The peri-operative pain management of total abdominal hysterectomy patients at an academic hospital

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DECLARATION

I, *Lauren Dawn Dougall*, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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ABSTRACT

This study was undertaken to assess the performance of the peri-operative pain management and describe the patient satisfaction following elective total abdominal hysterectomy cases at Rahima Moosa Mother and Child Hospital in Johannesburg, South Africa.

The data obtained were collected utilising the questionnaire of the international pain registry PAIN-OUT, to allow for a standardised means of assessment and follow-up.

All patients who presented for this procedure during a three-month period from September to November 2015 were approached on the first post-operative day.

Patient demographics and details regarding the peri-operative interventions were collected from patient charts and a self-reported patient questionnaire was completed. The data obtained examined the personal pain experience as well as resultant functional limitations and emotional factors involved. Medication side-effects, patient opinions regarding appropriateness of their pain management, their degree of participation, whether information was offered to them and their overall satisfaction levels with care was sought.

The study included 76 patients and highlighted unacceptable acute pain levels. It revealed deficiencies in administration of analgesics on the ward and a lack of standardised protocols or collaboration between Anaesthesiology and Gynaecology in managing acute post-operative pain. Patients were not uniformly advised regarding the post-operative expectations of their pain and non-pharmacological measures were not emphasised by the treating team. Despite these deficiencies, patients reported high levels of satisfaction with the care received.

The information provided allows for a more focused quality improvement strategy to manage acute post-operative pain in this group more effectively and move toward better collaboration between departments involved in the care of patients peri-operatively.

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The Vancouver style of referencing has been utilised in this research report.

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LIST OF ABBREVIATIONS

IPO: International Pain Outcomes (Questionnaire used by PAIN-OUT)

NRS: Numerical Rating Scale

PCA: Patient-controlled analgesia

POD1: First post-operative day

POQ: Patient Outcomes Questionnaire

PQ: Process Questionnaire

RMMCH: Rahima Moosa Mother and Child Hospital

SOPs: Standard operating procedures

TAH: Total abdominal hysterectomy

TAP: Transversus abdominis plane (regional block)

UCT: University of Cape Town

WITS: The University of the Witwatersrand, Johannesburg

Chapter 1: Overview of the study

Background

Anaesthesiology is concerned with the peri-operative management of patients, involving multiple dimensions of their care, as part of a multidisciplinary team (1). An important focus of the anaesthetist is the pain management aspect of the patient's surgical procedure alongside the recognition and management of any pre-existing conditions or medication usage that would impact on the treatment of acute pain.

Acute postoperative pain is a large problem worldwide, as it is not being adequately recognised or managed appropriately. The majority of patients following an operation (between 50% to over 80%) will report unsatisfactory pain levels (2). There is a paucity of identifiable and published data that accurately highlights the extent of the problem in the South African setting, in terms of acute post-operative pain management and levels of patient satisfaction with the care offered.

Acute pain which is not adequately treated can lead to chronic debilitating pain, which can be both difficult and costly to manage, especially in resource-poor settings (3). Chronic pain may affect all aspects of a patient's life and have far-reaching consequences (4). The aim therefore, with any patient, is to manage pain well to prevent chronic pain syndromes from developing and to facilitate a speedy, uncomplicated surgical recovery to baseline functioning (5).

There are many factors which influence the perception of care received by patients (6), pain control and medication-related issues are only one small aspect thereof. Some patients in a great deal of pain may still report satisfactory treatment, whereas other aspects of care such as interpersonal relationships with the treating team may impact more significantly than the experience of pain in terms of perception of the quality of care received (7).

The most appropriate management of patients involves a biopsychosocial approach incorporating the wishes of the patient to allow for shared decision-making. A multimodal anaesthetic and analgesic regimen that confers less individual drug side-effects is preferable and should be determined according to each patient's individual characteristics and needs. The risk to benefit ratio of every modality would need to be carefully considered. The inclusion of non-pharmacological methods of pain relief should be sought wherever feasible. (8)

With the offering of better knowledge on post-operative expectations and outcomes, patients may become increasingly involved in their care, which should lead to more

favourable and acceptable outcomes of improved service delivery in the field of anaesthesiology.

Rahima Moosa Mother and Child Hospital (RMMCH) had recently been enrolled in the international PAIN-OUT registry on post-operative outcomes and pain management strategies. By collecting data on the post-operative total abdominal hysterectomy (TAH) patients with the help of chart reviews and patient-completed questionnaires, it would be possible to assess the current standard of post-operative care delivered and to define the various problems relating to acute pain management and patient satisfaction.

Analysis of the data would allow for determination of specific factors, in this setting, which may likely improve overall care perceptions and therefore allow for focused interventions and efforts to remedy the problem of acute post-operative pain in this population.

Problem statement

The treatment of pain is a basic human right, and is an integral part of striving for the highest attainable standard of health for every person, as laid out in the 1948 Universal Declaration of Human Rights, adopted by the United Nations (9). However, the incidence of acute post-operative pain is still unacceptably high and is both under-recognised and under-treated worldwide (1). Even when pain levels are actively recorded and found to be high, it appears that little was being done to act on this information and remedy the problem. Various barriers to effective pain management have been identified, both from the patient and from the medical team. Untreated pain has multiple negative implications, both for the patient and for the healthcare system as a whole (3).

The myriad of negative physiological effects associated with pain could result in complications that may be life-threatening, but invariably slows post-operative healing and will delay recovery to the patient's pre-surgical functional level. (9)

Acute pain that is poorly managed in particular at-risk patients may lengthen hospital stays and complicate cases with problems related to decreased mobilisation and compromised respiratory function, such as: deep venous thrombosis, respiratory atelectasis and infection and also additional cardiovascular strain, which may precipitate ischaemic events in those with underlying cardiovascular disease (4).

Untreated post-operative pain may often cost more to manage per case and could result in a wide variety of psychological effects for the patient. It is a recognised risk

factor for the development of chronic pain, which is difficult to manage, and often limits functional capacity and results in decreased quality of life (10).

Not only is the treatment of pain considered to be a basic human right, the way that pain is managed by the treating team has a large impact on the way in which the patient perceives the quality of healthcare that is received, and may contribute to the level of patient satisfaction, but not always in a predictable manner (11).

There was an identifiable gap in the knowledge regarding the degrees of post-operative pain experienced by patients at RMMCH, however it was thought to be high, following an international trend (12). The optimal anaesthetic and post-operative pain management techniques, which would improve acute pain levels and reduce any complications thereof, in the patients presenting for TAH at RMMCH, had not been determined. There was no formal identifiable record of the perceptions of care of patients who had undergone anaesthesia in this department nor how well they had fared post-operatively. There was also no means, at that time, of comparing these outcomes with other departments worldwide to guide practice and improve patient care.

It is believed that “we do not need to develop new techniques for treating acute pain, rather we need to learn how to provide the existing techniques more effectively.” (11)

Aim

The aim of this study was to describe the peri-operative pain management of TAH patients at RMMCH using the International PAIN-OUT Questionnaire.

Objectives

The primary objectives of this study were to describe:

- medication (sedatives and analgesia) prescribed pre-surgery;
- the intra-operative pain management;
- pain management in recovery room and

at the time of assessment on the first post-operative day (POD1):

- pain management in the ward;
- the pain intensities, using the NRS:
    - the worst pain since surgery

        - the least pain since surgery
        - the percentage of time in severe pain
- the pain interference with the following functions:
        - mobility (in and out of bed)
        - breathing and coughing
        - sleeping
- the pain interference with the following emotions:
        - anxiety
        - helplessness
- the following side-effects experienced: nausea, drowsiness, itching and dizziness
- the patients' perception of pain treatments:
        - amount of pain relief
        - adequacy of pain relief offered
        - adequacy of pain relief information offered
        - involvement in pain relief decisions
        - overall satisfaction
- any alternative pain relief methods used;
- the impact of chronic pain on pain relief.

Research assumptions

The following definitions were used in this study.

Adult patient: is a patient 18 years and older.

PAIN-OUT: "is a multi-national research project that provides a unique and user-friendly web-based information system to improve treatment of patients". (13)

International Pain Outcome (IPO) Questionnaire: was developed for use by PAIN-OUT, which includes the Process Questionnaire (PQ) and the Patient Outcomes Questionnaire (POQ). (See Appendices A and B)

The first post-operative day (POD1): The day following the day of surgery, between midnight of the day of surgery and midnight of the day thereafter (11).

