A CROSSECTIONAL STUDY OF FACTORS CONTRIBUTING TO MODERATE TO SEVERE POST OPERATIVE PAIN AFTER A LAPAROTOMY

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DECLARATION

I declare that this dissertation is my own work. It is being submitted for the Masters degree in Anaesthesia and Critical Care at the University of Zambia, Lusaka. It has not been submitted before for any degree or examination at this or any other University.

Signed.....

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2017

CERTIFICATE OF APPROVAL

This dissertation of USHMABEN PATEL has been approved as fulfilling the requirements or partial fulfilment of the requirements for the award of Masters of Medicine in Anaesthesia and Critical Care by the University of Zambia; and

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Examiner 3 Name (External) ……

ABSTRACT

Having pain relief is a basic human right. This thesis provides a descriptive profile of pain before and during the first 72 hrs after a laparotomy at University Teaching Hospital, Lusaka, Zambia, from July 2014 to January, 2015. The objective was to identify independent risk factors associated with moderate to severe pain after laparotomy. To determine the incidence of moderate (FPS 5-6) and severe (FPS 7-10) postoperative pain in patients within 72 hrs of laparotomy. To identify factors associated with moderate to severe post-operative pain. Both elective and emergency cases where included. Cases where enrolled through convenience sampling from The Gynecology, General surgery and Urology theaters and then followed up in their respective post-operative wards at the University Teaching Hospital, Lusaka, Zambia. It was found that age, sex, weight, residential location, grade of anaesthetist and surgeon and type of procedure did not contribute significantly to moderate to severe pain. Most patients experienced moderate to severe pain in the pre-operative phase and some degree of pain in the immediate post-operative period. Overall 31.2 % of the patients had moderate to severe pain in the immediate post-operative period. The incidence of moderate to severe pain at 24 hrs and 48 hrs post operatively was 39.3 % and 39.1 %respectively. This pain reduced to 26.5 % at 72 hrs. Patients who had received Ketamine or Morphine and Ketamine combinations had relief in the immediate 2 hrs post-operative phase. Patients who had a spinal anaesthesia where 2.5 times more likely to experience moderate to severe pain in the immediate post-operative period. The study revealed that pre-operative is a major area of concern and adequate pain management is lacking in this area. It was established that there was an incidence of moderate to severe pain though lower than what was reported in literature previously and it remains a significant problem following a laparotomy in our environment. I established that moderate to severe pain remains a significant problem following a laparotomy in our environment. Simple easily accessible drug like ketamine or a combination of ketamine and morphine given intra operatively will provide adequate analgesia for up to 6 hrs post operatively. Patients who received spinal anaesthesia and had transverse incision had moderate to severe pain in the first 6 hours post op. A midline incision was more painful than transverse at 24 hrs, 48 hrs and 72 hrs post-operative period. Other contributing factors to post-operative pain in Laparotomy patients at University Teaching Hospital in Lusaka which were not in the scope of this study but could be explored is shortages of nurses; inadequate to lack of tools for assessing pain; and random drug regimens.

DEDICATION

To all the patients who silently endure pain.

To all the pillars in my life who made it possible to for this dissertation to see fruition.

God Bless You.

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ABBREVIATIONS

ACTH-	Adrenocorticotrophic hormone
ADH -	Antidiuretic Hormone
ASA-	American Society of Anaesthesiologist
BPI-	Brief Pain Inventory
GCS-	Glasgow Coma Scale
LMIC-	Low to Middle Income Countries
FCT-	Full Cup Test
FPS-	Faces Pain Scale
MICU-	Main Intensive Care Unit
NRS -	Numerical Rating Scale
UTH -	University Teaching Hospital
VAS -	Visual Analogue Scale
VRS-	Verbal Rating Scale
WBFPS-	Wong Baker Faces Pain Scale

CHAPTER 1
INTRODUCTION

1.1 Background

The 1948 Universal Declaration of Human Rights states that the highest attainable standard of health is a fundamental right of every human being and that relief from pain is part of that basic human right to health.[1, 2] The International Association for the Study of Pain has defined pain as '…an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage'.[3] Pain is a presenting symptom of many conditions and complicates peri-operative care following major surgery. Except from the evident humanitarian issues in relieving suffering from pain, poor peri-operative analgesia can lead to immobility, prolonged recovery and hospital stay, and may increase cardiovascular, respiratory and gastro-intestinal complications.[4] Efficient pain management is a key aspect of the optimal care for any patient undergoing surgery.

Surgical procedures result in local tissue damage which results in release of algogenic substances including prostaglandins, serotonin, H^+, K^+, and histamines which in turn sensitise and stimulate nociceptors and so produce nociceptor impulses that are transmitted to the neuraxis by A delta and C fibres. These nociceptor impulses result in segmental reflex responses such as an increase in skeletal muscle tension with simultaneous decrease in chest wall compliance, and also stimulate sympathetic neurons, that result in an increase in cardiac work and myocardial oxygen consumption and concurrent reduced tone of gastrointestinal and urinary tract. Also there is a marked increase in the secretion of catabolic hormones including catecholamines, cortisol, ACTH, ADH, glucagon, and aldosterone, and a concomitant decrease in the secretion of the anabolic hormones such as insulin and testosterone. These result in a catabolic state due to the many metabolic effects of the endocrine changes. And so, post-operative pain can directly or indirectly result in impairment of the function of multiple organ systems if not effectively managed[5].

In low- and middle-income countries many factors lead to inadequate pain therapy. Studies done in resource limited countries like Nigeria [6, 7] and Kenya[8] have shown that some of these factors include lack of adequately trained personnel to administer pain therapy, poor access to the analgesic agents, and patients not being asked about their level of pain.[9] Perceived drawbacks are possible side effects like depression of respirations, nausea and vomiting, addictions and fear of them and hence the inconsistent use of the therapy options. Surveys done in low to medium income countries have shown that approximately 70 % of patients face discomfort and moderate to severe pain after surgical procedures.[10,11] These patients experienced pain and discomfort on movement and at rest.[10,11] A 2008 survey showed that Zambian anaesthesiologists play a minor role in pain therapy and also that there was a large lack of oral opioids for pain management in sub-Saharan Africa.[12] Currently, no published data was available on factors leading to post-operative pain in our environment.

Globally one of the commonest surgical procedures done is laparotomy. From unpublished University Teaching Hospital (UTH) surgical theatre records and recovery bay theatre records, approximately 15 % of the major surgical procedures are laparotomy. At UTH the anaesthetist/anaesthesiologist are required to give analgesia for the peri-operative period and enough for analgesia for the immediate postoperative period in recovery bay. Postoperative analgesics is given by nurses as ordered by the medical doctors or anaesthetists (clinical officers) or anaesthesiologist. It was noted that no pain assessment was done on the post-operative wards. No proper pain assessments are done from as noted from unpublished data on the post-operative wards. This meant many patients wake up from anaesthesia in moderate to severe pain or no pain in the recovery period and continue to suffer pain up to 72 hrs post operatively.

In order to acknowledge that a patient was in pain we first need to assess the pain. There are several pain scales available to choose from, including the Visual Analogue Scale (VAS), Verbal Rating Scale (VRS), Numerical Rate Scale (NRS).

The Numerical Rate Scale (NRS) is a segmented numeric pain scale in which the patient selected whole numbers (0-10) that best reflects their pain intensity. Similar

to the VAS it is a horizontal bar with numbers 0 to 10 anchored with verbal descriptors of 'no pain' 0 and 'worst imaginable pain' 10 at either end. It can be administered verbally by telling the patient to pick a number from 0 to 10 with 10 representing the worst imaginable pain and 0 representing no pain. This is an 11-point pain measure. This score is interpreted as 0- 2 is no pain, 3 – 4 is mild pain, 5 - 7 is moderate pain and 8-10 is severe pain.[13,14] This can give data which can be used for parametric analysis.[13,14]

The Faces Pain Scales (FPS) and Wong Baker Faces Pain Scale (WBFPS) are visual measurement featuring six images of facial expressions to help the patient describe the intensity or severity of pain. It combines pictures and numbers to allow pain to be rated by the user. The six faces range from smiling face to sad to crying face and a numerical rating of 0- 10 is assigned to each face. In this tool the numerical rating of 0-1 represents no pain, 2-4 represents mild pain, 5-6 represents moderate pain and 7-10 represents severe pain. It is a useful pain scale especially in cognitively impaired patients of all, age groups. The data collected from this can be used for clinical analysis.[14, 15]

The Full Cup Test (FCT) is a drawing of a cup and then the patient is told that when the cup was completely full this was the most unbearable pain they are having. The patient is then asked to draw a line in the cup to indicate the level of pain they are feeling. Then the height of the line (cm)/ height of cup (cm) x100 will give the level of pain. 0-20 % has been described as no or minimal pain, 20-49 % mild pain, 50-70 % moderate pain and 71-100 % as severe pain.[16]

The Visual Analogue Scale (VAS) is a 100mm line drawn on a paper with verbal descriptor labels of 'no pain' and 'worst imaginable pain' at each end. The patient was asked to mark the line in relation to their pain intensity. A score of 0-4mm was considered no pain, 5-44mm was mild pain, 45 -74mm was moderate pain, and a score of 75- 100 mm was severe pain. One of findings from this study was that it was to be administered on paper or electronically and when photocopying the scale we need to be very accurate so that when measured there were no errors. [13,14]

One of the limitations faced by the studies done in Nigeria and Kenya was that some of the patients didn't understand the pain assessment tools like VAS making it difficult for the medical staff to assess their pain level.[9] Another study done in China found that FPS helped cross language and cultural differences.[17] This tool was easier to understand and patient could easily related their pain to the facial expression in the tool compared to VAS. [17,18] In this study patients across different ages and educational level preferred using the FPS compared to VAS.[17,18] So a simple pain scale like the Wonk- Baker Faces pain scale or Faces Pain Scale (FPS) can to help with pain assessment in patients who are of different cultures and languages as is the case in our population.

As information was gathered to form a data sheet there were several schools of thoughts being used at UTH for post-operative laparotomy pain management hence this study was a stepping stone towards identifying what is working in our environment and what is not by identifying patients who were in moderate to severe pain and patient who were in mild to pain respectively in the postoperative period. The use of simple pain assessment scales like the NRS, FCT and FPS helped to identify patients at risk of having moderate to severe post-operative pain after a laparotomy.

The goal of this study was to help identify which patients were most at risk for this negative outcome -as well as its incidence – and understand the scale of the problem. We hope that this will be able to guide future interventions in improving post-operative analgesia in these populations as well as protecting against opiate-related side effects especially in our setting and environment.

1.2 Statement of the Problem

Research also shows that pain contributes to patient discomfort, delayed mobility of patient out of the bed and delays hospital discharges. Literature from other resource limited settings have suggested that factors that lead to moderate to severe pain after a laparotomy were limited supply of analgesic agents, inadequate doses of analgesic agents given peri-operatively, lack of adequate trained recovery staff and nursing

staff on the ward. However, the adequacy and determinants of post-laparotomy pain control have not been well-described in our setting.

1.3 Study Justification

Pain management is an essential part of peri-operative care for a patient. In resource limited settings as is the case in University Teaching Hospital this component of peri-operative care is not widely documented and no pain management guidelines are available. This study aimed to assess the adequacy and efficacy of postoperative pain management during recovery from laparotomy. It helped identify factors contributing to postoperative pain in our patients. The results from the study will contribute to improving the postoperative pain management.

