meant for the wellbeing of my relative.

Signature/thumb print of
surrogate…………………………………………………………………………….

Signature/thumb print of
witness…………………………………………………………………………

Date …………………………………………………………………………

Appendix 3

SURROGATE INFORMATION SHEET

PATIENT ID #   :
INVESTIGATOR   **:** Hazel Mumphansha
SUPERVISORS   : Dr D. Bould
          : Dr. Ferusa Ismailova

INTRODUCTION

I, Hazel Mumphansha, a Master of Medicine (MMED) in Anaesthesia and Critical Care student in the School of Medicine at the University of Zambia hereby request your relative to participate in a research study of pain assessment tools among women undergoing manual vacuum aspiration of retained products of conception at UTH. She will be among several women selected to participate in this study. By law, she is not eligible to consent as she is below 18yrs. I am humbly requesting you as her guardian to take this responsibility after having been furnished with all the necessary information. The purpose of this study is to note which simple pain scale, among three different pain tools, can be best used to assess pain in this population of women, to assess whether or not the current analgesia protocols are consistently adhered to and optimal and to develop a pain assessment scale that is useful for this particular population. My role in this study is to administer the questionnaire to you and further analyze the information I will collect to come up with the most suitable pain tool for this setting.

PURPOSE

Optimal pain management can only be given if pain patterns in a particular cohort are known. To establish this, pain needs to be assessed with a valid, useful and sensitive tool that is standard across everyone and which can be an indication as to whether current pain management being followed is adequate. The outcome of the study will be identification of a simple tool that is useful for ascertaining the severity of pain among these women, pain pattern, and it will also highlight the effectiveness of the current pain protocol and try to bring out its pitfalls.

STUDY PROCEEDURES

A questionnaire will be administered in which the participant will be asked to as honestly and objectively score pain she experienced during the procedure, 10 minutes after and 1 hour after. You will also be asked on analgesia offered to you,

Three (3) different pain tools will be used and you will be required to answer each as accurately as possible. Each session will last between five (5) to ten(10) minutes.

The questionnaire will be administered in CO3 by your bedside by myself(HM) or a trained research assistant.

RISKS

There are no risks to you. She may find the assessments repetitive. Kindly bear with me as it is vital that for the study to repeat the questions. Your cooperation will be greatly appreciated.

BENEFITS/COSTS OF PARTICIPATION

There will be no cost on yours or her part for participating in this study. Neither you nor your relative will be paid to participate in it either. However your participation will aid in revolutionizing pain management in women having similar procedures through pain assessment.

CONFIDENTIALITY

The information collected in the study will be kept confidential. However the research assistants will be able to inspect her medical records to have access to information pertaining to the study.

Her name will not be used in any information that is published, and neither will her name be used by the government if it uses the information from this study to implement pain assessment tools for pain management.

PARTICIPATION/WITHDRAWAL

Participation in this study is completely voluntary and you are free to withdraw your surrogate consent to participate at any time, without prejudice against further care she may receive in this institution.She is free not to answer any question that she deems uncomfortable

Persons to contact for questions/problems

If you are not clear about anything before and after enrolling in this study please contact **Dr Hazel Mumphansha** or **ERES Converge IRB** on the following:

Dr Hazel Mumphansha,	ERES Converge IRB office
University of Zambia	33 Joseph Mwilwa Road
Department of Anaesthesia and Critical Care	Rhodes Park
P/B RW1X	Lusaka
Lusaka	Zambia
Zambia	Email to eresconverge@yahoo.co.uk
Phone +260 969 239620	Phone +260 955 155633
+260 955 155634	