Satisfaction: This definition of "satisfaction" was self-determined by the patient, as it is a subjective concept.

Demarcation of study field

Data were collected from post-operative patients undergoing elective TAH at RMMCH.

RMMCH is a provincial hospital situated in the suburb of Coronationville in Johannesburg Gauteng, located west of the Johannesburg CBD with just under 340 beds. Referrals feed in from hospitals and clinics on the West Rand of Johannesburg, namely: Leratong Hospital, Dr Yusuf Dadoo Hospital, Discovery Clinic, the Carletonville area and also further away, from centres in the neighbouring Northwest Province. (14)

RMMCH "is the main Academic Hospital of the West Rand, as well as one of the teaching hospitals of the University of the Witwatersrand", providing "tertiary level care to women and children." (15) There are two gynaecology wards at RMMCH, each with around 22 beds, shared amongst four clinical units. Each clinical unit typically has two consultant gynaecologists managing the patients admitted from their outpatient clinics and any walk-in cases alongside two registrars, undergoing specialist training, and a combination of medical officers and intern doctors.

Ethical considerations

Permission to conduct this study was obtained from the Human Research Ethics Committee (Medical) and the Postgraduate Committee of the University of the Witwatersrand. Permission for the study was also subsequently granted by the Ethics and Postgraduate Committees at the University of Cape Town.

Permission was granted from the Chief Executive Officer of RMMCH to undertake the study at the hospital (Appendix C). The nursing unit managers were informed about the study.

Furthermore, permission to make use of the PAIN-OUT questionnaires and methods had been granted in terms of RMMCH's affiliation with the international registry and data collection project and as such, the standard operating procedures (SOPs) for data collection were adhered to. (11)

Patients were approached in the ward on POD1 and invited to take part in the study. An information letter (Appendix D), providing brief details of the study was given to the relevant patients. Completion of the questionnaires by the patient and the researcher only followed after written consent (Appendix E) had been obtained for inclusion in the study.

The researchers ensured that all patients' information was collected in a completely anonymous manner (no names appeared on the questionnaires). A separate list was kept, detailing the participants' names and hospital numbers linked to the patient codes which were used on the questionnaires. Confidentiality was maintained as only the researchers and supervisors had access to the data. The data will be stored securely for a period of six years following the study.

If a patient's level of pain was found to be unsatisfactory at the time of assessment, the researcher notified the patient's treating doctor.

The study was conducted whilst adhering to the standards set out in the Declaration of Helsinki (16), updated in 2013, and the South African Good Clinical Practice Guidelines (17).

Research methodology

Research design

A descriptive, cross-sectional, contextual study design was used with retrospective elements in the questionnaires.

Study population

The study population included all women who presented for elective TAH at RMMCH.

Study sample

Consecutive, convenience sampling method was used to include all post-TAH patients in a three-month period.

Inclusion and exclusion criteria

Inclusion criteria used in this study were:

- patient equal to or older than 18 years of age
- post-operative patients, following elective TAH or vaginal hysterectomy cases converted to abdominal hysterectomy approach intra-operatively
- voluntary consent obtained by the patient to participate in the study
- able to communicate in English.

Exclusion criteria used in this study were:

- not within the prescribed time periods for data collection, on POD1 between 08:00 to 17:00. If data could not be collected by the researcher between 08:00 and 17:00 on the first post-operative day, data could not be utilised as per the PAIN-OUT SOPs.

Data collection

The study methods followed were those as set out by PAIN-OUT.

The researcher alone collected data during the three-month period at RMMCH. In order for the data collected to be of the highest possible standard, the researcher had to pass an online assessment test that described the standard operating procedures (SOPs) in great detail and ensured that adherence to the PAIN-OUT study methods was maintained. The researcher was not involved in the anaesthetic management nor did they have any clinical responsibilities in the ward.

The PAIN-OUT IPO Questionnaires were completed following instructions provided in the detailed SOPs (11).

Patients were invited to participate voluntarily in the study. An informatory cover letter was given to each individual and if patients were agreeable, they signed a written consent form.

The data were collected on a data collection sheet, the PQ and POQ sections of the IPO Questionnaire (Appendix A and B).

The questionnaires' data were entered online into the PAIN-OUT database using unique log-in details and passwords generated for each active participating site and research assistant. The data were also stored in a Microsoft Excel™ spreadsheet to allow for separate analysis of the data for the purposes of this study.

Data analysis

Data were analysed using Microsoft Excel™. Descriptive and inferential statistics were used. Categorical variables were summarised using frequencies and percentages and continuous variables using means and standard deviations or medians and inter-quartile ranges, as appropriate.

Significance of the study

Patient satisfaction with the care received is recognised as being complex and not necessarily related solely to the pain intensities experienced post-operatively. Patient expectations in light of their background knowledge about the operation, the amount of information shared with them and the perceived attitudes and actions of the treating staff play a large role. Acute post-operative pain that was not being actively and effectively managed resulted in complications and an increased burden to an already over-loaded health care system. The adequate treatment of pain should be prioritised in any healthcare setting, as it is considered a basic human right to have access to pain management and be cared for in a manner that protects dignity. In order to improve the care of patients with our current anaesthetic practices, we needed to identify and then highlight any shortcomings in our management as per the patient's report of the quality of care delivered.

The acquisition of such information from this study assisted with internal benchmarking between staff in our anaesthetic department and amongst other departments (in consultation with the gynaecologists treating the patients post-operatively). The information could be used as a quality assurance tool to ensure the application of appropriate anaesthetic protocols for this particular type of surgery and patient population in order to achieve the best possible treatment outcomes in the future (11).

The information obtained in this study, as means of quality assurance, would be used to align current practice with international centres that are leading the field in post-operative pain management and patient satisfaction outcomes with TAH procedures, utilising the PAIN-OUT external benchmarking capabilities. (13)

Validity and reliability

The valid and reliable IPO questionnaire designed by PAIN-OUT was used in this study and further measures were taken to ensure the validity of the study.

Study outline

The chapters in this research report include:

- Chapter 1: Overview of the study
- Chapter 2: Literature review
- Chapter 3: Research methodology
- Chapter 4: Results and discussion
- Chapter 5: Summary, limitations, recommendations and conclusion

Chapter 2: Literature review

Effective pain management is “a basic human right” and therefore needs more urgent attention (18). Decreasing the amount of pain experienced after a surgery aids in facilitating earlier mobilisation, faster recovery and shorter hospital stays, with subsequently lower rates of complications (9).

A description of acute post-operative pain will follow in more detail in the next section, probing its incidence, pathophysiology and the resultant problems associated with untreated post-operative pain. Some of the multiple confounding factors which may affect pain will also be highlighted, along with the current management strategies and guidelines for the treatment and prevention of acute post-operative pain.

Patient satisfaction, although difficult to consistently define or attain, is quickly becoming a measure of quality and performance in healthcare, in line with the idea that the patient is the driver of their own health and should be an active participant in decisions made by the healthcare team. Ideally, patients need to play an active role in the effective and efficient management of their post-operative pain and assist in decreasing the likelihood of the development of any complications.

Definitions

Pain

The International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (19), a concept initially proposed by Mersky in 1979 (1).

It is still, however, argued that this current definition of pain is somewhat lacking and is not accurate enough to pinpoint the multiple subjective aspects of a pain experience (20). Another definition of pain, proposed by Wright (20), attempts to avoid the problems inherent with trying to associate pain with a particular damaging stimulus, namely: “Pain is the unpleasant sensation that has evolved to motivate behaviour which avoids or minimises tissue damage, or promotes recovery”.

Margo McCaffery, considered the “godmother” of nursing care of patients in pain, stated in 1968 that “pain is what the person says it is and exists whenever he or she says it does”. (21)

Pain can be classified as being acute or chronic.

Acute pain is short-term pain with a “limited duration” and “is related to an identifiable cause (trauma, surgery, inflammation etc)”. (1, 22)

Chronic pain is pain that is continuous and long-term, persisting “after the time that healing would have been thought to have occurred in pain after trauma or surgery” (22).

Acute post-operative pain

Acute post-operative pain can be described as that pain “which is present in a surgical patient because of a pre-existing disease, the surgical procedure (associated drains, chest drains, nasogastric tubes, complications, etc.) or a combination of disease-related and procedure-related sources” (23).

Put another way, acute post-operative pain “is a complex physiological reaction to tissue injury, visceral distension, or disease. It is a manifestation of autonomic, psychological, and behavioural responses that result in patient-specific unpleasant, unwanted sensory and emotional experiences” (24) following a surgical operation.