1.4 Research Question

What factors are associated with postoperative pain in adult laparotomy surgery patients at UTH?

1.5 Objectives

1.5.1 Main Objective

To identify independent risk factors associated with moderate to severe pain after laparotomy.

1.5.2 Specific Objectives

1. To determine the incidence of moderate (FPS 5-6) postoperative pain in patients within 72 hours of laparotomy.
2. To determine the incidence of severe (FPS 7-10) postoperative pain in patients within 72 hours of laparotomy.
3. To identify factors associated with moderate to severe post-operative pain.
4. To identify independent risk factors associated with severe post-operative pain when adjusting for other covariates.

CHAPTER 2

LITERATURE REVIEW

2.1 Laparotomy and its impact on pain

Laparotomy is a commonly performed surgical procedure worldwide. It is also known as one of the most painful surgical procedures. A surgical procedure is painful due to the tissues damage and the consequent pathophysiological changes. Research has shown that all patients undergoing laparotomy will experience pain[4,5,9]. In an ideal hospitals where perioperative care is efficient patients will wake up comfortably with mild to no pain. In a setting where perioperative care is inadequate in pain management patients are bound to wake up in unbearable pain (moderate to severe).[9,10]

Another note to make is the type of incision, studies have shown that midline incision for intra-abdominal surgery like a laparotomy is painful. A study done on gallbladder surgery patients concluded that the midline incision was more painful than a transverse incision in the first post-operative 24 hours.[19,20] Another study showed that transverse incision was associated with less postoperative pain that vertical incision for abdominal surgery, but better access was gained using a vertical incision.[20,21] Hence the conclusion was that laparotomy was painful and a vertical incision was more painful than a transverse incision.[20,21]

2.2 Pain assessment tools

Pain being subjective, we depend on patient's self-reporting to assess the pain. Pain assessment needs to be done with simple tools, especially in patients with low education or some language barriers. Adult literacy rate is defined as the percentage of people ages 15 and above who can, with understanding, read and write a short, simple statement on their everyday life. Zambia has an adult literacy 61.4 % with a ranking of 154 out of 194.[22]According to UNICEF data for 2007-2011 the adult literacy rate was 71 %, with illiteracy more pronounced in females. The primary and secondary enrollments were high for both sexes standing at 91-94 % but the

completion of school percentages are low. For primary the survival rate to last grade was 53 % and for secondary the attendance rate to the end was 36-38 % for both females and male respectively.[23]At UTH we have a mixture of patients (as we deal with low cost and high cost patients), meaning we have patients who can read and write, we have those who know the value of numbers but can't read or write, those who are cognitively impaired and those who relate best to a picture, as it is the only tertiary hospital in Zambia. Hence a tool which was efficient for all groups of patient would be to our advantage. In order to use pain-rating scales well clinicians need to understand the pain scale. Also the clinician needs to appreciate the potential for error within the tools, and the potential they have to provide the required information.[22,23]

The Faces Pain Scale (FPS) was initially invented to help with pain assessment in children but many studies have shown that it was a reliable and valid to use for adult patients. A study done by Carey et al in 1997 [24], another done by Stuppy in 1998 [25] and one done by Kim et al in 2006 [26]found the Faces Pain Scale reliable to use in adults. Stuppy[25] found that 53 % of her study population preferred FPS and 30 % preferred NRS. The validity of this test was also confirmed as this test was used together with the VAS, NRS and VRS. The FPS was also found to be useful in cognitively impaired patient, in fact these patients preferred the FPS in comparison to VAS, NRS and VRS.[25,26] The FPS when compared to the VAS and NRS was found to be more reliable and accurate in a multicultural background as the faces helped patients express what where feeling better than a line and numbers.[17,25,26,27]

Currently no data is available on which pain tool would be appreciated by the population in this environment. From international data and the current mixture of the patients being admitted to UTH the best tool which could be used is the FPS.

2.3 Studies done in Low to Medium Income Countries

Very few research papers have been written specifically on pain management in laparotomy patients the LMIC. The only related research found was in surgery patients and caesarean section patients.

A study done in 1999, at the University College Hospital, Ibadan, Nigeria, showed that 46 % and 49.5 % of the patients experienced moderate to severe pain respectively immediately after surgery. In the first 24 hrs, 38.3 % experienced severe pain, 29.9 % experienced moderate pain, 27.9 % had mild pain and 3.4 % had no pain. In 48 hrs it was reported that 9.5 % had no pain, 38.3 % had moderate pain
6.1 % had severe pain.[6,7] These patients had received only Pentazocine (synthetically-prepared prototypical mixed agonist–antagonist narcotic drug of the benzomorphan class of opioids) pre - operatively. Intra operative and Post- operatively 75.5 % received pethidine, 14.3 % received Dipyrone (metamizole- is a nonsteroidal anti-inflammatory drug) and 10.2 % received pentazocine by intramuscular injection. On average patients received 2 daily doses of the prescribed medication was given in 48hours. Pain was assessed using a verbal rating score.[6,7]

A paper published in 2003, talked of a research done in 1999 at University of Ilorin Teaching Hospital (UITH), Ilorin, Nigeria, where 88 elective caesarean section patients who had undergone general anaesthesia where assessed for pain using the verbal rating score. They had all received Pentazocine after delivery of the baby. 79.6 % of these patient experienced moderate to severe pain in the recovery room.[28] Both studies done in Nigeria had their drawbacks, for instance, they didn't specify the doses of analgesic drugs and also they used unfamiliar drugs like Pentazocine and Dipyrone that are not available in the Zambian context.

In 2000 the East African Medical Journal published a paper of a study done in 1996 in Kenya, at the Kenyatta National Hospital, Nairobi, where the patients undergoing thoracic or laparotomy. 97 % had received intramuscular 50 mg pethidine and 2.8 % received tramadol intramuscularly pre-operatively and where maintained on nitrous oxide, oxygen and halothane intra operatively.[29] Opioids like pethidine (97.2 %) and morphine (2.8 %) where then prescribed for the post-operative period. 78 % received the opioids intramuscularly only, 20.8% received it intramuscular and intravenous and 0.9 % received it intravenous only. The time intervals of the administration of these drugs varied from 4hourly (6.6 %), 6 hourly (22.6 %), 8hourly (57.9 %) and 12hourly (13.2 %). The verbal rating scale was used to check for pain intensity. It was found that 60 % of the patients experienced moderate to severe pain in the immediate recovery period.[29] This study is more relevant to the Zambian context as in

this study they used common familiar drugs like pethidine and morphine. Also this study gave doses given and the time interval at which the drug was given.

A prospective clinical study was done in The Georgetown and New Amsterdam Public Hospitals, Guyana (a low-income country in South America). In this study, 200 patients undergoing major abdominal surgery where recruited and assessed for pain during the first 24 hrs post-operative. Pain was assessed using verbal rating scale where 1 was mild pain, 2 was moderate pain, and 3 was severe pain. All the patients experienced pain postoperatively. 61 % of patients considered their pain severe, 30 % rated it moderate and only 9 % mild. Reasons for this deficiency of care are partly attributable to lack of patients education and empowerment as they don't know they are entitled to analgesia and also the health care staff, as have no knowledge on the proper pain management. A conclusion of postoperative pain is being poorly managed in their general hospitals was made. [30] This study only looked at the incidence of pain and didn't talk about the analgesic drugs given.

To date no pain score studies are available for Zambian patients undergoing laparotomy.

2.4 Factors contributing to postoperative pain in low and middle income countries

In low and middle-income countries (LMIC), many factors contribute to inadequate postoperative pain management.[6] A survey carried out in the LMIC of Sub Saharan Africa established that some of these factors are lack of properly trained staff to administer the drugs[33], inadequate supply of the drugs[31], some restrictions on acquisition of the drug[32,33] (for example each patient needs 3 prescriptions written by a medical doctor to get morphine, especially oral morphine), and pain management was not a priority. In a certain LMIC hospital in sub-Saharan Africa, it was not uncommon to have two nursing staff looking after a ward of 50 patients, the overstretched nursing staff may be unavailable to administer analgesic drugs and, indeed, the safety of administering these potent analgesics was questioned.[31] The lack of analgesia in LMIC was but one of a vast number of perioperative challenges facing these regions.[6] Access to pain relief was an integral part of perioperative care jointly

managed by clinicians and nursing staff. Simple regimens, relying on inexpensive drugs, are often not followed.[34]

The study done by Soyannwo on patients undergoing major surgery at University College Hospital, Ibandan, Nigeria in 1999, pointed out that therapeutic failure of the intramuscular injection could be attributed to the skill of drug administration of the nursing and medical staff. Furthermore, time interval between the administrations of the drugs played a role in pain management. It was reported that patients who received pain medication at an interval of 4-6 hour interval had mild to no pain whilst patient who didn't receive analgesia at 6 hour intervals had moderate to severe pain.[6,7]

In 1996, a study on laparotomy patients in Kenya, attributed some of the factors contributing to post-operative pain was the lack of proper knowledge on the pharmacodynamics of the most prescribed drug pethidine (which has a duration of action of about 4hours), the fear of side effects of narcotic drugs lead to inadequate doses being prescribed like 50 mg of pethidine instead of 100 mg and patients not knowing they had a right to pain relief.[29]

Currently the only literature available for Zambia[12] was a study done by Jochberger in 2008 which stated that surgical patients received intraoperative drugs for postoperative pain management in recovery bay and that they were later given more pain relief drugs by the nurse on the ward as ordered by the surgeon.[12] This study stated that the anaesthesiologist needed to be more involved in the postoperative pain management of surgical patients. It also highlighted the need for more trained staff to administer these drugs for pain management.[12]

2.5 Modes of pain relief that have been known to work

Many methods may be used to combat postoperative pain in laparotomy patients in recovery bay and these can be peri-operative administration of analgesic agents like opioids and non-steroidal anti-inflammatory drugs, local infiltration of the incision site, patient controlled analgesia and administration of drugs in recovery bay by trained medical staff.[4, 5]

In women undergoing gynaecologic surgery, postoperative pain can be severe, interfere with sleep and appetite, and can result in chronic pain. Analgesics helped more patients get back to sleep than any other intervention.[35]

2.5.1 Opioids

There is very sparse literature on opioids given by nurse at a fixed time interval as post-operative pain management in laparotomy patients. There is more published literature on opioids given by patient controlled analgesia. A study done on caesarean section patients showed that morphine was the drug of choice for postoperative analgesia but oxymorphone and meperidine were also good alternatives.[36] This study was a randomized controlled trail and the VAS and VRS was used to assess pain at 2 hrs, 4 hrs, 6 hrs and 24 hrs. Initially a loading dose was given when the patient first complained of pain then the patient controlled analgesia was used. Patients where then assessed for pain intensity using the VAS and VRS, nausea and vomiting, level of sedation, pruritus and number of attempts made to give themselves drugs.[36] All three drugs had similar pain profile at rest in a 24 hour period. However patients on morphine in the first 4 hrs had a high mean VAS 3.5 -4 which declined progressively to a VAS mean of 1.2 whilst with oxymorphone the peak was achieved within 15 min but the decline only went to a mean VAS 2. With meperidine a similar peak to that of morphine was seen but the decline wasn't as low as morphine.[36] Therefore in the first 4 hrs patient's on morphine tried to inject themselves more often than those on oxymorphone.[36] With morphine more severe pruritus and a higher level of sedation was observed compared to oxymorphone. Patients had more nausea and vomiting with oxymorphone and meperidine.[36]This study has highlighted that morphine and oxymorphone were ideal drugs for pain management.