Appendix 4

QUESTIONNAIRE

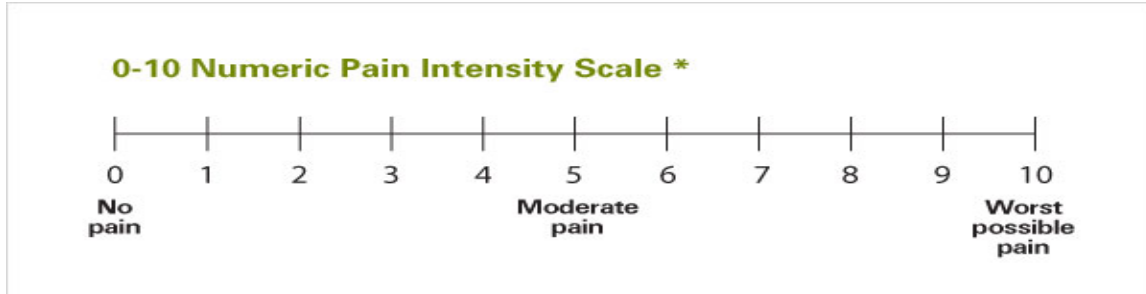Name: sex:
File #:   age:
Schooling: none   completed primary school   completed secondary school
completed university

Part 1

Kindly recall the most severe pain you experienced during the evacuation. As accurately as possible, using the pain scales below, please indicate in blue how you rate your pain.

0-10 Numeric Pain Intensity Scale *

Full Cup Test
empty-no pain   partly full-moderate   full-severe
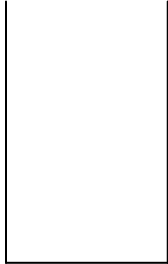
Faces Pain Scale – Revised

Part 2
Using the same scales, as accurately as possible kindly rate pain now (10 minutes)

0-10 Numeric Pain Intensity Scale *

```
|----|----|----|----|----|----|----|----|----|----|
0    1    2    3    4    5    6    7    8    9    10
No                        Moderate                Worst
pain                       pain                  possible
                                                  pain
```

empty-no pain   partly full-moderate   full-severe

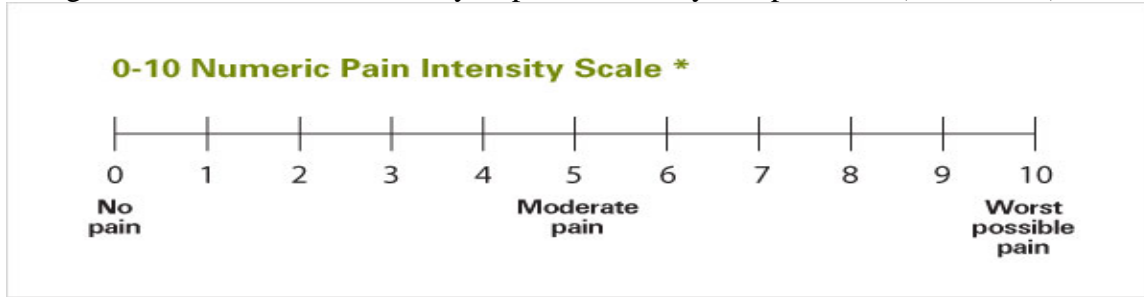**Faces Pain Scale – Revised**

```
  0        2        4        6        8        10
```
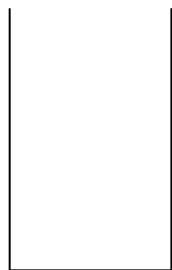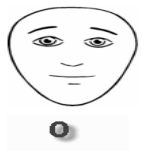
Part 3
Using the same scale, as accurately as possible kindly rate your pain now (at 1 hour)