Acute post-operative pain management includes “actions before, during, and after a procedure that are intended to reduce or eliminate post-operative pain before discharge”. (25)

For the purposes of this study, acute post-operative pain will be focused on.

Incidence

Acute post-operative pain is under-treated worldwide, despite multiple attempts at highlighting the issue and efforts to institute better practice to address this problem (12).

At least half of all post-operative patients for all types of surgical procedures report experiencing moderate to severe pain, as per the European-based PAIN-OUT project. (13)

A survey performed in the United States, spanning twenty years, revealed that only one-quarter of patients had adequate post-operative pain relief (26). A telephonic-interview based review performed in the United States in 2003 showed that nearly 80% of 250 post-operative patients were experiencing pain, 86% of these cases falling into the “moderate, severe or extreme pain” categories and with patients reporting that they experienced more pain after discharge from hospital than before (27).

The WHO publishes data on measures of health in the developing world, for example, the leading causes of death, life expectancy and mortality risks, but there

is very little or no data on the quality of health care offered or the management of acute pain worldwide. The developed centres are able to produce data from their own settings, detailing their performance in this regard and therefore, most of the data on acute pain incidence is from the United States and Europe. However, a review performed in Nigeria in 2001, demonstrated that two-thirds of patients had "moderate to unbearable pain 24hr postoperatively". (9)

There were no identifiable data describing the burden of acute post-operative pain in Africa, at the time of review. In terms of the South African setting, no literature could be identified that details the incidence, prevalence or the magnitude of the problem of acute post-operative pain in general terms, or specifically following TAH.

A study published in 2014 in the South African Journal of Anaesthesia and Analgesia (SAJAA) examined the post-operative pain levels, techniques of anaesthesia and patient satisfaction in orthopaedic surgery at a state hospital in Cape Town. Two audits took place one year apart with a period of intervention between them to improve the service offered for acute pain control (pain rounds were implemented, staff educated, the use of patient-controlled analgesia pumps increased, increasing post-operative epidural time and indwelling femoral catheters for regional analgesia following knee-replacements). These patients used the VAS to rate their pain over 48 hours following surgery and day-cases were followed up telephonically. The initial audit revealed "unacceptable" mean pain intensity levels ranging from 4 to 5.1 out of 10. Following the improved post-operative monitoring and pain management strategies, the second audit found that mean pain scores were below 4 "at every time point measurement" and "significantly lower than in audit 1 at most assessment times". Patient satisfaction with their pain control in audit 1 was 32.4% and improved to 54.9% in audit 2. (28)

Pathophysiology

"Pain is a complex interaction of sensory, emotional and behavioural factors" (1). It is the brain's central interpretation of experiences which are typically noxious or have the potential to cause injury to body tissues (19). Potential noxious influences (pressure, temperature and chemicals) are sensed by the body at the site of exposure by specialised nerve endings (nociceptors), which send signals along the nociceptive pathways to the spinal cord and the brain's higher centres to interpret and respond to the stimuli in order to limit further injury. These self-protective mechanisms are usually self-limited but can become defective and long-standing despite the removal of the harmful stimulus and develop into neuropathic pain (1), therefore "acute and chronic pain represents a continuum" (29, 30).

Acute pain, also known as nociceptive pain can be either somatic or visceral in origin (29).

There are four basic processes of pain development, starting with the perception of a noxious stimulus by the body's nervous system and relay of this information to the spinal cord and higher centres of the brain to allow an immediate reaction to limit tissue injury and then to facilitate interpretation of its precise characteristics and develop an associated appreciation of its unique quality in terms of pain, by the following steps (31):

- "Nociception and transduction", whereby nociceptors convert information about noxious stimuli at the site of injury and inflammation into electrical signals.
- "Transmission" of these electrical signals along nerves, typically the A delta and C fibres, of afferent neurons to the dorsal horn of the spinal cord and then up to the brainstem region and into the cerebral cortical higher centres.
- "Modulation" of nociceptive signals at the level of the spinal cord and brainstem, by either "amplification or dampening" of the signal and subsequent excitation or inhibition of the nociceptive signal.
- "Perception and plasticity". This is a multifactorial process whereby different parts of the brain of the reticular, limbic and somatosensory systems interact with one another once stimulated by nociceptive pathway signals and the "subjective phenomena" of pain is developed. Physiological "nociception" is converted into a subjective "pain" experience.

Nociceptors in the peripheral tissues recognise noxious stimuli and feed this information centrally. When tissue injury takes place, an "inflammatory soup" is released from the damaged tissues and surrounding blood vessels. This "inflammatory soup" contains a mixture of substances, for example: hydrogen ions, potassium ions, bradykinin, histamine, noradrenaline, serotonin, prostaglandins, substance P, leukotrienes, nerve growth factor and others (1). "Inflammation itself is painful", but pain can also "induce inflammation" with humoral mechanisms (5), therefore, the ongoing inflammatory processes need to be controlled in order to manage pain. (32)

There are two main types of neurons involved in nociception, the A delta and C fibres. The A delta fibres account for about 10% to 20% of afferent pathways and are of small diameter, "thinly myelinated" and mainly transmit signals regarding "mechanothermal stimuli"; pressure, touch and heat. The C fibres (accounting for 80 to 90% of nociceptive pathways) are larger, unmyelinated nerves that transmit a

variety of sensory modalities. These primary afferent neurons which communicate with the spinal cord interact with multiple other afferent neurons and interneurons (second-order neurons) and also have connections with descending inhibitory neurons from higher centres. (31)

Excitatory neurotransmitters for nociceptive signals at the spinal cord level include: substance P, neurokinin 1 (NK-1) and glutamate. Inhibitory signals are fed into the spinal levels from higher central sites and are mediated via the "descending inhibitory pathways", through transmitters such as: dopamine, noradrenaline, serotonin, histamine, oxytocin, acetylcholine, anti-diuretic hormone, GABA (gamma-aminobutyric acid), glycine and opioids (both endogenous and exogenous). Analgesic agents act by either blocking the activation or potentiating the inhibition, by means of these substances, at multiple various receptor sites to reduce nociceptive signal transduction. (33)

From the level of the spinal cord, ascending nociceptive pathways run in the spinothalamic tracts to the thalamus and then into the somatosensory cortex of the brain. This allows for definition of the site and type of stimulus causing pain. The spinomesencephalic tract also arises from the spinal cord and "mediates the affective and emotional component of the nociceptive stimulus" and is involved in the coordination of the autonomic components of sensory nociception. Various areas in the brain (the cingulate cortex, insula, periaqueductal gray matter, reticular formation and the prefrontal cortex) receive multiple inputs to orchestrate the autonomic and emotional outputs of pain experienced. Descending inhibitory pathways from the cortex, periaqueductal gray matter and the brainstem nuclei "modulate" signals at the level of the dorsal horn of the spinal cord to prevent or decrease transmission to higher centres. This relates to the "gate control theory" of pain signal inhibition, first proposed by Melsack and Wall in 1965, which suggested that the larger fibres (A beta fibres associated with mechanoreceptors), when activated, were effectively closing the gate to nociceptive signal transmission through the spinal cord dorsal horn to the higher brainstem and cortical centres. This explains why rubbing the skin around a painful area may alleviate the pain experienced as the pressure sensory signals (travelling in the A beta fibres) are delivered to the higher centres and can "block out" the nociceptive signals. The effects of the "descending inhibitory pathways" at the second-order neuron level were recognised by them in 1982. (32)

The autonomic nervous system (responsible for "fight-or-flight" behavioural responses) plays an important role in the pain response, principally through the effects of the sympathetic nervous system (SNS) component. In the dorsal horn of

the spinal cord, afferent nociceptive signals feed into efferent sympathetic pathways and peripherally, the SNS is contributory in creating the “inflammatory soup” by release of catecholamines and stimulates the release of other neurotransmitters and mediating local vascular tone and blood flow to the injured site to effect healing. (1)

The body also releases endogenous opioids (enkephalins and endorphins), which act on the opioid receptors at the level of the primary afferent nerves and the interneurons (second-order neurons) at the spinal cord level. (1)

Untreated pain or “unopposed nociceptor input” can lead to increased excitability of nociceptive pathways and the “altered perception” of even normal stimuli, like touch, causing allodynia (5). Allodynia is “pain due to a stimulus that does not normally provoke pain” (19). This process of “neural wind-up” is complex and poorly understood but implies that “pain will precipitate more pain” (5) and can result in the development of chronic pain syndromes which may be difficult to treat (34).