There was scanty data on the effectiveness of pethidine as an analgesic drug for post-operative pain management. In Kenya[29] which used pethidine at 50 mg intramuscular at 4 or 6 hourly intervals for thoracic and abdominal surgery patients still had 60 % of their patients reporting of moderate to severe pain.

2.5.2 Ketamine

A meta-analysis done in 2006 showed that low-dose ketamine can play a primary role in pain management.[37] Ketamine has fewer side effects like nausea and vomiting than opioids and can also be opioid sparing. Another good effect was that it can be used as a rescue analgesic for acute pain where there was poor response to opioids.[37] In 2010 it was found that sub-anaesthetic doses of ketamine were useful in reducing the amount of morphine needed to manage moderate to severe postoperative pain. It was found that in the 37 trails identified in this review, the VAS was reduced in the first 24 hrs in the treatment arms containing Ketamine. In this review 5 trails compared the amount of morphine when given on its own and when given in combination with ketamine and found that the mean morphine consumption was reduced up to 50 %.[38] Therefore the adverse side effects of morphine were avoided and better patient satisfaction achieved.[39] This property of ketamine could be useful in our setting for quick and safe pain management.

2.5.3 Non-Steroidal Anti Inflammatory Drugs

NSAIDS play an important role in management of acute pain after 24 hrs hours. When used in combination with opioids reduces the analgesic requirement of opioids by 30 %. This was safer for the patient as the major side effects of opioids like sedation, respiratory depression, nausea and vomiting may be reduced or totally avoided. [38, 40]

A review article done in 2011 showed that intravenous acetaminophen can be given peri-operatively for management of mild to moderate postoperative pain. It was well tolerated compared to opioids with favorable side effects and no drug interactions. Also as compared to other NSAIDS it does not affect platelet aggregation and so can be used in patients when surgical bleeding is a problem.[41]

2.5.4 Local and Spinal Anaesthetic

According to a review article done in 2008 it showed that using epidural local anaesthetic and epidural with added opioid was more effective for postoperative pain treatment compared to intravenous opioid based analgesic.[42] In this review 6 out of 8 trails showed that the mean VAS reduced from 32mm to 8mm (24mm difference) on the first post-operative day in patients who had a combination of epidural/spinal local anaesthetic plus opioid compared to those who only had local anaesthetic. It also

showed that epidurals had less side effects compared to intravenous opioid based analgesia.[42]

Studies have shown that immediate post-operative can be treated in a multi-modal manner. First peri-operative analgesic agents such as pethidine, morphine, non-steroidal anti-inflammatory agents are important. Then local infiltration of incision wounds with lignocaine and bupivacaine is equally as important. Administration of local anaesthetic agents and opioids into an epidural or spinal anaesthesia have been shown to be is very helpful in immediate post op analgesia and adverse effects are markedly reduced.[43]

There are many different modes of postoperative pain management in laparotomy patients being used currently but no published data is available to show what is best. This study will provide data that will bridge that gap. To date no studies have been done in Zambia to show the pain profile in laparotomy patients and what actually is effective for the patients in our environment. Also there aren't any statistics available in to relation to laparotomy and pain in Zambia. This study helped to identify if the challenges faced in other nearby countries is what is happening in our environment or are other factors involved too.

CHAPTER 3
METHODOLOGY

3.1 Study design

This was an observational prospective study of adult patients who had undergone laparotomy at UTH with a follow-up period of 3 days (72 hrs).

3.2 Setting

The Surgical and Gynaecological Theatres, recovery rooms in these theatres and respective wards the patients were admitted in post operatively at The University Teaching Hospital, Lusaka, Zambia.

3.3 Study population

The Anaesthesia Department at UTH give anaesthesia and analgesia to over 80 patients undergoing laparotomy per month from the surgical and gynaecological theatre records. The study population for recruitment was adult patients who were undergoing laparotomy at UTH. Patients were recruited into this study from Phase V (emergency surgical theatre), Phase III (elective surgical theatre) and Gynaecology theatre. The patients were later followed up in their respective wards. Recruitment took 7 months so the sample size was captured.

3.4 Sample Size

Convenience sampling method was used; meaning all patients undergoing laparotomy at University Teaching Hospital were captured over a period of 7 months and assessed for Immediate Postoperative pain.

As there is no data from Zambia, I used data from the Sub Saharan region like Nigeria and Kenya and also another study from a LMIC country in South America, Guyana. I averaged the percentages from these studies to arrive at the expected

incidence of immediate moderate to severe postoperative pain after laparotomy was 61 %. Java Applets for Power and Sample Size a statistical software was used to calculate sample size.[44] At 95 % confidence interval, with margin of error of +/- 5 % and assuming a fall out of 10 %, the sample size needed was 366. [44]Fall outs were attributed to patients not being assessed for pain in the first 6 hours post operatively, patient's files going missing or patients ending up sedated in Main Intensive Care Unit (MICU).

3.5 Sampling

Male and Female Patients between the age of 18-75yrs undergoing laparotomy who have fulfilled the study inclusion criteria were recruited in a 7-month period.

3.6 Inclusion Criteria

i. Emergency and elective laparotomy surgery patient
ii. Patients between the age of 18-75 years
iii. Consented patients

3.7 Exclusion Criteria

i. Patients undergoing laparoscopic surgery
ii. Patients undergoing a caesarean section
iii. Patients with GCS <12
iv. Patients going to Main Intensive Care Unit (MICU)
v. Patients who don't give consent

3.8 Clinical Procedure

Recruitment of patients was done by admitting anaesthetist (clinical officer) or anaesthesiologist on all days of the week in the emergency and elective surgical and gynaecological theatres at the University Teaching Hospital. The study population was all patients undergoing laparotomy in these theaters. The admitting anaesthetist

(clinical officer) or anaesthesiologist then informed the primary investigators that they had recruited a patient undergoing laparotomy.

Admitting anaesthetist or anaesthesiologist obtained consent from the patient. After which a detailed history by admitting anaesthesiologist or the researcher was taken from each of the recruited patients. Information gathered would include patient demographic characteristics (age, sex), drug history, past medical history, use of alcohol and smoking. A physical examination would be performed on the recruited patients. Vital signs obtained on admission will include blood pressure, heart rate, temperature and respiratory rate. If blood results were available baseline full blood count, renal function and liver function tests were checked.

Trained recovery staff assessed for post-operative pain in recovery bay (at 2 hrs) using the FPS pain score and document results on the data sheet. Other trained research assistants or primary investigator then followed up patients to do pain scores using the FPS at 6 hrs, 24 hrs, 48 hrs and 72 hrs and record drugs given as per drug chart. The primary investigator then collected the data sheets, file and drug charts of the patient within 72 hrs of operation. The clinical procedure followed and timeline are shown in Figure 1 and Table 1 below.

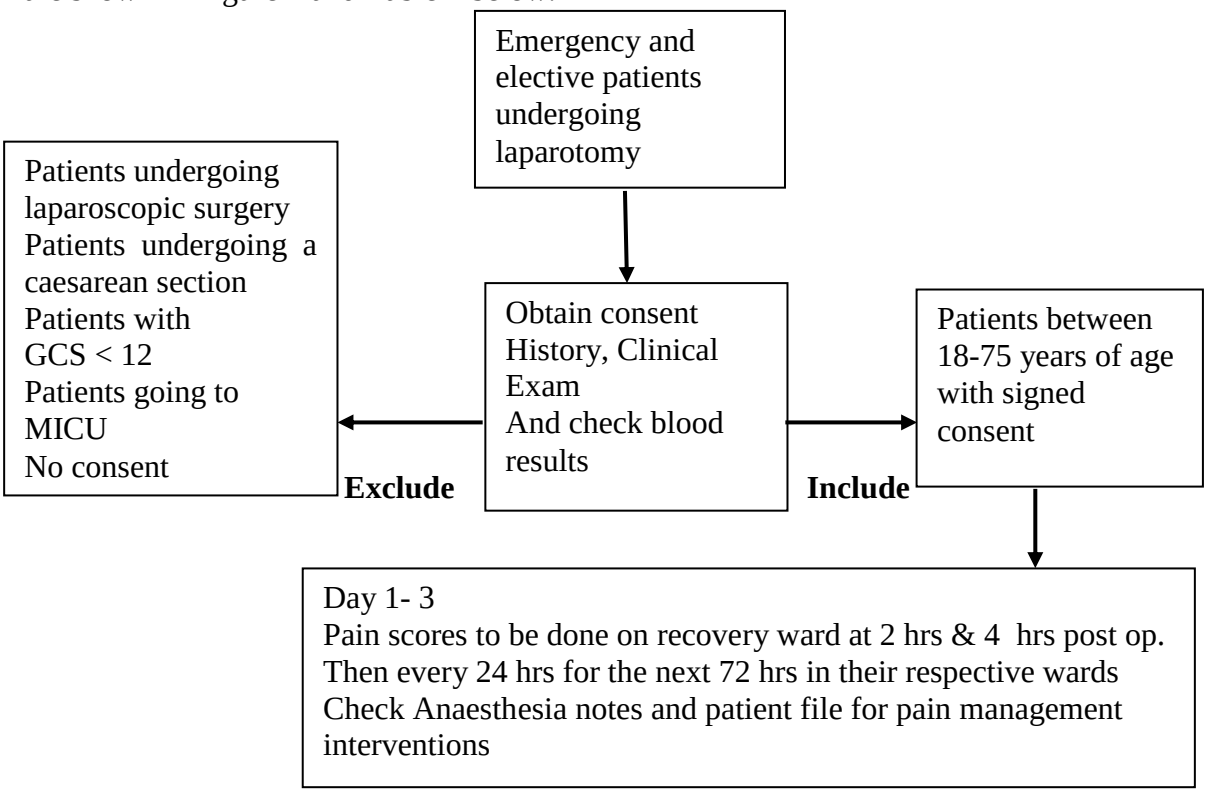


Figure 1: Study Process

Table 1: Timeline for Clinical Procedure

	Admission to Theater	2hrs Post Op	6hrs Post op	24hrs Post Op	48hrs Post Op	72hrs Post Op
Consent	Obtained					
Baseline Information	Anaesthetist or Anaesthesiologist					
Pain Assessment using FPS	Anaesthetist or Anaesthesiologist	Trained Recovery Staff	Trained Research Assistant	Trained Research Assistant	Trained Research Assistant	Trained Research Assistant
Drug Chart Review		Primary Investigator	Primary Investigator	Primary Investigator	Primary Investigator	Primary Investigator
File Review		Primary Investigator or Trained Research Assistant	Primary Investigator or Trained Research Assistant	Primary Investigator or Trained Research Assistant	Primary Investigator or Trained Research Assistant	Primary Investigator or Trained Research Assistant

3.9 Variables

3.9.1 Dependent variables:

Post-operative Pain scores assessed by Faces Pain Scale

3.9.2 Independent variables:

Factors contributing to moderate to severe pain

- Pre-op acute pain
- Grade of surgeon
- Grade of anaesthetist doing the case
- Grade of anaesthetist
- Emergency or elective case
- Type of surgery – e.g. gynaecology, bowel surgery, cholecystectomy – and incision
- Occupation
- Gender
- Weight
- GCS at presentation
- ASA score
- Length of surgery
- Use and doses of opiate analgesics pre-op, intra-op and post-op
- Use and doses of NSAIDS intra-op and post-op
- Use and doses of paracetamol intra-op and post-op
- Use of regional anaesthesia/ local infiltration

3.10 Analysis

3.10.1 Data Entry

The data was collected on a hard copy data entry sheet. Patients were given identity numbers to ensure confidentiality. After checking the completeness of the questionnaire, the data was entered into a computer database. Double entry was

performed to reduce human error and other mistakes. Data was then transferred to SPSS version 22 and analysed.