0-10 Numeric Pain Intensity Scale *

0 1 2 3 4 5 6 7 8 9 10
No   Moderate   Worst
pain   pain   possible
pain
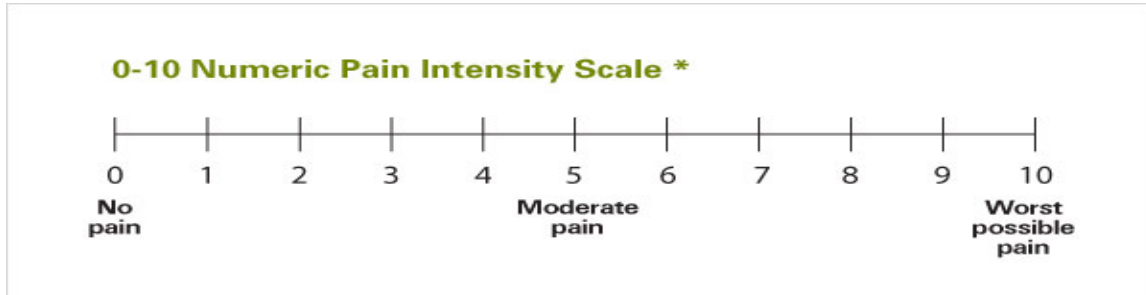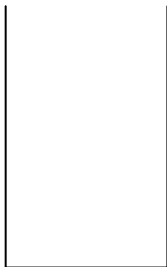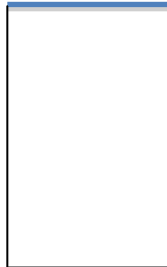
empty-no pain   partly full-moderate   full-severe

Faces Pain Scale – Revised

0   2   4   6   8   10

Part 4
For nurse
Did patient receive any medications pre operatively   Y / N
Has patient received any post-operative analgesia   Y / N
Note medication, dose and time
Paracetamol   dose………… time……….
Diclofenac   dose………… time……….
Ibuprofen   dose………… time……….
Pethidine   dose………… time……….
Morphine   dose………… time……….
Other   dose………… time……….
Time of procedure

For patient
Are you satisfied with the analgesia offered to you   Y / N
Do you have a preference for one of the scales?
If yes, which one?
Of the various scales, which one was:
Easiest to understand
Easiest to complete
Any other reasons for preference
……………………………………………………………………………………………………
…
……………………………………………………………………………………………………
…
Number of times that scale is explained to patient before completing.

Appendix 5

Data collection sheet

Patient NO.	File NO.	Preop analgesia? Which?	pain tool preferred	Easiest tool understood	Education level

Appendix 6

Pepala la Chibvumekezo

Ine………………………………………………………………………

Wamene ankala…………………………………………………………………..

Pa mbuoy paku (belenga/ kuni belengela pepala la chivibitso na kuni masulila zoonse zopezeka mu punzilo ili, Na bvomela kutengako mbali muku punzilo ili mwa ufulu kopanda kutayapo ndalama yanga.

Signature/Ku fwatika kwa odwala ……………………………..…………………….

Signature/Kufwatika kwa mboni……………………………..……………………

Siku ………………………………………………………………………………

Appendix 7

CHIZIBITSO

Nambala ala Odwala: #   :

Udindo   :

Ofufuza   **:** Hazel Mumphansha

Oyanganila Ofufuza   : Dr D. Bould

                             : Dr. Ferusa Ismailova

KAMASULIDWE KA PUNZILO

Ine, Hazel Mumphansha, otenga ma punziro a kuya a Master of Medicine (MMED) mu chi gao cha makwala olezeletsa ndi kuyanganila antu odwala kwambili pa Sukulu la University of Zambia nikupempani kuti mutengeko mbali mu punzilo lo fufuza tamangilo la kunvela kuwawapakati pa azimai aku sukikdwa mu mimba ku chipatala cha UTH.Lingalolo la punzilo ili ndi kuti ti zibe kabelengwedwe ka adzimai amene ama nvela kubaba na ku ona ngati dotolo a kusatila mo pasila makwala olesta kubaba mofunikila ndi moyenela. Pambuyo pache tiza kazikitsa mo pimila kubaba mu antu akubwela ku chipatala ichi.