Emotion and pain

There is wide consensus (35) that a patient’s peri-operative emotional state can influence the ways in which they will interpret their pain and whether they would be able to cope with it, reinforcing the concept of subjectivity of pain and it needing a biopsychosocial approach for management (35). Anxiety, low mood, pain “catastrophising”, and coping skills of the patient will influence their experience of pain (1).

The level of pre-operative anxiety is considered closely correlated to levels of post-operative pain reported by patients as demonstrated by a repeated-measures design study (36), in 2000 undertaken by the Yale Department of Anesthesiology, which investigated a group of fifty-three “homogeneous” elective patients presenting for abdominal hysterectomy. They removed potential confounding variables by excluding all cases that had any history of chronic illness, psychiatric problems or potential malignant gynaecological conditions. The resultant patient population was considered homogeneous in terms of surgical procedure and indication and they received a standard anaesthetic. They were able to conclude that the self-reported pain experienced post-operatively in these women was unrelated to “sociodemographic” factors such as their age, stress experience and “social index” (using the Hollingshead index which includes education, occupation, and relationship status). They did however show, using multiple tools to examine the baseline “trait anxiety” and “state anxiety” levels throughout the peri-operative period, that “the effects of trait anxiety on post-operative pain are mediated through the effects of trait anxiety on pre-operative state anxiety” and subsequently that

“pre-operative state anxiety was a significant direct positive predictor of immediate post-operative pain”. It was noted by the researchers, that patients presenting for hysterectomies may have a “specific type of anxiety”, for example, younger women without children may likely have an added emotional component as their potential desires for fertility would be lost following the procedure. Therefore, it may not always be easy to predict the post-operative outcomes in terms of anxiety levels and post-operative pain experienced, particularly with patients presenting for hysterectomy. (36)

Sjöling et al (35), in 2003, performed a prospective experimental design study investigating two groups (treatment and control) each with 30 patients undergoing total knee replacement surgery. Their study gave both groups basic information on the anaesthetic, surgical and post-surgical expectations and how they would go about charting their experienced pain scores. The treatment group received additional, detailed information specifically designed to encourage their active participation in their pain management post-operatively. This information included detailed explanations for the rationale for treating post-operative pain adequately, informing patients of the complications of acute pain and the problems that would ensue if left untreated, in the hope that this would decrease peri-operative anxiety levels. They were able to show that the patients in the treatment group, who were better informed and encouraged to be actively involved in seeking additional pain treatment when necessary, were more satisfied with their care than the control group but that their pain intensity scores were not much different than the control group. The researchers believe that the treatment group may have had better pain control overall as their pain intensity assessments were discontinued much sooner (on day 3) than the control group which would suggest that they were pain-free before the controls. The researchers would stop measuring VAS scores in patients when they had reported scores of less than 4 on at least three occasions. (35)

There have been conflicting findings in the literature, as the example above demonstrates, attempting to link pre-operative anxiety with post-operative pain and the interaction of a patient’s “baseline trait anxiety” on this complicated process (36).

Involvement in the decisions regarding care post-operatively and discussion with the patient of expected post-operative pain levels and outcomes has been shown to improve patient satisfaction with care and has helped to improve overall pain management in multiple settings as rated by the patients themselves (35).

Fraenkel et al (37), in 2011, highlighted the complex interactions of individual, experienced pain with the treatment offered to and accepted by patients with chronic musculoskeletal-type pain and addressed the “pain impact” which reflected a

patient's "illness perception" (composed of factors such as "personal control and emotion", "treatment control", "timeline" and "vigilance"). It was shown that pain impact was associated with the patient's varying treatment preferences and that NRS intensity scores and functional limitations were not. This study looked at 249 patents attending a Veterans Association medical centre in the United States, particularly those enrolled with chronic, non-cancerous musculoskeletal pain. Any patients with an active substance-use problem or "mental illness" with psychosis or dementia were excluded. This study demonstrates that the pain impact, which is more complex and relevant to the patients' experience of pain than the simple recorded NRS pain scale results, will affect patients' different preferences for treatment of their chronic pain with "adaptation" over time to the effects of their pain on their lifestyles. (37)

The psychological effects of pain can contribute to the aggravation and perpetuation of the initial pain experience, leading to chronic pain (5). To recognise pain as "a deeply human experience" and not merely as "a neurologic phenomenon" may help to appreciate the emotional links to pain and suffering (21).

Complications of acute post-operative pain

Untreated pain leads to multiple potentially deleterious effects with activation of the sympathetic nervous system, which may be especially harmful in high-risk individuals, for example those with cardiac disease or limited physiological reserves (4).

Pain affects all systems of the body, to varying degrees, based on the individual characteristics of the patients, their surgery and underlying health. The "stress response" is manifested by multiple, interrelated "neuro-humoral" effects, and is typically a "catabolic state" marked by "sympathetic stimulation" and "immunosuppression". (1)

The central nervous system effects are related to a state of "hyper-stimulation" and can often result in decreased sleep and altered memory or impaired mental functioning (29). Psychological effects of untreated acute pain are numerous, potentially causing anxiety and depression alongside insomnia and a sense of "loss of control" and can lead to poorer outcomes and deceased quality of life in patients and may also contribute to the development of chronic pain (1).

The cardiovascular system would be under additional pressure as all measures of cardiac output would be challenged to increase as a result of the sympathetic nervous system reactions to painful sensations. Heart rate, blood pressure and

systemic vascular resistance increase. Myocardial oxygen demand may outstrip supply and result in ischaemia and infarction in those at risk. (29)

Respiratory complications stem from the “splinting” of the respiratory movements to limit the amount of pain associated with abdominal wall incisions and “can contribute to hypoventilation” which will lead to hypercarbia (contributing to a respiratory acidosis) and hypoxia (38). Cough ability is impaired in order to restrict pain with muscle movements, therefore secretions may not be adequately cleared from the respiratory tract post-operatively (1), leading to atelectasis of lung segments and possible infection. Lung function is decreased overall in times of post-operative recovery following abdominal surgery as there is corresponding limitation of diaphragmatic movement and subsequent decreases in the functional residual capacity and other lung volumes as a result of the effects of pain (39).

Gastrointestinal function is affected to varying degrees dependant on the actual surgical procedure but there will invariably be decreases in gastric and intestinal motility as a result of sympathetic stimulation (29).

Endocrine responses involve the release of hormones which have effects on multiple systems, and with pain, this can involve water and salt retention through the effects of anti-diuretic hormone. There is also increased release of adrenocorticotropic hormone (ACTH) and subsequently increased catecholamines and cortisol. The stress response to pain invariably results in increased circulating levels of angiotensin-II, interleukin-1, interleukin-6 and tumour necrosis factor (TNF), which play a role in altering blood flow to tissues and perpetuating inflammation by driving processes favouring a catabolic state. There is also an increased risk of deep venous thrombosis and thromboembolic phenomena resulting from multiple potential risks following surgery (immobility due to pain, dehydration, sepsis and the stress response) with activation of coagulation pathways (1).

Untreated or inadequately treated acute post-operative pain is a risk factor for developing chronic post-surgical pain, working alongside “environmental influences” and the “patient’s psychological factors” (4, 40). Crombie et al (41) found that as many as 25% of patients attending a chronic pain clinic were suffering from pain which was related to a prior surgical procedure. As many as 40% of American adults reported that they were suffering from chronic pain (from all causes), with around 20% of Australian adults and 19% of people in Denmark; highlighting the enormity of the issue (4).

Chronic post-surgical pain is becoming an increasing problem, with up to one third of patients reporting “persistent or intermittent pain one year after common surgical

procedures. The risk factors are being actively sought, with a few proposed being: “psychological factors” for example “lack of resilience” and “pain catastrophising leading to vulnerability”, any acute post-operative pain, pre-existing pain syndromes or pre-operative pain at surgical site, younger age and genetic influences, the surgical technique and incision pattern or presence of nerve injuries intra-operatively and disease recurrence at the site of surgery. (42)

Half the patients followed in a prospective study (performed in 2012 in Portugal, involving 186 women) had persistent post-surgical pain at four months after TAH, according to Pinto et al (40).

Management

The effective and timely relief of pain is “fundamental human right” as much as it is a concept of “good clinical and ethical practice” in medical care. (18, 43)

Pain management should be multifaceted and involve the use of appropriate pharmacotherapy, psychological methods, patient education and non-medicine methods and is best undertaken using a multidisciplinary-team approach (10). Multiple international guidelines exist to encourage the adequate treatment of pain, however multiple barriers at various levels exist, which limit their successful implementation.