3.10.2 Data Analysis

The data was analysed using SPSS version 22. In the analysis, frequency counts and cross tabulations were done. For the FACES pain scale (FPS), data was analysed both as discrete outcome (0-10 score) and dichotomized as no pain/mild pain and moderate/severe pain. Categorical variables were described using frequency and percentages. Cross tabulation of categorical exposures and dichotomized outcome was done using use chi square.

Discrete outcomes was described by median (I and R) and by mean (SD) to check if distribution is normal. T-test/ was used to compare mean pain scores among the categories. Multiple Logistical regression was used for discrete variables which were not normally distributed. Confidence levels, p – values and odds ratios were computed in order to determine factors that are associated with the dependent variable; moderate/severe pain or mild/no pain. In my study, the statistical significance level of 5 % (i.e. p value ≤ 0.05) was used. Thus, results that showed a p value of less than or equal to 0.05 was considered to be statistically significant. The 95 % confidence interval was used, meaning being 95 % confident that the sample mean represents the population mean.

CHAPTER 4

RESULTS

/

4.1 Factors associated with Post-operative pain

A total 366 patients who had a laparotomy where recruited. The Faces Pain Scale (FPS) was used to assess pre-operative (our reference point) and post-operative pain. Out of these 259 where females and 107 where males between the ages of 18-75 years. These are tabulated in Table 2. Majority of these patients were from the urban location (292) while the rest were from a rural location (74). As shown in table 3, 69.7 % of the recruited cases where urgent and 30.3 % where elective. 54 % of these cases where gynaecological, 44 % general surgery and 2 % urology as shown in table 3 and 4. No statistical significance was noted between age, sex, and area of residence in relation to the perception of pain (table 7). Also the urgency of the case, procedure done, grade of the anaesthetist and surgeon had no significance on the post-operative pain as shown in Table 6 and 7. Patients who had weight >99 kg showed to effect pain (p-value 0.005). Also patients who had longer surgery time >240min had a significance on pain (p-value 0.042).

Table 2. Demographic distribution of post laparotomy patients

	n	%
Age		
18 – 28	125	34.2
29 – 49	203	55.5
50 – 58	25	6.8
>58	13	3.6
Sex		
Female	259	70.8
Male	107	29.2
Residence		
Rural	74	20.2
Urban	292	79.8

Table 3. Distribution of Speciality

Speciality	Number	%
Gynaecology	200	54
General Surgery	162	44
Urology	4	2
Total	**366**	**100**

Table 4. Distribution of the Surgical Procedure done.

Procedure	Frequency	%
Drainage, Lavage and repair	78	21.3
Total Abdominal Hysterectomy, Bilateral Salpingo-opherectomy, Abdominal Mass Excision	103	28.1
Evacuation And Lavage	90	24.6
Intestinal Obstruction Release and Anastomosis	64	17.5
Other	31	8.5
Total	**366**	**100.0**

Table 5. Distribution of urgency for Laparotomy

Urgency	Number	%
Elective	111	30.3
Emergency	255	69.7
Total	**366**	**100.0**

Table 6. Shows Urgency of laparotomy by FPS 2 and 6 Hours

n=366	None	Mild	Moderate	Severe	Statistics	
	n (%)	n (%)	n (%)	n (%)	x^2	p
FPS 2 Hours					7.21	0.065
Elective	52 (46.8)	17 (15.3)	10 (9.0)	32 (28.8)		
Emergency	113 (44.3)	70 (27.5)	18 (7.1)	54 (21.2)		
Urgency FPS 6 Hours					2.53	0469
Elective	26 (23.4)	38 (34.2)	11 (9.9)	36 (32.4)		
Emergency	58 (22.7)	103 (40.3)	30 (11.6)	64 (25.1)		

Table 6 is shows that there was no significant difference in the magnitude of the pain where associated with the whether the laparotomy was elective or emergency.

Table 7. Univariate estimates for the odds of moderate or severe **FPS.

Variable	*UOR	95% CI	p-value
Age			
18-28 years	0.97	(0.76, 1.25)	0.836
29-49 years	1.52	(0.96., 2.39)	0.075
50-58 years	0.66	(0.40, 1.09)	0.106
Sex			
Female (Ref)	1	n/a	n/a
Male	0.89	(0.69, 1.15)	0.374
Pre-operation acute pain			
No pain (Ref)	1	n/a	n/a
Mild	1.59	(1.01, 2.50)	0.046
Moderate	1.52	(0.98, 2.34)	0.059
Severe	1.40	(1.00, 1.95)	0.051
Grade of surgeon			
Junior registrar (Ref)	1	n/a	n/a
Senior registrar	0.80	(0.57, 1.12)	0.199
Consultant	0.88	(0.62, 1.25)	0.472
Grade of anaesthetist			
Junior registrar (Ref)	1	n/a	n/a
Clinical officer	0.99	(0.76, 1.28)	0.935
Consultant	0.83	(0.62, 1.11)	0.208
Urgency			
Elective (Ref)	1	n/a	n/a
Emergency	1.02	(0.80, 1.30)	0.867
Type of procedure			
Other (Ref)	1	n/a	n/a
Drainage	0.86	(0.55, 1.32)	0.485
Total abdominal hysterectomy	0.92	(0.61, 1.40)	0.701
Evacuation	0.86	(0.56, 1.32)	0.495
Release	0.91	(0.58, 1.44)	0.693
Weight			
<51 Kg (Ref)	1	n/a	n/a
51-60 kg	1.57	(0.92, 2.67)	0.098
61-80 kg	1.32	(0.79, 2.20)	0.295
81-99 kg	1.27	(0.63, 2.59)	0.503
>99 kg	3.89	(1.52, 9.96)	0.005
Duration of anaesthesia			
0-60 minutes (Ref)	1	n/a	n/a
61-120 minutes	1.05	(0.80, 1.38)	0.742
121-180 minutes	0.83	(0.60, 1.14)	0.247
181-240 minutes	0.85	(0.55, 1.30)	0.449
>240 minutes	0.20	(0.04, 0.95)	0.042
Pre-operation analgesia			
No (Ref)	1	n/a	n/a
Yes	1.07	(0.85, 1.35)	0.564
Pre-operative analgesia paracetamol			
No (Ref)	1	n/a	n/a
Yes	1.12	(0.89, 1.42)	0.326
Pre-operative analgesia Diclofenac			
No (Ref)	1	N/a	n/a
Yes	1.17	(0.85, 1.63)	n/a
Pre-operative analgesia Ibuprofen			
No (Ref)	1	n/a	n/a
Yes	1.39	(1.04, 1.87)	0.077
Pre-operative analgesia Pethidine			
No (Ref)	1	n/a	n/a
Yes	0.82	(0.39, 1.74)	0.610

***UOR= Unadjusted odds ratios, using generalised estimating equations.**

****FPS= faces pain scale**

Table 8: Multiple logistic regression for severe pain at 2 hours
Variables in the Equation

			Standard				Odds	95% C.I. for Odds ratio	
		B	Error	Wald	d.f.	Sig	Ratio	Lower	Upper
Step 1[a]	Pre-op pain (FPS)	-.046	.039	1.368	1	.242	.955	.885	1.031
	Incision (transverse)	.547	.291	3.528	1	.060	1.728	.977	3.059
	Spinal anaesthetic	.945	.423	4.982	1	.026	2.573	1.122	5.900
	Pethidine OR (1 mg/kg)	-.766	.407	3.533	1	.060	.465	.209	1.033
	Fentanyl OR (1 mcg/kg)	.165	.336	.242	1	.623	1.180	.611	2.278
	Ketamine OR (1 mg/kg)	-.475	.149	10.164	1	.001	.622	.464	.833
	Pethidine in PACU (1 mg/kg)	-.469	.471	.993	1	.319	.626	.249	1.574
	Morphine OR (0.1 mg/kg)	-2.995	.713	17.640	1	.000	.050	.012	.202
	Constant	-1.056	.502	4.421	1	.036	.348		

* OR – drugs given in the intraoperative period

The logistical regression showed patients with spinal anaesthetic were about 2.5 times more likely to have severe pain at 2 hours. Patients with ketamine were about 30% less likely to have severe pain at 2 hours per 1 mg/kg ketamine (Odds Ratio 0.62). Patients that had received morphine were about 20 times less likely to have severe pain for each 0.1 mg/kg morphine received.

Table 9: Multiple logistic regression for severe pain at 6 hours
Variables in the Equation

		B	Standard Error	Wald	d.f.	Sig.	Odds Ratio	95% C.I. for Odds ratio	
								Lower	Upper
Step 1[a]	Pre-op pain (FPS)	-.039	.035	1.234	1	.267	.962	.898	1.030
	Incision (transverse)	-.172	.271	.404	1	.525	.842	.495	1.432
	Regional	-.260	.405	.413	1	.521	.771	.349	1.704
	Pethidine OR (1 mg/kg)	.323	.318	1.037	1	.308	1.382	.742	2.575
	Fentanyl OR (1mcg/kg)	-.183	.334	.302	1	.583	.833	.433	1.601
	Ketamine OR (1 mg/kg)	.069	.116	.353	1	.553	1.071	.853	1.345
	Pethidine in PACU (mg/kg)	.037	.396	.009	1	.925	1.038	.478	2.254
	Morphine OR (0.1 mg/kg)	.418	.473	.778	1	.378	1.518	.600	3.839
	Severe pain 2 hours (FPS)	.438	.285	2.370	1	.124	1.550	.887	2.707
	Constant	-.673	.477	1.990	1	.158	.510		

- OR – drugs given in the intra operative period

After multiple logistical regression no factors were found to contribute to severe pain at 6 hrs

4.2 Pain scores

Pre operatively 67.5 % of the patients reported severe pain whilst 9.8 % reported moderate pain. Only 25.4 % of the patients reported mild to no pain.

Moderate and severe pain was reported by 28 patients (7.7 %) and 86 patients (23.5 %) respectively in the immediate recovery period (2 hrs). The incidence of the pain increased in the first 24 hrs with 44 patients (12 %) reporting moderate pain and 100 patients (27.3 %) reporting severe pain. The pain remained the same at

48 hrs, 143 patients still reported moderate (13.1 %) to severe (26 %) pain. In the subsequent day the magnitude of pain decreased, though at 72 hrs, 97 patients

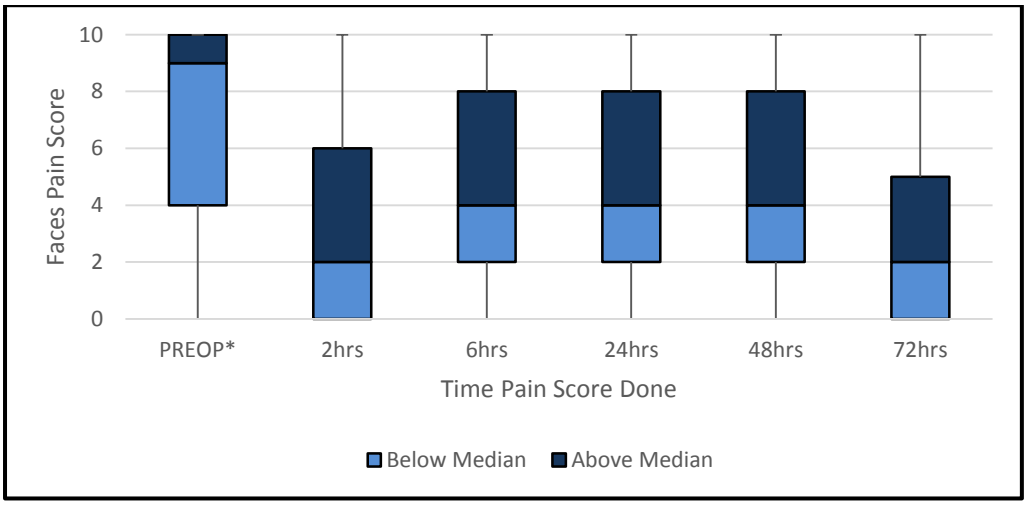
reported moderate (8.25 %) to severe pain (18.3 %). This is shown in table 10 and figure 2.