LINGALORO LA PUNZILO

Kuletsa kubaaba kunga yendeletsedwe bwino ngati ka baabidwe mu gulu lantu kazibiwa Ku kwanilitsa izi, kufunikila ku sebenzesa vida voyenela ku antu onse ndipo vinga onsese ngati antu akusatili zofunikila

Tifuna kuti pambuyo pa punzilo ili ti kazikise mundandanda wa zo konka paku fufuza kubaaba mu gulu ili la azimai, kufufuza kababidwe, ndi to yanganila ngati zo konka zamene zilipo zikwanilitsa ku gwila nchito bwino

ZO CHITIKA MUPUNZILO ILI.

Tiza kufunsani mafunso kotero ti ziba kubaaba kwamene muna mvela maku suka mumimba,kubaaba paka pita 10 min, ndi ola limozdi posilidza kusukaTiza sebenzesa njila zitatu(3), ndipo muza funikila kuyanka mafunso mo kulupilika.

ZIYOPYESO

Zulibe voyofya koma muza pezako mafunso yenangu yaza bwezedwa kwambili. Tiku pempani kuti musa leme.

Zopezamo kapena mutengo wotengako mbali

Simuzalipila ndalama zilizonse pokutengako mbali mupunlo ili kapena kulipilidwa ndalama.

Muku yanka mutandizila ngako kuyamba kwa ka sebenzedwe ko gwila nchito bwino.

CHISINSI

Vonse vamene tiza tengako mupunzili ili viza sungidwa mwa chisinsi, otandizila chabe ndiye aza chabe ndiye aza yanganamo mupapepala muma pepala a kuchipatala apunzilo ili

Zina lanu siliza lembwedwa pamapepala alosonse amu punzilo ili ngankale boma ngati la funa kusebenzesa viza pezekamo mupunzilo ili.

Kutengako mbali kapena kuchokako mu punzilo

Muli omasuka kutengako mbali mu punzilo mwa ufulu ndipo ngati mufuna ku chika mo muli omasuka kopanda chilango chilichonse, kapensa kukulesani kuonewa ndi a dotolo kapena a nurse.

Ngati muli nama funso kapena mabvuto munga kambe ndi antu awa:
Ngati mukalibe kukutila pazopezekamo mupunzilo ili mukalibe kutengako mbali, kapena pambuyo pakulembesa munga kambe naba Dotolo Hazel Mumphansha Kapena aku ERES converge IRB pama lamya ndi ka keyala aya:

Dr Hazel Mumphansha,
University of Zambia
Department of Anaesthesia and Critical Care
P/B RW1X
Lusaka
Zambia
Phone +260 969 239620
+260 955 155634

ERES Converge IRB office
33 Joseph Mwilwa Road
Rhodes Park
Lusaka
Zambia
Email to eresconverge@yahoo.co.uk
Phone +260 955 155633

Appendix 8

Pepala lachivomekezo cha oimilila odwala

Ine………………………………………………………………………………… wanmene
ankala…………………………………………………………………….. Pambuyo paku
belenga/kunibelengela pepala la chizibiso ndi kamasuludwe kavopezeka mupunzilo ili, ndi
vomekez kuti bululu wanga atengeko mbali mupunzilo ili/ko panda kulipila ndala zili zonse ine
kapena bululu wanga
Ni ziba kuti ndife omasuka ku leka mu punzilo ili kopanda kupasiwa chilango kapena kuti bululu
watu kulesewa kutengako makwala kana kuonewa no a Dotolo olo a nurse

Signature/Kufwatika kwa o imilila ………………………………………………….