Guidelines on acute pain management

The World Federation of Societies of Anaesthesiologists have adapted the WHO analgesic ladder and developed a “modified ladder for acute pain” which starts with stronger, intravenous opioids, Ketamine and local anaesthetic techniques and subsequently advises a step down to weaker agents, when possible, namely: oral opioids, and non-opioid analgesic agents. They advocate for the use of multimodal analgesic techniques in every patient, the prescription and provision of regular analgesia and the consideration for additional measures and repeat dosing for the treatment of breakthrough pain experienced. (9)

The IASP has set out pain management guidelines and their aim is to promote the application of such in developing countries in order to improve the treatment of pain worldwide. The gap between the “increasingly sophisticated knowledge of pain and its treatment” and the application of this knowledge is “large and widening” (18). There are IASP guidelines specifically related to treatment “wait-times” which suggest that acute pain, for example post-operative pain, should be treated immediately (44).

The American Society of Anesthesiologists (ASA) have a task force which deals specifically with the problem of acute pain. They released an updated report in 2012 following on from the original guidelines published in 2004 which examine the evidence for the use of the various multimodal techniques of administering analgesia. They also address analgesic considerations in specific subgroups, the elderly and paediatric populations. (25)

The Agency for Healthcare Research and Quality of the United States Department of Health and Human Services have published evidence-based clinical practice guidelines found in the National Guideline Clearinghouse which details the available recommended options for management of pain and gives the level of the evidence available for the relative cited options. (45)

The Australian and New Zealand College of Anaesthetists' statement on "Patients' Rights to Pain Management" address the issue by recognising "that severe unrelieved pain can have severe adverse physical and psychological effects on patients, with associated emotional, social and spiritual effects causing suffering in patients, their families and those close to them". Many other professional bodies, the world over, have released similar statements acknowledging that pain is an issue that requires more urgent attention and advocate for the implementation of guidelines for best practice in each setting, as appropriate. However, the availability of guidelines do not necessarily equate to changes in behaviour by treating healthcare workers. (18)

The South African Acute Pain Guidelines were published in 2016 which put forward the recommended strategies for dealing with acute pain in detail (1), however, no literature could be identified in the South African setting that examines the effects of implementing such guidelines.

Treatment options

The Joint Commission, formerly known as the Joint Commission on Accreditation of Healthcare Organization, is a non-profit entity in the United States that accredits healthcare organisations and programs (46). They developed their recommended "Pain Management strategies" in 2001, which "require all health care organizations to recognize that patients have a right to appropriate assessment and management of pain and that pain should be assessed in all patients" (47). Acknowledging that pain is subjective, the patient's self-report of pain is an invaluable indicator of the quality and intensity of any pain experienced (47) and should be sought wherever pain measures are made, both at rest and with activity (48).

The South African Acute Pain Guidelines (1) also acknowledge that pain is "subjective" and propose that for acute pain, pain intensity is the only measure of value to assess outcomes of management and to facilitate improved care, because the qualitative aspects of pain are only considered relevant in the setting of chronic pain management where these multiple influences are explored and dealt with. Therefore, using the Numerical Rating Scale (NRS) to qualify acute postoperative pain would be sufficient.

Measuring patients' pain intensity using scales such as the NRS may improve documentation but have failed to show improved pain outcomes as yet according to studies already done, most likely because the high pain scores by patients have not altered management or have not been acted upon (2). Not only does pain need frequent assessment, but the pain intensity scores reflecting inadequate control need to be acted upon "immediately" (1).

In 1999, an American Veterans Health Administration initiative proposed that pain be measured as "the fifth vital sign" in any patient encounter. A study by Mularski et al (49), published in 2006 examined the pain scores reported by patients and noted the management implemented in a veterans outpatient medical setting in Los Angeles, America utilising a retrospective analysis of 300 cases prior to implementation of the initiative (actively assessing pain as "the fifth vital sign") in 1999 and 300 cases afterwards. It was determined that very little had changed in terms of patient care or medication prescribed, suggesting that this additional clinical information that was highlighting inadequate pain management was essentially ignored. Fifty-two percent of patients in this study that reported pain scores above 4 out of 10 had no additional or alternative pain treatment prescribed. (49)

Similarly, a different study using retrospective reviews of a large number of files, by Narasimhaswamy et al (50), observing the effects of implementation of "pain practice standards" following the active recording of pain scores at a hospital in New Jersey showed no improvement in pain outcomes with simply increasing the number of observations or recordings (using a NRS) for pain levels.

One proposed reason for the lack of treatment shift with high reported pain scores is that patients are refusing to escalate pain management regimens when this is offered to them as demonstrated in a review (51) of one-hundred-and-forty cases at an American Veterans Association medical centre in 2010. Both medical professionals and patients can prevent the adequate management of pain if they have misconceptions about the adverse effects of medication or the potential risks of addiction (52).

There are “numerous factors” which would affect why the NRS intensity scales may not directly influence management, such as “limitations in physician training, patient-physician communication, and lack of effective therapies” beside “patient refusal to escalate care”, and this may support the idea that these simple scales “do not adequately reflect the patients’ experience of pain”. (37)

Baker (53), on behalf of the Joint Commission, in a review published in March 2017, examined the possible link between the call for increased pain vigilance and resultant over-treatment with the large problem of opioid dependence the United States is now facing. The proposed standard of assessing pain quantitatively, “as the fifth vital sign”, has now begun to fall out of favour with an observed “overreliance on opioids” and evidence that shows a trend toward oversedation and respiratory depression with increasing length of hospitalisation and poor outcomes. The ideas put forward now have moved away from a simple algorithm based on treating a pain-score, but rather emphasise the use of non-pharmacological methods of pain management and reiterate the need to individually manage pain, aware of the unique risk factors for developing addiction. (53-56)

The current trend is to classify pain as being mild, moderate or severe, particularly in terms of its interference with a patient’s activity and ability to perform in a range of daily activities.

Biological Methods

Pharmacotherapy “choices should be rational, multimodal and safe” as recommended by all published guidelines on pain management. (45)

Pharmacotherapy should ideally be “multimodal” in its approach as supported by the WHO ladder for pain management (57). Multimodal analgesia refers to the simultaneous administration of two or more agents with differing mechanisms of action (57). This typically involves the use of “simple analgesics” such as NSAIDs (Non-steroidal anti-inflammatory drugs) and Paracetamol, weak opioids (for example Codeine and Tramadol), and then stronger opioids such as Alfentanil, Fentanyl, Sufentanil, Morphine and Pethidine. Local anaesthetic agents are used regionally for blocking specific nerves or groups of nerves or as local infiltration into the surgical wound. Adjuvant therapies include the use of antidepressants and anticonvulsants, which have been found to have analgesic effects, typically with managing chronic pain. Ketamine acts by antagonising the excitatory NMDA (N-methyl-D-aspartate) receptor and works synergistically with other analgesics and may reduce the opioid requirements, although this has not been proven. Corticosteroids have a modulating effect on pain through their anti-inflammatory

effects inhibiting arachidonic acid and subsequently cyclooxygenase (COX) and the prostaglandins and leukotrienes (via the lipoxygenase pathway). (1)

Opioids are commonly used during anaesthesia to augment the pain response. They act at the opioid receptors in nociceptive pathways to inhibit signal transmission. Common adverse effects relate to their effects at other receptors and include: respiratory depression, sedation, nausea and vomiting, pruritus and constipation. Opioid tolerance and dependence may become an issue, but the (oftentimes misinformed) perceptions held by healthcare workers regarding the possibilities thereof can often lead to the under-treatment of pain as a result of withholding treatment in the fear that patients may become addicted. (1)

Psychological and social aspects of treatment

There are recognised non-medicine methods of controlling acute pain, which may be classified in terms of psychological approaches and complementary methods. Psychological approaches include the use of: information-sharing with patients, “cognitive re-framing”, relaxation, distraction, the use of music and biofeedback. Complementary methods include: massage, aromatherapy, acupuncture, therapeutic touch and transcutaneous electrical nerve stimulation. (10)

A simple discussion with a patient about the “cause and likely duration of pain” that may be experienced post-operatively will go a long way in terms of allowing patients to cope with what they are experiencing, stressing the importance of the patient as an active participant in their care (9).