Table 10. Distribution of pain scores following laparotomy

Pain level	Pre op*	2 hrs	6 hrs	24 hrs	48 hrs	72 hrs
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
No	47 (12.8)	165 (45.1)	84 (23)	41 (11.2)	32 (8.7)	120 (32.8)
Mild	46 (12.6)	87 (23.8)	141 (38.5)	181 (49.5)	191 (52.2)	149 (40.7)
Moderate	36 (9.8)	28 (7.7)	41 (11.2)	44 (12.0)	48 (13.1)	30 (8.2)
Severe	247 (67.5)	86 (23.5)	100 (27.3)	100 (27.3)	95 (26)	67 (18.3)
Total	**366 (100.0)**	**366 (100.0)**	**366 (100.0)**	**366 (100.0)**	**366 (100.0)**	**366 (100.0)**

***Pre op – pre operative**

The graph in figure 2 shows that there was a very high level of pain in the pre-operative period with a median of 9. Another interesting finding was that pan in the first 2 hrs post-operative was well managed with a median of 2. At 6 hrs, 24 hrs and 48 hrs post operatively the median was 4 with a higher distribution of patient in the pain score range of 5 to 10. At 72 hrs post operatively the median was found to be 2 which is mild to no pain which is acceptable.



***PREOP – pre operative Faces Pain Score: 0-1 = no pain; 2-4 = mild pain; 5-6 =moderate pain; 7-10 =severe pain**

Figure 2: This is showing pain score distribution over 72 hrs post operatively.

4.3 Type of Incision

Table 11 shows that 56.6 % of the cases had midline incisions while 43.4 % had transverse incision. Table 12 shows that at 2 hrs post op the patients with a transverse incision 28.3 % had severe pain and 11.9 % had moderate pain. The patients with a midline incision 19.8 % had severe pain and 4.3 % had moderate pain. This trend changed at 24 hrs, 48 hrs and 72 hrs as the midline incision had more patients in severe pain compared to the transverse incision as shown by the percentages in table 12.

Table 11. Distribution of type of incision.

Type of Incision	Frequency	%
Transverse	159	43.4
Midline	207	56.6
Total	**366**	**100.0**

Table 12. Type of Incision to pain distribution using FPS

n=366	None	Mild	Moderate	Severe
	n (%)	n (%)	n (%)	n (%)
FPS 2 Hours				
Transverse	65 (40.9)	30 (18.9)	19 (11.9)	45 (28.3)
Midline	100 (48.3)	57 (27.3)	9 (4.3)	41 (19.8)
FPS 6 Hours				
Transverse	31 (19.5)	62 (39.0)	23 (14.5)	43 (27.0)
Midline	53(25.6)	79 (38.2)	18 (8.7)	57 (27.3)
FPS 24 Hours				
Transverse	22 (13.8)	72 (45.3)	30 (18.9)	35 (22.0)
Midline	19 (9.1)	109 (52.7)	14(6.8)	65 (31.4)
FPS 48 Hours				
Transverse	11 (6.9)	93 (58.5)	28 (17.6)	27 (17.0)
Midline	21 (10.1)	98 (47.3)	20 (9.7)	68 (32.9)
FPS 72 Hours				
Transverse	64 (40.3)	67 (42.1)	14 (8.8)	14 (8.8)
Midline	56 (27.1)	82 (39.6)	16 (7.7)	53 (25.6)

The graph below shows that at 2 hrs post op patients who had a transverse incision had a pain score median of 4 compared to midline incision patients who had a median of 2. At 24 hrs post op the median was found to be 4 for both incisions but for midline incision the 3rd quartile group report a score of 8 compared to the transverse incision group which report a score of 6. At 48 hrs post op the transverse incision patient had a median 3 and the 3rd quartile group report a score of 6 compared to the midline incision patients who had a median of 4 and the 3rd quartile group reporting a score of 8. This showed that the midline incision maybe more pain full than the transverse incision.

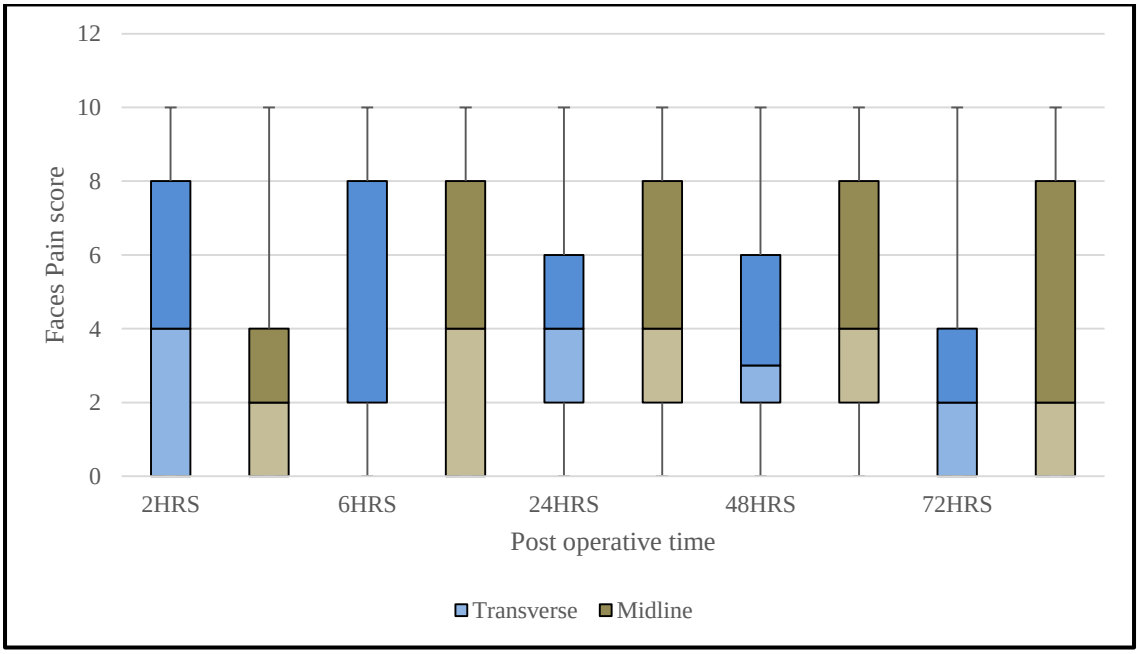


Figure 3: The incisional pain after laparotomy: transverse vs midline

4.4 Post-operative analgesia drugs administered

Table 13: Peri Operation Drugs by FPS at 2 Hours

n=365	None	Mild	Moderate	Severe	Total	Statistics
	n (%)	n (%)	n (%)	n (%)	n	p
No Drugs						
	36 (37.5)	21 (21.9)	8 (8.3)	31 (32.3)	**96**	0.984
Fentanyl						
	5 (21.7)	4 (17.4)	4 (17.4)	10 (43.5)	**23**	0.015
Fentanyl and Ketamine						
	4 (40.0)	3 (30.0)	0 (0.0)	3 (30.0)	**10**	0.756
Ketamine						
	30 (46.2)	23 (35.4)	3(4.6)	9 (13.8)	**65**	0.035
Morphine						
	23 (56.1)	9 (22.0)	2 (4.9)	7 (17.2)	**41**	0.45
Morphine and Fentanyl						
	4 (26.7)	4 (26.7)	2 (13.3)	5 (33.3)	**15**	0.475
Morphine and Ketamine						
	24 (72.7)	4 (12.1)	2 (6.1)	3 (9.0)	**33**	0.009
Pethidine						
	11 (30.6)	12(33.3)	3 (8.33)	10 (27.8)	**36**	0.299
Pethidine and Ketamine						
	16 (55.2)	5 (17.2)	2 (6.9)	6 (20.7)	**29**	0.695
Pethidine and Morphine						
	11 (64.7)	2 (11.8)	2 (11.8)	2 (11.8)	**17**	0.252
Total	**164**	**87**	**28**	**86**	**365**	

Table 14: Peri-operative Drugs by FPS at 6 Hours

n=365	None	Mild	Moderate	Severe	Total	Statistics
	n (%)	n (%)	n (%)	n (%)	n	p
No Drugs						
	18 (18.8)	40 (41.7)	11 (11.5)	27 (28.1)	**96**	0.984
Fentanyl						
	3 (13.0)	6 (26.1)	5 (21.7)	9 (39.1)	**23**	0.129
Fentanyl and Ketamine						
	4 (40.0)	5 (50.0)	0 (0.0)	1 (10.0)	**10**	0.263
Ketamine						
	18 (27.7)	27 (41.5)	6 (9.2)	14 (21.5)	**65**	0.513
Morphine						
	11 (26.8)	15 (36.6)	3 (7.3)	12 (29.3)	**41**	0.782
Morphine and Fentanyl						
	4 (26.7)	6 (40.0)	0 (0.0)	5 (33.3)	**15**	0.558
Morphine and Ketamine						
	6 (18.2)	16 (48.5)	4 (12.1)	7 (21.2)	**33**	0.62
Pethidine						
	7 (19.4)	14 (38.9)	5 (13.9)	10 (27.8)	**36**	0.931
Pethidine and Ketamine						
	8 (27.6)	8 (27.6)	4 (13.8)	9 (31.0)	**29**	0.647
Pethidine and Morphine						
	4 (23.5)	4 (23.5)	3 (17.6)	6 (35.3)	**17**	0.549
Total	**83**	**141**	**41**	**100**	**365**	

Drugs given peri-operatively provide analgesia in the immediate postoperative period (2 hrs and 6 hrs). Several drug regimens where given as shown in table 13 and 14. Regimens which provide the analgesia at 2 hrs where ketamine and a combination of morphine with ketamine with p values of 0.035 and 0.009 respectively. It was also found Fentanyl given at induction at a dose of 0.98 mcg/kg on its own did not provide any post-operative analgesia at all with 14 patients out of 23 patients having moderate to severe pain.