Signature/Kufwatika kwa mboni …………………………………………………

Siku …………………………………………………………………………

Appendix 9

Pepala la chizibiso cha oimilila odwala

Nambala ala Odwala: #   :
Udindo   :
Ofufuza   **:** Hazel Mumphansha
Oyanganila Ofufuza   : Dr D. Bould
          : Dr. Ferusa Ismailova

KAMASULIDWE KA PUNZILO

Ine, Hazel Mumphansha, otenga ma punziro a kuya a Master of Medicine (MMED) mu chi gao cha makwala olezeletsa ndi kuyanganila antu odwala kwambili pa Sukulu la University of Zambia nikupempani kuti mutengeko mbali mu punzilo lo fufuza tamangilo la kunvela kuwawapakati pa azimai aku sukikdwa mu mimba ku chipatala cha UTH.Lingalolo la punzilo ili ndi kuti ti zibe kabelengwedwe ka adzimai amene ama nvela kubaba na ku ona ngati dotolo a kusatila mo pasila makwala olesta kubaba mofunikila ndi moyenela. Pambuyo pache tiza kazikitsa mo pimila kubaba mu antu akubwela ku chipatala ichi.

LINGALORO LA PUNZILO

Kuletsa kubaaba kunga yendeletsedwe bwino ngati ka baabidwe mu gulu lantu kazibiwa Ku kwanilitsa izi, kufunikila ku sebenzesa vida voyenela ku antu onse ndipo vinga onsese ngati antu akusatili zofunikila

Tifuna kuti pambuyo pa punzilo ili ti kazikise mundandanda wa zo konka paku fufuza kubaaba mu gulu ili la azimai, kufufuza kababidwe, ndi to yanganila ngati zo konka zamene zilipo zikwanilitsa ku gwila nchito bwino

ZO CHITIKA MUPUNZILO ILI.

Tiza kufunsani mafunso kotero ti ziba kubaaba kwamene muna mvela maku suka mumimba,kubaaba paka pita 10 min, ndi ola limozdi posilidza kusukaTiza sebenzesa njila zitatu(3), ndipo muza funikila kuyanka mafunso mo kulupilika.

ZIYOPYESO

Zulibe voyofya koma muza pezako mafunso yenangu yaza bwezedwa kwambili.
Zopezamo kapena mutengo wotengako mbali
Simuzalipila ndalama zilizonse pokutengako mbali mupunlo ili kapena kulipilidwa ndalama

CHISINSI

Vonse vamene tiza tengako mupunzili ili viza sungidwa mwa chisinsi, otandizila chabe ndiye aza chabe ndiye aza yanganamo mupapepala muma pepala a kuchipatala apunzilo ili
Zina lanu siliza lembwedwa pamapepala alosonse amu punzilo ili ngankale boma ngati la funa kusebenzesa viza pezekamo mupunzilo ili.
Kutengako mbali kapena kuchokako mu punzilo
Muli omasuka kutengako mbali mu punzilo mwa ufulu ndipo ngati mufuna ku chika mo muli omasuka kopanda chilango chilichonse, kapensa kukulesani kuonewa ndi a dotolo kapena a nurse.
Ngati muli nama funso kapena mabvuto munga kambe ndi antu awa:

Ngati mukalibe kukutila pazopezekamo mupunzilo ili mukalibe kutengako mbali, kapena pambuyo pakulembesa munga kambe naba Dotolo Hazel Mumphansha Kapena aku ERES converge IRB pama lamya ndi ka keyala aya:

Dr Hazel Mumphansha,
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Lusaka
Zambia
Email to eresconverge@yahoo.co.uk
Phone +260 955 155633