Patient education and information-sharing is an often overlooked area for improvement in healthcare in our setting. Research has shown that patients who are informed about what to expect post-operatively and what amount of pain may be considered reasonable will often report experiencing less peri-operative anxiety and increased satisfaction with care (58), despite them also experiencing the same levels of pain intensity as the control group who received no information about what to expect. The inference is that those patients that were informed about the care they would be receiving were also enabled to become more involved in their pain management and to seek additional measures when they were in pain (35).

Total abdominal hysterectomy

The following section will address hysterectomy as a surgical procedure in general terms and then move on to focus specifically on the abdominal approach.

Introduction

Hysterectomy is a surgical procedure whereby the uterus is removed from a woman and may also involve the removal of the surrounding anatomy, namely: the cervix (in most cases), the fallopian tubes and the ovaries. A total, or complete, hysterectomy implies the removal of the cervix with the uterus, and a subtotal, incomplete or supracervical hysterectomy if the cervix is left in situ. A radical hysterectomy may need to be performed for cancer, and would potentially include the dissection and excision of the upper vagina, lymph tissue and the parametrium around the uterus. The approach may be abdominal: via a Pfannenstiel, vertical midline incision or laparoscopically, or it may be performed vaginally. There are factors for the gynaecologist to consider in order to determine whether or not a vaginal approach would be favoured in a particular patient. (59)

Incidence

Hysterectomy is the most common gynaecological surgery performed worldwide (60) and the second most common surgery performed in women of reproductive age, following caesarean sections (61). Estimations made from a sample analysis of the 2009 Nationwide Inpatient Sample database in America place the number of annual hysterectomies just over 490 000 with the majority (57%) performed abdominally, 23% laparoscopically, 17% vaginally and 3% by another technique (62).

There are various indications for a gynaecologist to perform a hysterectomy, the vast majority being for benign problems. Common indications are: uterine leiomyomata (most common), genital prolapse, endometriosis and precancerous or malignant conditions of the cervix, uterus or ovaries. (61)

Uterine leiomyomas or fibroids are firm, benign tumours of the myometrial smooth muscle layer, stimulated by oestrogen. Fibroids are the most common benign growth in women, present in about 30% of all women and half (40 to 50%) of women over the age of 50 years. They can result in dysmenorrhea and menorrhagia by increasing the uterine cavity surface area for menstrual bleeding (submucosal fibroids) and can become large enough to compress surrounding structures to cause pain and urinary symptoms. Multiple fibroids obstructing the uterine cavity

can lead to infertility or miscarriage if they distort the uterine cavity so much as to impede on the growth of the foetus. (63)

Ninety-percent of all hysterectomies (around 600 000 cases per year) in the United States were for benign causes in 2003 (61). The age-adjusted rate for hysterectomies in America has been calculated to be 472 per 100 000 women between 1995 and 2002 (61). One in every three women in the United States are expected to have had a hysterectomy by the age of 60 (61), as calculated by the National Centre for Health Statistics, based on the data from 2004. Seventy percent of these cases will include an oophorectomy.

Canada, with a much smaller population relative to the United States, performed around 40 000 hysterectomies between 2012 and 2013, the majority being for benign pathology, either menstrual abnormalities or fibroids. The rate varies by region in Canada between 311 per 100 000 to 512 per 100 000 according to data sourced from the Canadian Institute for Health Information. (64)

According to a journal article published in 2013 (65), the United Kingdom has a recent hysterectomy rate of around 42 per 100 000, with very different comparative figures from those reported by other countries, namely: 143 per 100 000 in the US and 108 per 100 000 in Canada. They claim that the hysterectomy rate in Germany is reported to be around 236 per 100 000 and 165 per 100 000 in Australia. (65)

In South Africa there were no identifiable data in the literature regarding the number of annual hysterectomies performed nor any information detailing the indications for this procedure in our setting. No data could be identified that detailed the incidence of acute postoperative pain following TAH.

Pain impact with differing surgical methods

Hysterectomies may be open or laparoscopic, depending on the surgeon's preference and expertise. A laparotomy (open) approach would require a post-operative recovery period of around 4-6 weeks, potentially longer if there are complications such as wound infection, as there has been a significant incision through abdominal muscle layers (38). The surgical incision, tissue dissection, diathermy (electrosurgical cautery) burns, tissue retraction and "packing of bowel" to move it away from the surgical field all contribute to tissue injury, inflammation and pain following hysterectomy (60).

Minimally invasive approaches, utilising laparoscopy, enable quicker recovery times and therefore shorter hospital stays and decreased complications as patients may mobilise more freely with less restrictive pain, earlier on (60). Vaginal or

laparoscopic approaches may need to be converted to abdominal or open routes if there are difficulties encountered with adhesions from previous intra-abdominal surgery or a uterus too large to remove vaginally (60). A minimally-invasive surgical approach is favourable to limit the injury to tissues and resultant inflammation (5).

The pain experienced following a hysterectomy would depend on the structures dissected during the surgical procedure, either via the abdominal or vaginal route. An anterior abdominal wall incision would pass through various layers, superficial to deep, they are: the skin, connective tissue covering the muscles composed of fascial layers (Camper's fascia which is superficial and fatty and Scarpa's fascia which is deeper and fibrous), the muscles (rectus abdominis in the midline, external oblique, internal oblique and transversus abdominis layers beneath and the pyramidalis muscle, which is absent variably in about 20% of people) with the transversalis fascia below the muscles, abutting the peritoneum (parietal and visceral layers). The female reproductive organs are situated below the reflections of the peritoneum (subperitoneal) in the pelvic cavity. (66)

The sensory innervation to the structures of the anterolateral abdominal wall come from the anterior rami of the T7 to L1 spinal nerves which form the intercostal nerves (from T7 to T11), the subcostal nerve (T12) and the iliohypogastric and ilioinguinal nerves (L1). The incision made for an abdominal hysterectomy would typically involve the dermatomes below the umbilicus (T10 to L1). The anterior divisions of T7 to T11 enter the abdominal wall between the internal oblique and transversus abdominis muscles, where they run anteriorly to emerge through the rectus abdominis muscles on either side of the midline to terminate as the anterior cutaneous branches supplying the skin and subcutaneous tissues of the anterior abdomen. These nerves travelling from the spinal cord to the anterior abdominal wall on either side will give rise to a branch (the lateral cutaneous branch) midway, laterally through the internal oblique and external oblique muscle layers to provide innervation to muscles and skin of the lateral wall of the abdomen via the anterior and posterior branches arising from the lateral cutaneous branch. The anterior branch of T12 (subcostal nerve) communicates with the iliohypogastric nerve (L1) to supply the pyramidalis muscle, if present. The hypogastric nerve (L1) supplies the hypogastric region below the umbilicus anteriorly after branching into lateral and anterior cutaneous branches near the iliac crest. The ilioinguinal nerve (also derived from L1 spinal rami) communicates with the iliohypogastric nerve near the iliac crest and supplies the upper and medial thigh and gives sensation to part of the external genitalia. (66)

Therefore, the larger the incision, the greater the injury to the tissues with ensuing inflammation and greater pain experienced post-operatively. Patients who had vertical midline incisions for gynaecological procedures reported the highest pain scores in a study by Chee Seong Tan et al (67) examining the amount of Fentanyl required to control post-operative pain levels utilising a Fentanyl PCA (67). The study enrolled 94 patients post-gynaecological laparotomy and investigated the relative usage of patient-controlled analgesia to determine which surgical factors were associated with the most post-operative pain. The smaller, multiple entry points necessary for laparoscopic techniques offer the advantage of decreased abdominal incisional pain and resultant negative effects thereof (38). The surgical manipulation and excision of the reproductive organs within the pelvic cavity will usually produce a dull pain of visceral origin from the sensory innervation of these structures and surrounding anatomy. (63)

Different anaesthesia for TAH addressing pain

Typical anaesthetic regimens for hysterectomies would involve the use of a general anaesthetic with complete muscle relaxation to allow adequate surgical access. A “multimodal”, “pre-emptive” analgesic approach would be practiced tailored to each patient’s ideal body weight and calculated needs. Pre-existing medical conditions could influence the medication used, for example, patients with a history of peptic ulcer disease or renal dysfunction should not receive NSAIDs. If a multimodal approach is adopted, the opioid requirements to control pain both intra-operatively and post-operatively will be reduced, thereby limiting the potential multiple adverse effects associated with these agents and utilising local anaesthetic techniques will decrease opioid requirements even further. (45)