Table 15. Distribution of analgesic Drugs given Post at 24 Hours by FPS 24 Hours

	None	Mild	Moderate	Severe	Total
	n (%)	n (%)	n (%)	n (%)	n
No drug					
	7 (7.1)	57 (58.2)	14 (14.3)	20 (20.4)	**98**
Pethidine 100 mg Intramuscular Total					
	1 (4.2)	7 (29.2)	3 (12.5)	13 (54.1)	**24**
Pethidine 200 mg Intramuscular Total					
	3 (6.5)	15 (32.6)	8 (17.4)	20 (43.5)	**46**
Pethidine 300 mg Intramuscular Total					
	15 (14.0)	57 (53.3)	10 (9.4)	25 (23.4)	**107**
Pethidine 300 mg and Diclofenac 75 mg Intramuscular Total					
	0 (0.0)	5 (50.0)	0 (0.0)	5 (50.0)	**10**
Pethidine 400 mg Intramuscular Total					
	12 (17.4)	35 (50.7)	6 (8.7)	16 (23.2)	**69**
Pethidine 300 mg and Paracetamol 1000 mg					
	3 (27.3)	5 (45.5)	3 (27.3)	0 (0.0)	**11**
Total	41	181	44	100	**365**

Table 15 shows the different combinations of drugs given in the first 24 hrs postoperatively against the pain perceived. This showed that 54.1 % of the patients who received pethidine 100 mg IM had severe pain. Also 43.5 % patients who received pethidine 200 mg IM had severe pain. In the patients who received pethidine 300 mg IM with 1000 mg paracetamol 45.5 % had mild pain, 27.2 % had no pain and 27.2 % had moderate pain.

Table 16. Distribution of analgesic Drugs given at 48 Hours by FPS 48 Hours

n=365	None	Mild	Moderate	Severe	Total
	n (%)	n (%)	n (%)	n (%)	n
No drug					
	18 (8.1)	115 (51.6)	27 (12.1)	63 (28.3)	**223**
Diclofenac 75 mg Intramuscular Total					
	1 (11.1)	6 (66.7)	0 (0.0)	2 (22.2)	**9**
Diclofenac 150 mg Intramuscular Total					
	1 (5.9)	15 (88.2)	1 (5.9)	0 (0.0)	**17**
Diclofenac 225 mg Intramuscular Total					
	1 (12.5)	7 (87.5)	0 (0.0)	0 (0.0)	**8**
Paracetamol 3000 mg Per Oral Total					
	0 (0.0)	5 (50.0)	0 (0.0)	5 (50.0)	**10**
Paracetamol 3000 mg and Ibuprofen 1200 mg Per Oral Total					
	3 (20.0)	11 (73.3)	1 (6.7)	0 (0.0)	**15**
Pethidine 100 mg Intramuscular Total					
	1 (1.8)	16 (28.0)	13 (22.8)	27 (47.4)	**57**
Pethidine 100 mg and Diclofenac 150 mg Intramuscular Total					
	4 (28.6)	7 (50)	2 (14.3)	1 (7.1)	**14**
Pethidine 100 mg Intramuscular and Paracetamol 200 mg Per Oral Total					
	1 (8.3)	7 (58.3)	2 (16.7)	2 (16.7)	**12**
Total	**30**	**189**	**46**	**100**	**365**

At 48 hrs the opioid drugs are being weaned off and patients a moved on to a combination of non-steroidal anti-inflammatory drugs (NSAIDS). Table 16 shows from all the patients who received Pethidine 100 mg intramuscular 70.2 % had moderate to severe pain. From the patients who had a combination of pethidine 100 mg and Diclofenac 150 mg intramuscular 21.4 % had moderate to severe pain. In patients who had received Pethidine 100 mg intramuscular and oral paracetamol 200 mg 33.4 % had moderate to severe pain. Diclofenac at doses 75 mg, 150 mg and 225 mg intramuscular was found to give effective pain relief as most patients had mild to no pain. All this is shown in table 16.

Table 17. Distribution of Total analgesic Drugs given at 72 Hours by FPS 72 Hours

n=365	None	Mild	Moderate	Severe	Total
	n (%)	n (%)	n (%)	n (%)	n
No drug					
	29 (19.6)	45 (30.4)	16 (10.8)	58 (39.2)	**148**
Diclofenac 75 mg Intramuscular Total					
	6 (28.6)	12 (57.1)	0 (0.0)	3 (14.3)	**21**
Diclofenac 100 mg Intramuscular Total					
	12 (38.7)	13 (41.9)	4 (12.9)	2 (6.5)	**31**
Diclofenac 225 mg Intramuscular Total					
	10 (45.5)	11 (50.0)	1 (4.5)	0 (0.0)	**22**
Paracetamol 975 mg and Ibuprofe**n 1200 mg Per Oral Total**					
	10 (50.0)	10 (50.0)	0 (0.0)	0 (0.0)	**20**
Paracetamol 2000 mg and Ibuprof**en 800 mg Per Oral Total**					
	2 (22.2)	5 (55.6)	1 (11.1)	1 (11.1)	**9**
Paracetamol 3000 mg Per Oral Total					
	11 (30.6)	17 (47.2)	6 (16.7)	2 (5.6)	**36**
Paracetamol 3000 mg and Ibuprof**en 1200 mg Per Oral Total**					
	40 (51.3)	35 (44.9)	2 (2.6)	1 (1.3)	**78**
Total	**120**	**148**	**30**	**67**	**365**

At 72 hrs many drug regimens where used and the most significant regimen found was a total of paracetamol 3000 mg with ibuprofen 1200 mg given per oral, with 96.2 % of the patient having mild to no pain. It was found that 95.5 % of patients who received Diclofenac at 225 mg intramuscular reported mild to no pain. As shown in the table 17.

4.5 Spinal anaesthesia and local infiltration

From 366 patients, 53(14.4 %) patients received a spinal anaesthesia. At 2 hrs post op 28.3 % had severe pain and 9.5 % had moderate pain. 39.6 % had no pain. At 6 hrs post op the trend remained the same. This is shown in table 18 below.

Table 18. Drugs given in Spinal Anaesthesia by FPS 2 and 6 Hours

n=53	None	Mild	Moderate	Severe
	n (%)	n (%)	n (%)	n (%)
FPS 2 Hours				
	21 (39.6)	12 (22.6)	5 (9.5)	15 (28.3)
FPS 6 Hours				
	9 (17.0)	22 (41.5)	7 (13.2)	15 (28.3)

From the 366 patients enrolled, 46 patients (12.5%) where given a local infiltration of lignocaine with adrenaline at the incision site. At 2 hrs post operatively only 6(13.1%) patients recorded moderate to severe pain and at 6 hrs post operatively 15(32.6 %) patient reported moderate to severe pain. This is shown in table 19 below.

Table 19. Distribution of pain score using FPS at 2 and 6 Hours in patients who received local infiltration.

n=366	None	Mild	Moderate	Severe	Total
	n (%)	n (%)	n (%)	n (%)	n
FPS 2 Hours					
No	136 (42.5)	76 (23.8)	26 (8.1)	82 (25.6)	**320**
Yes	29 (63.0)	11 (23.9)	2 (4.4)	4 (8.7)	**46**
FPS 6 Hours					
No	71 (22.2)	123 (38.4)	37 (11.6)	89 (27.8)	**320**
Yes	13 (28.3)	18 (39.1)	4 (8.7)	11 (23.9)	**46**

CHAPTER 5
DISCUSSION

5.1 Factors associated to post-operative pain.

Pain assessment and management following surgery are central to the post-operative care of a patient.[46] For pain to be treated it needs to be assessed. Patients have to describe their pain by self-reporting. Patients need to know that pain relief is a basic human right. It was established by Taylor et al[47] and Size etal[9] the common reasons for poor pain management are inadequate trained staffing, knowledge deficit, unhelpful staff and patient attitudes, poor pain assessments, fear of analgesia side effects and lack of accountability.[47]

Postoperative pain is acute traumatic pain caused by tissue damage as a result if the surgical procedure.[5, 13] This pain is usually self-limiting and amendable to treatment, but still remains as a major problem following surgery. Many studies have shown the benefits associated with proper pain relief.[6] These include reduced post-operative morbidity, early mobilization, and decreased length of hospital stay. It also enhances patient comfort and wellbeing.[28]

5.2 Pain score findings and analgesic drugs administered

Our results showed that to start with 9.8 % and 67.5 % of our patients reported moderate to severe pain respectively pre-operatively. This means for our laparotomy patients one of our area of concerns should be in the pre-operative period and what is leading to these patients pain not being managed. From the data collected it was found that 51.6 % of these patients received some form of analgesia pre-operatively whilst the others didn't. Unfortunately no prior data is available for pre operatively pain management for us to compare our results to.

The results showed an incidence of moderate and severe pain to be 7.7 % and 23.5 % respectively in the immediate post-operative phase. This is significantly lower than what Soyannwo reported in Nigeria[28] which was 68 %, and Ocitti et al

reported an incidence of 60 % in Kenya.[39] Although our results showed a lower incidence it still a problem as no patient should have the discomfort of severe pain post operatively.

At 24 hrs post operatively 27 % had severe pain and 12 % had moderate pain which is more than what we found at 2 hrs post op. A possible explanation for this is that unavailability of opioids and proper trained staff to administer the drugs but this needs a further study to establish as a reasonable factor. Size et al also reported that pain management was not adequate due to lack of trained nurses to administer the opioids drugs needed for analgesia during their research in 2007.[9] At 48 hrs and 72 hrs post operatively pain management improved as patients are weaned off the opioids and given more NSAIDS which may be easier to administer and more accessible for the nurses and patients.

At 24 hrs, 48 hrs and 72 hrs post op patients were given a variety of regimen of analgesia. This made it difficult to know which drug combination was best to use. Further studies are needed to see which regimen works best for our environment.

Pain in the immediate post-operative period can be attributed to inadequate administration of analgesia intra operatively. Patients who had received ketamine (1 mg/kg) or morphine (0.1 mg/kg) woke up with less pain than those who received other analgesic drugs. This drug combination provided analgesia for the first 2 hrs post operation. After this opiods were prescribed for the 24hr period. These findings were based on multiple regression analysis.

5.3 Local and Spinal Anaesthetic effects on pain

Local anaesthetic can stop pain at the incision site whilst opioids and NSAIDS alleviate pain systemically. The data collected showed that 46 patients of the 366 patients received local anaesthetic and only 8.7 % had severe pain whilst 86.9 % had mild to no pain in the immediate post-operative period. Some studies found 90 % of their patients where pain free form this mode of analgesia. This was according to Marc etal[45] who gave bupivacaine as local anaesthetic for abdominal

surgery and Keats etal[48] who reviewed research on post-operative pain: treatment and research.

Patients who had received spinal anaesthesia had more pain in the immediate 2 hrs post operatively period. According to the multiple regression analysis patients who had a spinal analgesia where 2.5 time more like to have pain at 2 hrs post-operatively. Factors contributing to this finding need to be explored further as it was beyond the scope of this study. It may have been due to patients not receiving any analgesic drugs in the first 6 hrs post-operatively as the nurse waited for the spinal anaesthesia to wear off but at this point we can just speculate. Another likely reason may be the lack of personnel to administer the much need opioids for post-operative analgesia.as this was one of the problem also stated by Size et al in their publication.[9,25] Kolawole et al also noted this problem is his study in Nigeria in 1996.[7,28]

5.4 Type of incision and its relation to pain

Transverse incision was found to be less painful than midline incision. [19,20,21,45] During our study 43.4 % of our patients had a transverse incision and 56.6 % had a midline incision. At 2 hrs post op the transverse incision patients had more moderate to severe pain (11.9 % and 28.3 % respectively) compared to those who had a midline incision which had 4.3 % with moderate pain and 19.8% with severe pain. Other research has found the opposite but in our study most patient who had a transverse incision had a spinal anaesthesia as well and this would account for our findings. Midline incision patients were given some form of analgesia during their intra-op period which would provide the necessary pain management in the immediate 2 hrs post-operation.