Appendix 10

Ma funzo

Dzina: Amuna/Akadzi:
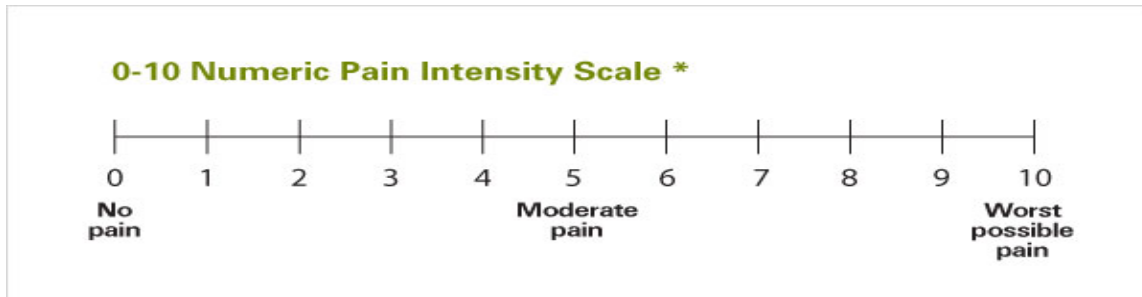Nambala la mapepala achipatala #:   Zdaka:
Afika skulu yangi: Kulibe   primary   ana silidza secondary   asilidza
university

Chigawo Choyamba
Ni pempa mu kumbukile pamene muna nvela kubaaba maningi pamene benze ku suka. Ku
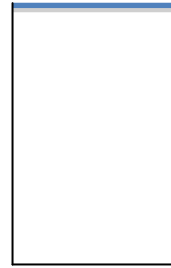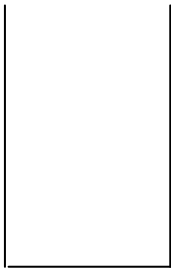sebenzsa chikope chili pansi apa, sonyezani tamangilo la kubaaba

Kusonyeza monga ku zuula kwa chiko
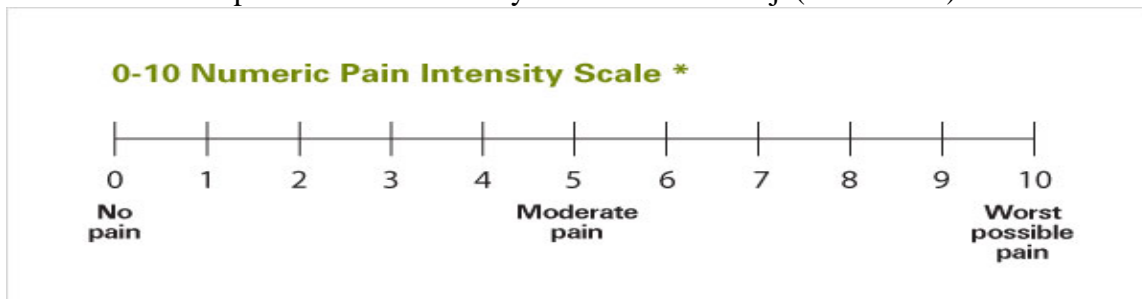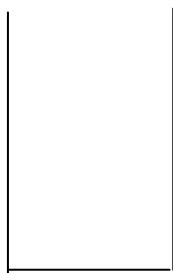kulibe chintu kuli ku baaba   Pakatil-kubaaba pakati   kuzula ku baaba kochuluka

Chigawo chachibili
Kusebenzesa vikope ndi mafanizilo sonyezani kubaaba manje(10 minutes)

0-10 Numeric Pain Intensity Scale *

| | | | | | | | | | | |
|0|1|2|3|4|5|6|7|8|9|10|

No
pain

Moderate
pain

Worst
possible
pain

kulibe chintu kuli ku baaba   Pakatil-kubaaba pakati   ku baaba kochuluka

Faces Pain Scale – Revised

0   2   4   6   8   10

Chigawo chacitatu
Kusebenzesa vikope ndi mafanizilo sonyezani kubaaba manje(pa pitaola limozi)