Local anaesthetic agents infiltrated into the wound at the time of surgery will alleviate some of the pain experienced at the skin incision, subcutaneous fat and connective tissue in the areas of drug deposition, however this effect is short-lived (60). A regional procedure such as a transversus abdominis plane (TAP) block would offer complete anaesthesia and then some degree of analgesia until the drug wears off (longer with Bupivacaine than with Lignocaine) on the side of the block for the areas supplied by the spinal nerves targeted. For an abdominal hysterectomy, bilateral TAP blocks would cover the skin, subcutaneous tissue and muscle layers down to the level of the parietal peritoneum. This would offer adequate cover for the incisional pain and allow early mobilisation, increased comfort and better respiratory function post-operatively. (1)

TAP blocks performed for hysterectomy cases showed improved post-operative pain for the first 24 hours, at rest and with activity, compared with no block in a meta-analysis review (68) undertaken in 2013. The opioid requirements (and therefore the extrapolated pain levels) were similar in both groups by 48 hours post-operatively. (68)

Different settings utilise alternate anaesthetic techniques to those considered routine in the South African setting (69). It is not uncommon for hysterectomy cases to be performed under spinal anaesthetic or with an epidural for pain management. The neuraxial block can be the only anaesthetic method or it may be used in combination with a general anaesthetic. A Danish study, (69) exploring the possible risk factors for the development of chronic pelvic pain at one year following hysterectomy found that those cases performed under spinal compared with general anaesthesia had lower rates of chronic pain. An “open, prospective, randomised, controlled multicentre study” performed by Borendal Wodlin et al (70) in 2010, which included 162 women presenting for elective hysterectomy for benign causes, compared general anaesthesia to spinal anaesthesia for hysterectomy cases with the aim of achieving sooner discharge from hospital post-operatively. They found no significant difference in length of hospital stay between the two groups with these methods (70).

Spinal anaesthesia with intrathecal Morphine, as a method utilised for hysterectomies, frequently had increased post-operative nausea, vomiting and pruritus. Neuraxial techniques may lower pain intensity ratings post-operatively, but if this is associated with increasing drug adverse effects then patient satisfaction is not necessarily achieved. (71)

Patient-controlled anaesthesia (PCA) pumps can be given to patients post-operatively for use in the initial recovery period in the recovery room and the ward if the nursing staff are familiar with its use. Usually the PCA pump will be filled with Morphine (1 milligram per millilitre of solution) with a delivery of 1 mg with each press of the button or lever by the patient. The pump typically has a lockout time of seven minutes. There are guidelines to suggest a recommended framework for using the PCA pump and detailing when it would be appropriate to give additional boluses or increase the dosages given (1). If a patient is found to require at least three to four opioid medication doses for pain in the first 24 hours post-operatively, they may benefit from a PCA pump (5).

The PAIN-OUT database

Studies have shown that clinical data registries can be useful tools “to improve knowledge and quality of clinical care in many fields of medicine” (72). PAIN-OUT is the first of its kind, a “comprehensive, multinational registry in pain medicine” (72).

Background

PAIN-OUT is an international data registry and research project, that was initially funded by the European Union, aimed at improving post-operative pain management (13). Using a standardised procedure and questionnaires, information is collected from patients describing aspects of their post-operative pain and satisfaction levels and collates relevant basic clinical data which is then entered into an online database or registry to allow analysis and feedback of these outcomes to each site and can track changes over time, thereby serving as a means of internal quality assurance, or to compare outcomes with other sites and act as a tool for benchmarking each hospital’s practice (72).

Over 200 hospitals are involved with the PAIN-OUT registry and combined with the German equivalent (QUIPS), which is a partner of the project, over 300 000 sets of patient data had already been collected worldwide by 2012. By the end of 2013, 40 000 patient data sets were collected from at least 60 PAIN-OUT sites. (13)

An interested hospital applies for admission into the data collection registry for their post-operative patients and if approved by the hospital’s ethics committee, they would then proceed to pay PAIN-OUT an annual fee of 1500 Euros and begin the training for data collection to be standardised. The PAIN-OUT initiative was funded by the European Commission’s 7th Framework Programme between 2009 and 2012. It is currently (since 2013) being continued independently and supported by the fees paid by participating sites (17 participants from 11 countries) and is supported by the IASP, the European Society of Anaesthesiology and the German QUIPS project, which has run for over six years in over 100 centres and has established the “feedback and benchmarking facilities” which are used by PAIN-OUT. (11)

The aim of PAIN-OUT “is to develop and to validate a system for measurement and feedback of outcome quality and support of decision making”. Their overall goal “is to improve clinical care of patients with postoperative pain, in developed as well as in developing countries”. (13)

The PAIN-OUT data collection involves the completion of two documents or questionnaires, namely the Process Questionnaire (PQ), Appendix A, and the Patient Outcomes questionnaire (POQ), Appendix B.

If a patient consents and is eligible to be included in the data collection (i.e. case from desired study population, consenting age, able to communicate in English although not necessarily literate and with normal mental status) they will be given the Patient Outcomes Questionnaire (POQ) to complete whilst the researcher completes the Process Questionnaire (PQ).

The POQ is a four page document with an explanatory cover page inviting the patient to be included in the study. A separate consent document has been devised by PAIN OUT for use in the South African setting for the purposes of this study and ongoing data collection.

The POQ has 13 questions investigating the post-operative aspects of the patient's perception of the care received. Specifically, it looks at the post-operative pain experienced, both the worst and least pain scores using a NRS (0-10) and the percentage of time spent in "severe pain" since the operation. It explores how the pain may have interfered with mobility, deep breathing or coughing and sleeping and whether or not there is an emotional component playing a role. The questionnaire will attempt to identify any side-effects of pain medication received (particularly opioids) by evaluating the severity of symptoms such as: nausea, drowsiness, itching and dizziness. There are questions relating to the amount of pain relief received with treatments, whether the patient would have preferred more pain treatment and whether or not they were informed about or included in the treatment options available to them. (13)

There is an overall satisfaction rating scale for the post-operative pain management from 0-10 that the patients would also be asked to complete. The last section explores the use of "non-medicine methods" of pain relief and also attempts to establish whether the patient suffers from any chronic pain (more than three months' duration by their definition) or is taking any chronic pain therapy, which may have an impact on the post-operative pain management and subsequent interpretation of the data. (13)

The PAIN-OUT system further utilises an eleven-page Process Questionnaire (PQ) which is completed by the researcher collecting the data, without input from the patient. This information is extracted from the hospital records only as per the PAIN-OUT standard operating procedures. The PQ contains information regarding the study inclusion criteria, the demographic data of the patient, their past medical

history and the anaesthetic plan carried out. There are detailed sections describing the exact medications given pre-operatively, intra-operatively and post-operatively (both in the recovery room and in the ward) as well as procedural information and ICD-9 coding for the exact surgery performed (13).

Validation and reliability of PAIN-OUT methods

The questionnaires used by PAIN-OUT (the PQ and POQ together are known as the International Pain Outcomes or IPO questionnaire (72)) have been adapted and modified from the original American Pain Society Patient Outcome Questionnaire (APS-POQ) which has been revised from the initial American Pain Society (APS) quality improvement questionnaire and has been tested and validated previously in various studies and shown to be "an instrument with satisfactory psychometric properties" (8). The decision to use the APS-POQ-R (Revised) was made by the 17 EU-funded PAIN-OUT members in 2010, as this questionnaire most reflected the items considered to be of value when assessing pain post-operatively (72, 73). The validation of the IPO outside of Europe is underway (72).

The assessment of pain using patients' self-reported measures with the Numerical Rating Scale (NRS) are routinely used as direct pain measurement tools in clinical practice and research (74). These scales typically record the pain intensity experienced, not other aspects such as the pain's quality or the functional limitations caused by it or any emotional interplay (37). It is widely acknowledged (74) that pain is "multidimensional", although it is still the norm that it be represented using a single rating scale like the NRS. There are many other tools available, some include the VAS (Visual Analogue Scale), the verbal rating scale or the graphic Faces Pain Scale. They all have acknowledged limitations, some of which are discussed below, but they allow for a means of comparing pain amongst patients and as tools to assess responses to the interventions offered for pain experienced in each case individually.