Further studies with more focused groups will assist in understanding these findings. At 24 hrs, 48 hrs and 72 hrs the trend changed and it was found the midline incision was more painful than the transverse incision.

This study has provided baseline information needed for further studies eventually leading to setting up pain management protocols for our resource limited setting.

CHAPTER 6
CONCLUSION

This study revealed that pre-operative is a major area of concern and adequate pain management is lacking in this area. It was established that there was an incidence of moderate to severe pain though lower than what was reported in literature previously and it remains a significant problem following a laparotomy in our environment. Simple easily accessible drug like ketamine or a combination of ketamine and morphine given intra operatively will provide adequate analgesia for up to 6 hrs post operatively. Patients who received spinal anaesthesia had moderate to severe pain in the first 6 hours post op. A transverse incision was more painful than midline incision at 2 hrs post op. A midline incision was more painful than transverse at 24 hrs, 48 hrs and 72 hrs post-operative period. Other contributing factors to post-operative pain in Laparotomy patients at University Teaching Hospital in Lusaka which were not in the scope of this study but could be explored is shortages of nurses; inadequate to lack of tools for assessing pain; and random drug regimen contributed

6.1 Recommendations

1. Pain score tools should be adopted to assess and manage pre and post-operative pain.
2. Further studies to establish if lack of trained personnel to administer opioids is contributing to post-operative pain
3. A follow up paper to explore factors contributing to immediate 2 hours post-operative pain in spinal anaesthesia patients.
4. Special training in pain management for both nurses and doctors.
5. Set up protocols so as to have a uniform regimen for post-operative pain management.
6. Further studies be done on a more focused group to determine which regimen works best in our environment

7. REFERENCES

1. World Health Organization. *Questions and answers on: Health and Human Rights. Health and Human Rights Publication Series World Health Organization*; July 2002; Issue 1.
2. Brennan F, Cousins MJ. *Pain relief as a human right.* Pain: Clinical Updates 2004; Vol. XII; Issue 5; pp1–4.
3. Merskey H, Allbe-Fessard D, Bonica JJ, Carmon A, Dubner R, Kerr FWL, et al. *Pain terms: a list with definitions and notes on usage. Recommended by the IASP subcommittee on taxonomy*. Pain 1979; Vol 6; pp 249–52
4. Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine. *Acute Pain Management*; Scientific Evidence, 2005; 2nd edn; pp14–16.
5. Spacek A., *Modern concept of acute and chronic pain management*; Biomedicine & Pharmacotherapy; June 2006; Vol 60; pp 329-335
6. Soyannwo O.A., *Post-operative pain control--prescription pattern and patients' experience;* West African Journal of Medicine; Jul-Sep 1999; Vol 18; Issues3; pp 207-10.
7. Faponle AF, Soyannwo OA, Ajayi IO, *Post-operative pain therapy: a survey of prescribing patterns and adequacy of analgesia in Ibadan, Nigeria*; Cent African Journal of Medicine; 2001 Mar; Vol 47; Issue 3: pp 70-4.
8. Ocitti EF, Adwok JA, *Post-operative management of pain following major abdominal and thoracic operations*; East African Medicine Journal; 2000 Jun; Vol 77; Issue 6; pp 299-302
9. Size M, Soyannwo A. O and Justins D M; *Pain management in developing countries*; Anaesthesia 2007; Vol. 62; pp 38–43
10. Apfelbaum JL, Chen C, Metha SS, Gan TJ. *Postoperative pain experience: results from a national survey suggest postoperative pain continues to be undermanaged*. Anaesthesia Analgesia 2003; Vol 97; pp 534–540.
11. Rocchi A, Chung F, Forte L. *Canadian survey of postsurgical pain and pain medication experiences;* Canadian Journal Of Anaesthesia 2002;Vol 49; pp1053–1056
12. S. Jochberger, V. D. Mayr, and M. W. Du, *Anaesthesia and Its Allied Disciplines in the Developing World : A Nationwide Survey of the Republic of Zambia;* 2008; Vol. 106; No. 3; pp 942-948.

13. Anita Holdcroft and Sian Jaggar, *Core Topics in Pain*; Cambridge University Press, New York, USA; 2005; pp 71 -75

14. Patel N.B. and Andreas Kopf, *Guide to Pain Management in Low-Resource Settings*, International Association for the Study of Pain, Seattle; 2010; pp 67-78

15. http://www.wongbakerfaces.org/

16. Say B, Ergün U, Ozer G, Yildirim O, Kocatürk O, Konar D, etal, *Trial of a new pain assessment tool in patients with low education: the full cup test*, International Journal Clinical Practice; Oct. 2007; Vol 61; Issue 10; pp.1692-6.

17. Li L., Liu X., and Herr K., *Postoperative Pain Intensity Assessment : A Comparison of Four Scales in Chinese Adults*; Pain Medicine; 2007; Vol 8; No 3; pp 223-234

18. Stuppy D.J., *The faces of pain scale: reliability and validity with mature adults*, Applied Nursing Research; 1998; Issue 11; pp 84–89.

19. Burgess and P. J. Armstrong, *Choice of incision and pain following gallbladder surgery*; British Journal of Surgery; July 1990; Vol. 77; pp. 746–748.

20. J. M. Proske, J. Zieren, and J. M. Müller, *Transverse versus midline incision for upper abdominal surgery*; Surgery Today; Jan. 2005; Vol. 35; No. 2; pp. 117–121.

21. T. P. Grantcharov and J. Rosenberg, *Vertical Compared with Transverse Incisions in Abdominal Surgery;* European Journal of Surgery; 2001; Vol 167; pp260–7.

22. http://country-facts.findthedata.org/q/13/2395/What-is-the-literacy-rate-in-Zambia-a-country-in-the-continent-of-Africa

23. http://www.unicef.org/infobycountry/zambia_statistics.html

24. Carey S.J., Turpin C., Smith J., Whatley J., Haddox D., *Improving Pain Management in An Acute Care Setting*, Thee Crawford Long Hospital Of Emory University experience; Orthopedic Nursing; July/August1997; Vol 16; No 4; pp 29-36

25. Joo, Eun, and Marybeth Tank, *Reliability and Validity of the Faces Pain Scale with Older Adults*, International Journal of Nursing Studies; January 2006; Vol 43; pp 447–456.

26. Ware, Jowers, Epps C.D., and Herr K., *Evaluation of the Revised Faces Pain Scale , Verbal Descriptor Scale , Numeric Rating Scale , and Iowa Pain Thermometer in Older Minority Adults*; American Society for Pain Management Nursing; September2006; Vol 7; No 3;pp117–125.

27. Taylor, L.J., Herr, K., *Pain intensity assessment: a comparison of selected pain intensity scales for use in cognitively intact and cognitively impaired African American older adults*; Pain Management Nursing; 2003; Vol.4; Issue 2; pp 87–95.
28. Kolawole IK, Fawole AA, *Postoperative pain management following caesarean section in University of Ilorin Teaching Hospital (UITH), Ilorin, Nigeria*; West African Journal of Medicine; 2003 Dec; Vol 22; Issue 4; pp 305-9
29. Ocitti EF, Adwok JA, *Post-operative management of pain following major abdominal and thoracic operations*; East African Medicine Journal; 2000 Jun; Vol 77; Issue 6; pp 299-302
30. Amata AO, Samaroo LN, Monplaisir SN, *Pain Control after Major Surgery*; East African Medical Journal 1999; Vol. 76(5); pp 269-71.
31. Hodges SC, Mulumba C, Okello M, McCormick BA, Walker IA, and Wilson IH., *Anaesthesia services in developing countries: defining the problems*; Anaesthesia 2007; Volume 62; pp 4–11.
32. Pain & Policy Studies Group. *Availability of Opioid Anal-gesics in Asia: Consumption Trends, Resources*, Recommendations. Madison, WI: University of Wisconsin Pain and Policy Studies Group /WHO Collaborating Center for Policy and Communications in Cancer Care. Prepared for17th Study Programme for Overseas Experts on Drug Abuse and Narcotics Control; Tokyo, Japan, 26 June, 2002 (Monograph).
33. De Lima L, Sweeney C, Palmer JL, Bruera E. *Potent analgesics are more expensive for patients in developing countries: a comparative study*; Journal of Pain and Palliative Care Pharmacotherapy 2004; Vol 18; pp 59–70.
34. McQuay H, Moore A, Justins D, *Treating acute pain in hospital*; British Medical Journal 1997; Vol 314: pp 1531–5.
35. Marion G, Michael S, Jeffery A et al, *Pain After Gynaecologic Surgery*; Pain Management Nursing 2000; Vol 1; pp 96-104.
36. Sinatra. R. S. et al *A comparison of Morphine, Meperidine and Oxymorphone as utilized in patient controlled analgesia following caesarean delivery*; Anaesthesiology April 1989; Vol. 70; No 4; pp 585-590
37. E. Visser, S.A Schug, *The role of Ketamine in pain management*; Biomedicine & Pharmacotherapy; 2006; Vol. 60; pp 341-348
38. Smith H.S., *Review Article: Peri-operative Intravenous Acetaminophen and NSAIDS; Pain Medicine*; 2011; Vol. 12; pp 961-981
39. Bell RF, Dahl JB, Moore RA, Kalso EA., *Review: Perioperative ketamine for acute postoperative pain*; The Cochrane Collaboration; 2010; Issue 11
40. Smallman .B.J., *Postoperative management of pain, nausea and vomiting; Surgery*; 1992; Vol. 18; pp 179-182
41. Phillips P.J., Lema L.E.K, and Camiero P.M.R., *Comparison of pethidine and Diclofenac sodium as postoperative analgesia in major elective surgical procedures*, East African Medical Journal; 1985; Vol 62; pp 666-671

42. Jørgensen H, WetterslevJ, Møiniche S, Dahl JB, *Review: Epidural local anaesthetics versus opioid-based analgesic regimens for postoperative gastrointestinal paralysis, PONV and pain after abdominal surgery*; The Cochrane Collaboration; 2008; Issue 4

43. Marc, L., Edagar, D. and Elganzouri, *A. Continuous epidural infusion for Analgesia after major abdominal operations;* Surgery. 1985; Vol 98; pp718-728.

44. Lenth, R. V. *Java Applets for Power and Sample Size [Computer software];* (2006-9); http://www.stat.uiowa.edu/~rlenth/Power.

45. Sr, B., & Tiernan, J., Transverse verses midline incisions for abdominal surgery, The Cochrane Collaboration, 2011; Review, Issue 10.

46. Ferrell BR, Eberts MT, McCaffery M, Grant M. Clinical decision making and pain. Cancer Nurs 1991; 14: pp 289-97.

47. Taylor A, Stanbury L. *A review of postoperative pain management and the Challenges*; Current Anaesthesia Critical Care 2009; 20: pp 188-94.