0-10 Numeric Pain Intensity Scale *

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

No pain   Moderate pain   Worst possible pain
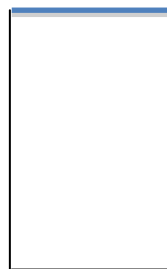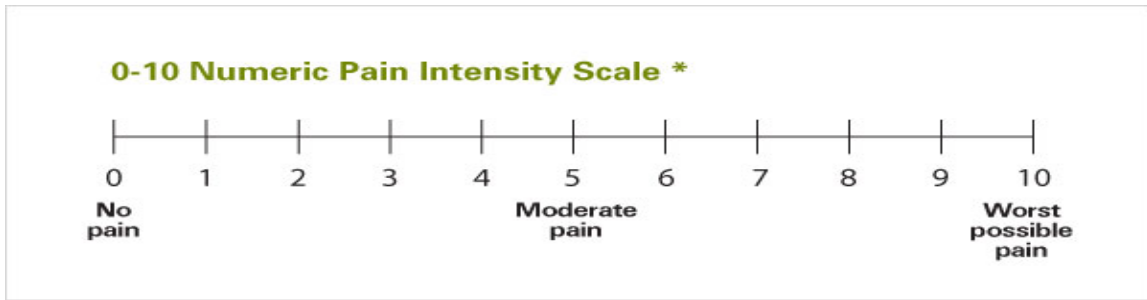
kulibe chintu kuli ku baaba   Pakatil-kubaaba pakati   ku baaba kochuluka

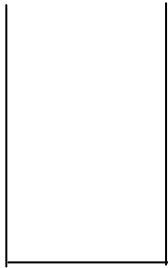Faces Pain Scale – Revised

0   2   4   6   8   10
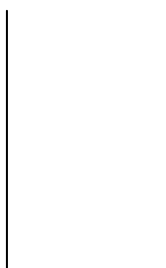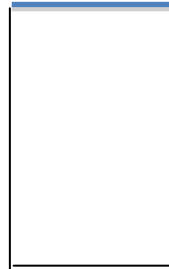
Chigawo cha chi nayi
Na nurse
Kodi odwala atengako mankwala mukalibe ku ba suka   eeye/iyayi
Kodi odwala atengako mankwala pakusiliza ku ba ona   eeye/iyayi
Lembani makwala, mo mwela, ndi ntawi
Paracetamol   mo mwela ………… ntawi ……….
Diclofenac   mo mwela ………… ntawi ……….
Ibuprofen   mo mwela ………… ntawi ……….
Pethidine   mo mwela ………… ntawi ……….
Morphine   mo mwela ………… ntawi ……….
Other   mo mwela ………… ntawi ……….
Ntawi ya kuyamba kusuka

Odwala
Koodi mwa kutila kumankwala   eeye/iyayi
Kodi kuli fanizilo lamene mukondesesa pali ya tatu yaja. Ngati eeye, liti?
Pali mafanizilo aya ndiliti lamene lili lo::
Fewa ku nvesela
Fewa ku sebenzesa
Kodi muli na chifukwa chamene muli kondela
………………………………………………………………………………………………………
…
………………………………………………………………………………………………………
…
Kabelengwedwa kangati kamene baku masulilani ma fanizilo aya .

Appendix 11

MVA Preemptive Analgesia Protocol

Initial Assessment

- Check Scan / Verify Diagnosis
- Check Vitals (RR, HR, BP)
- Amount of bleeding & assess for shock
- Check Hb if warranted (Pallor?)
- Pain severity

Stable Patient

- Normal vitals
- Hb > 10

PATIENT STRATIFICATION

Unstable Patient

- Drowsy
- Hb < 10
- BP (sys) < 100

Standard Management

Triple Analgesia:
- Paracetamol 1g
- Ibuprofen 400mg
- Oral morphine 20mg

1 HOUR BEFORE PROCEDURE

Conservative Management

- Fluid Resuscitation
- Paracetamol 1g
- If excessive bleeding, avoid NSAIDS if
- If drowsy, reduce morphine dose (10-15mg)

Continue Paracetamol & Ibuprofen as required (as per ZAPP Pain Ladder)

POST-PROCEDURE

Continue Paracetamol & / or Ibuprofen as required (as per ZAPP Pain Ladder)

'Lusaka Link' Project
Out to Africa