48. Keats, A.S., *Postoperative pain: research and treatment;* J. Clin. Dis.1968; Vol 4:pp 72-83.

8. APPENDICES

Appendix A

DATA COLLECTION SHEET : A CROSSECTIONAL STUDY OF FACTORS CONTRIBUTING TO MODERATE TO SEVERE POSTOPERATIVE PAIN AFTER A LAPAROTOMY

(Interviewer Administered Questionnaire)

PID No. __ __ __ __
Township : _____ _____
Date of Admission: ____/____/_____
Duration of anaesthesia : _____minutes
Grade of Surgeon : _____
Grade of Anaesthetist : _____
Grade of Recovery Staff :
Number of Recovery Staff :

HISTORY

1. **AGE:** _____ years
2. **SEX:** ☐ Male ☐ Female
3. **Tribe**: _____
4. **Occupation**: _____
5. [ ] Emergency [ ] Elective
6. **Which surgical specialty ?**
   [ ] General
   [ ] Urology
   [ ] Obstetrics
   [ ] Gyneacology
7. **Reason for Laparotomy/type of incision(midline or transverse)**

   _____

   _____
8. **HIV Status**: Positive ☐ Negative ☐ Unknown or refused test ☐
9. Latest CD4 (if known HIV status) ☐ Date of CD4

   _____
10. **Previous Medical History** :

Hypertension	[ ]
Diabètes Mellitus	[ ]
KidneyDisease	[ ]
Liver Disease	[ ]
Sickle Cell Disease	[ ]

Other Specify _____

11. **Previous Surgical History** : [ ] YES [ ] NO

    If Yes, Specify_____

8. **Previous Anaesthesia** : [ ] Spinal [ ]General [ ] Local

   Any complications due to Anaesthesia [ ] YES [ ] NO

   If YES, Specify _____

12. **Drug History**:HAART [ ]Past [ ]Present [ ]none

    Paracetamol [ ] Past [ ] Present [ ] none

    Diclofenac [ ]Past [ ]Present [ ]none

    Ibuprofen [ ]Past [ ]Present [ ]none

    Other, specify_____

13. **Allergies**: [ ] YES [ ] NO

    If Yes, Specify_____

14. **Social History:** Alcohol [ ] YES [ ] NO

    If Yes, What type _____

    How much _____

    How often _____

    Smoking [ ] YES [ ] NO

    If Yes, What does he smoke_____

    How much _____

    How often _____

PHYSICAL EXAMINATION ON ADMISSION

15. Weight: _____ Kg
16. Blood Pressure: _____/_____mmHg
17. Pulse: _____beats/min
18. Axillary temperature: _____^{0}C
19. Respiratory Rate:_____ breaths/min
20. Chest Examination:

    Specify _____

21. American Society of Anaesthesiologist physical status classification

    [1] A healthy patient with no systemic disease

    [2] Mild to moderate systemic disease

[3] Severe systemic disease imposing functional limitation on patient

[4] Severe systemic disease which is a constant threat to life

[5] Moribund patient who is not expected to survive with or without the operation

[6] A brainstem-dead patient whose organs are being removed for donor purposes

22. GCS on Admission:

Eyes: [4] – Opens spontaneously[3] – Opens to voice[2] –Opens to pain

[1] – Does not open

Verbal: [5] – Oriented [4]-Confused [3]-Inappropriate words

[2]- Incomprehensible sounds [1]- None

Limb Movement: [6] – Moves spontaneously [5]- Localizes pain

[4]–Withdraws to pain[3]-flexes to pain [2]- Extends to pain

[1]- No movement

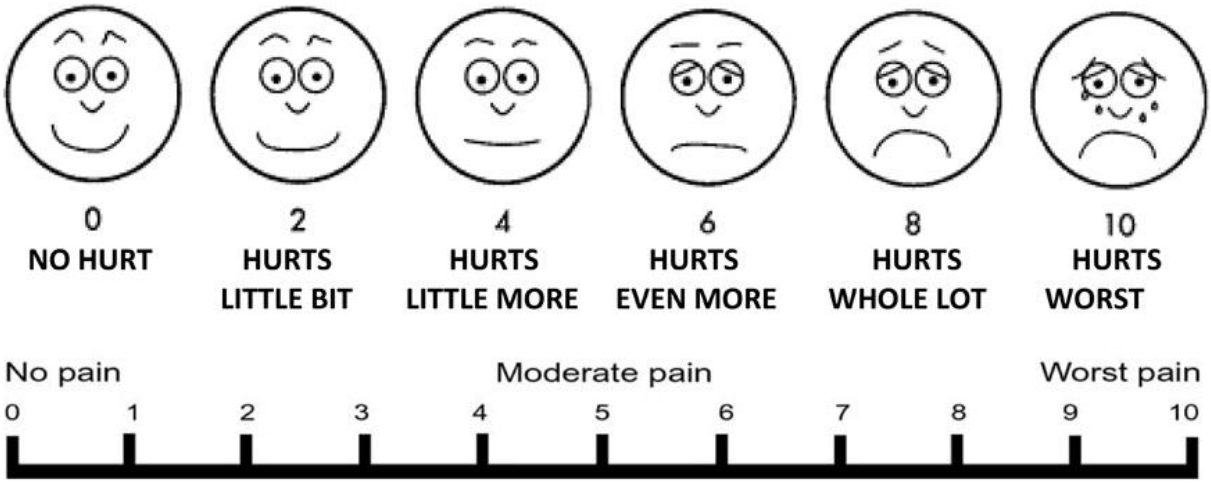
Total: _____/15

INVESTIGATIONS ALREADY DONE

23. Heamoglobin: _____g/dl
24. Platelets: _____
25. White Blood Cells: _____
26. Serum Urea: _____mmol/L
27. Serum creatinine: _____µmol/L
28. Alanine Transferase: _____
29. Aspartate Transferase: _____
30. Albumin: _____
31. Total Protien: _____

POSTOPERATIVE PAIN ASSESSMENT:

32. Blood Pressure _____ /_____mmHg
33. Pulse _____beats/min
34. Axillary temperature _____^{0}C
35. Respiratory rate_____ breath/min
36. Pain Scores: Done at 4 hrs, 6 hrs, 24 hrs, 48 hrs and 72 hrs posoperatively.



PostoperativeTime	**4 hrs**	**6 hrs**	**24 hrs**	**48 hrs**	**72 hrs**
FPS					

ANAESTHESIA NOTES:

37. Duration from end of anaesthesia to patient receiving analgesia procedure?
    _____ hrs_____Minutes
38. Vital at discharge from theatre:
    Blood Pressure_____ /_____mmHg
    Pulse _____beats/min
    Axillary temperature _____^{0}C
    Respiratory rate _____breath/min
39. Was any analgesic agent given peri-operatively?[ ]YES [ ]NO
40. If YES to above, which analgesic agent was used peri-operatively, dose, mode of administration?
    [ ] Pethidine Dose given_____ [ ]Intravenous [ ]Intramuscular
    [ ] Morphine Dose given_____ [ ]Intravenous [ ]Intramuscular
    [ ]Fentanly Dose given_____ [ ]Intravenous [ ]Intramuscular
    [ ] Tramadol Dose given_____ [ ]Intravenous [ ]Intramuscular
    [ ]Diclofenac Dose given_____ [ ]Intravenous [ ]Intramuscular
    [ ] Ketamine Dose given_____ [ ]Intravenous [ ]Intramuscular
    Othersspecify _____

41. How long before end of procedure was the last analgesic agent administered?

    _____Hrs _____Minutes

42. Was Local Infiltration used? [ ] YES [ ]NO

43. If YES to above, which agent was used? [ ]Bupivacaine [ ] Lignocaine

44. Was a regional or spinal block used? [ ] YES [ ]NO

45. If YES to the above Specify what type and agents used?

    _____

    _____

46. Where analgesic agents administered in recovery bay? [ ]Yes [ ]NO

    If YES, specify drug, dose and mode of administration _____

47. What analgesic agents where prescribed for Post Operative analgesia?

    [ ] Pethidine Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

    [ ] Morphine Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

    [ ] Paracetamol Dose _____Frequency ____ hourly [ ]Intravenous [ ]per oral

    [ ] Tramadol Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

    [ ]DiclofenacDose_____Frequency ____ hourly [ ]Intramuscular [ ]per oral

    [ ]Ibuprofen Dose _____Frequency ____ hourly [ ]per oral

    Others specify _____

48. What analgeics agents where administered during the Postoperative period? 24hrs

    [ ] Pethidine Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

    [ ] Morphine Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

    [ ] Paracetamol Dose _____Frequency ____ hourly [ ]Intravenous [ ]per oral

[ ] Tramadol Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

[ ]DiclofenacDose_____Frequency ____ hourly [ ]Intramuscular [ ]per oral

[ ]Ibuprofen Dose _____Frequency ____ hourly [ ]per oral

Others specify _____

48hr

[ ] Pethidine Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

[ ] Morphine Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

[ ] Paracetamol Dose _____Frequency ____ hourly [ ]Intravenous [ ]per oral

[ ] Tramadol Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

[ ]DiclofenacDose_____Frequency ____ hourly [ ]Intramuscular [ ]per oral

[ ]Ibuprofen Dose _____Frequency ____ hourly [ ]per oral

Others specify _____

72 hrs

[ ] Pethidine Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

[ ] Morphine Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

[ ] Paracetamol Dose _____Frequency ____ hourly [ ]Intravenous [ ]per oral

[ ] Tramadol Dose _____Frequency ____ hourly [ ]Intravenous [ ]Intramuscular

[ ]DiclofenacDose_____Frequency ____ hourly [ ]Intramuscular [ ]per oral

[ ]Ibuprofen Dose _____Frequency ____ hourly [ ]per oral

Appendix B

Information Sheet

An Observational Study Of Factors Contributing To Moderate To Severe Postoperative Pain After A Laparotomy.

Introduction

I am Dr. Patel Ushmaben, a student in the School of Medicine at the University of Zambia pursuing a degree of Master of Medicine in Anaesthesiology and Intensive Care. I kindly request your participation in the above mentioned research. This study is in partial fulfilment for the award of a Master of Medicine in Anaesthesiology and Intensive Care. Before you make up your mind whether to take part in the study or not, I would like to explain to you the purpose of the study and what is expected of you. If you agree to take part in this study, you will be asked to sign this consent form in the presence of a witness.

Nature and purpose of the study

This study is being conducted to determine factors that lead to postoperative pain during recovery from laparotomy.

Procedure of the study

If you agree to participate in this research, we will obtain information about you using a data entry sheet. Your contact details will be required. You shall be asked to take a pain assessment test and some relevant questions including your HIV status. Some peri-operative information will be obtained from your medical file/records.

Possible risks and discomforts

You will not be exposed to any risks by enrolling into the study.

Possible benefits

The information obtained in this study will help in your care and other patients who undergo this surgical procedure.

Confidentiality

All the collected is strictly confidential. Data that will be collected, analysed, and reported on will not include your name and therefore cannot be traced to you.

Consent

Your participation is strictly voluntary. You will not suffer any consequences if you decide not to participate in this study. You may also withdraw from the study at any time for any reason without consequences to you.

Thank you for considering participation in this study. If you have any questions, concerns, and clarifications, please contact Patel Ushmaben or The University of Zambia Research Ethics committee on the following addresses:

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Appendix C

Consent Form

I, _____ hereby confirm that the nature of this clinical study has been sufficiently explained to me. I am aware that my personal details including my HIV status will be kept confidential and I understand that I may voluntarily, at any point, withdraw my participation without suffering any consequences. I have been given sufficient time to ask questions and seek clarifications, and of my own free will do hereby declare my participation in this research.
I have received a signed copy of this agreement

_____	_____	_____
Name of Participant (Print)	Participant (Signature or thumbprint)	Date

_____	_____	_____
Witness (Print Name)	Witness (Signature)	Date