The PAIN-OUT questionnaire utilises the 11-point NRS pain scale (points 0-10) with the words "no pain" at point zero and "worst pain possible" at 10 and requires that the patient attribute a point on the scale to the level of pain experienced for each measurement in the specific questions. A score between 0 - 2 out of 10 may be considered to denote "no pain", 3 - 5 out of 10 equating with "mild pain", 6 - 8 out of 10 reflecting "moderate pain" and 8 - 10 "severe pain" (1). Williams et al (74) explored the potential idiosyncratic meanings hidden in these simple rating scales with a group of 78 chronic pain patients in London, and found that these patients preferred the NRS to the VAS, and more specifically, the 0-10 NRS as opposed to

the 0-100 NRS or the 0-20 NRS when given the choice. Interestingly, they also found repeated instances of these chronic pain patients interpreting the NRS in their own way, for example, taking the 0 point as meaning their baseline “everyday pain” or “manageable pain” level instead of “no pain”, as intended. This may have implications for standardised pain monitoring, perhaps less so when one is monitoring acute pain scores.

In 2006 Jowers Ware et al (75), in Georgia USA, found that these commonly used pain rating scales could be used in older adults (over 60 years), with or without cognitive impairment. Cognitively intact older adults (Mini-mental State Examination score > 24 out of 30) preferred the use of the NRS. These researchers, wanting to assess these scoring tools in cognitively-impaired individuals, had a study sample of patients with an average MMSE score of 23, ranging from 10 to 30 with a standard deviation of 5.4; 18% of patients had mild impairment (MMSE score of 19-23), 22% had moderate impairment (score of 11-18) and 1% had severe impairment in a sample of 68 patients. Thirty-two percent of their patients had completed high school or college (75).

Interestingly, the group with cognitive impairment reported more pain than the intact group. They were also able to show that these patients had stable memory recall, two weeks later, of a remembered painful event which was initially reported on and scored. The researchers propose that these pain scales are valid and reliable for use in older, cognitively-impaired minority adults suggesting that this group may be particularly vulnerable to the under-treatment of pain, either because pain scores may not be actively sought on the basis of the false belief that self-reporting would be inconsistent and inaccurate, or their management may simply be suboptimal as a result of the medical team’s fear of overdosing patients in this higher-risk group. (76)

A similar study by the same researcher, Jowers et al (77), in 2003, focused on the experience of a specific minority subgroup of cognitively-impaired older African-American patients and their expression of pain utilising these tools, and had similar findings but noted that “cultural and linguistic differences (…) may interfere with appropriate assessment and choice of scales.”

Application of PAIN-OUT as a study resource

The data collected can be used to define the magnitude of the problem of acute post-operative pain and then to track the progress made in the anaesthetic department to remedy this. The data will serve as an internal measure of quality and current service delivery standards with feedback from patients regarding their satisfaction levels. The study will allow the department to analyse current practice

pre-operatively, intra-operatively and post-operatively and identify areas needing improvement or a change in practice to deliver the best possible care and to reduce the problem of acute post-operative pain and its subsequent complications.

A study examining the usefulness of the additional questions added to the APS-POQ-R (Revised) in 1998 found that there was no significant difference between the severity of pain experienced at the time of assessment and the maximal post-operative pain experienced in the "satisfied" versus the "dissatisfied" patient groups. They did however find a difference in the average pain experienced over the preceding 24 hours between the groups, although not by very much. The dissatisfied group reported a calculated mean pain score of 9.2 out of 10, compared to the satisfied group which rated theirs around 8.07 (78), still at an unacceptably high level.

A recent study (79) also demonstrated that there was "no correlation between level of pain control and patient satisfaction" and suggested that a reported level of patient satisfaction be sought alongside pain intensity scores to obtain a clearer picture of outcomes in a quality audit of the care offered in pain management.

No literature could be identified in our setting in gynaecological post-operative patients to determine whether the pain intensity levels experienced were indeed related to post-operative patients' satisfaction ratings or not, or what the current levels of satisfaction are.

The perception that patients with high levels of post-operative pain may simply prefer additional doses or a change in treatment may not be true. Patients will often refuse additional treatment offered, despite their discomfort, for various reasons. They may be fearful of adverse effects or the potential risk for addiction of the medication used (78). Studies have demonstrated that patients believe that some level of post-operative pain is expected and acceptable, especially if this has been discussed with them by the treating team, and their satisfaction may be related more to the expected pattern of pain experienced with a "peak and trough" phenomena before the next analgesic dose is due for administration with "as-needed dosing", as opposed to the actual intensity levels (7).

An American study in 1998 by McNeill et al (78) utilising the revised APS-POQ as a template for a cross-sectional survey of post-operative outcomes and patients with cancer-related pain found that younger patients were more likely to request additional pain treatment, as well as those who experienced higher pain intensity scores and had experienced more functional limitation as a result of their pain, for example, being unable to sleep. They also found that they were unable to link the

various beliefs about pain management held by patients with the type of patient that would request or accept any additional pain medication offered. The study found that, despite receiving analgesic medication as per protocol, 40% of the 157 patients reported that they were still in pain (78).

A large study (around 5000 participants in both phases) proving the efficacy and utility of the PAIN-OUT International Pain Outcomes questionnaire (which includes the PQ and POQ which will be used in this study) after translation into multiple European languages (72), additionally demonstrated that 16.9% of these patients "would have wished for more pain treatment than they received".

Patient satisfaction is quickly becoming one of the more important measures of the quality of medical care delivered, especially in the field of Anaesthesia (6).

Patient satisfaction is difficult to predict as the factors associated with it vary among population groups, and with individual patient characteristics and beliefs. The issues surrounding patient satisfaction are "numerous and complex" (78), and one may find that patients are satisfied despite high pain intensity scores (7).

One proposed reason for this, as set out by the American Pain Society, is that the "caring attitude of the staff' may play a large role in the satisfaction reported by patients suffering from under-treated pain (78).

A significant sample containing 16 868 patients, collated from reviewed findings of the PAIN-OUT study in 42 centres in 11 European countries, as well as Israel, United States and Malaysia in 2013 by Schwenkglenks et al (80) found consistent findings across countries and centres, demonstrating that satisfaction with postoperative pain treatment is "associated with the patient's actual pain experience, but more strongly with impressions of improvement and appropriateness of care". They found improved satisfaction in cases with better pain relief and increased involvement in decision-making about care. (80)

A large study, using 10 811 patient cases interviewed post-operatively, performed in 2000 in Australia by Myles et al (81) demonstrated that the vast majority (96.8%) were satisfied with the care received, when interviewed on the first post-operative day. They attempted to identify which factors would result in patient dissatisfaction, in an effort to prevent this undesirable outcome. The presence of intra-operative awareness (odds ratio of 54.9) was the clear leading cause of dissatisfaction, followed by severe nausea and vomiting (odds ratio 4.09), moderate or severe post-operative pain (odds ratio 3.94) and finally, post-operative complications (odds ratio 2.04). Therefore, effect of acute severe pain may play a smaller-than-expected role in satisfaction ratings. (81)

Patients who receive information about their hospital stay, surgery and analgesic plan and feel as though they are involved in their management will often report better satisfaction overall compared with those that do not (82). This is in line with the recommendations by The Joint Commission as set out in their guidelines for pain management (83), which encourages the concept of patient management involving discussions with the patient that "promote education tailored to the patient's needs, and address underlying cultural and social attitudes impeding pain management" (83). Offering the patient a "clear plan for analgesia will improve satisfaction, even though pain is not completely avoided", this incorporates a balanced biopsychosocial approach (5).

It may be of benefit to institute "acute pain teams" in hospitals to address the problem of post-operative pain and direct attention to "continuous" monitoring and adequate, early treatment of pain whilst also striving for the ongoing education of both staff and patients regarding the benefits of and options for analgesia. (84)

The use of databases such as that belonging to PAIN-OUT may prove invaluable in highlighting the seemingly inapparent issue of untreated and potentially devastating acute post-operative pain, consequently demanding that greater action be taken to improve the current service delivery standards by the efficient and effective application of available techniques in order to offer our patients better care.

Chapter 3: Research methodology

Study design

The study design determines the way in which data would be collected, collated, analysed and interpreted and therefore, how it is presented and understood.

A descriptive, cross-sectional, contextual study design was used with retrospective elements to the questionnaires.

Descriptive study designs are used when there is insufficient information in the existing literature regarding the study population or the variable of interest, particularly when an experimental approach would be difficult or unethical. A descriptive study aims to describe a variable in its "natural setting" without influencing the course or context of events (85). This study is descriptive as it described the pain experience of patients following total abdominal hysterectomy at RMMCH.

A retrospective study examines previous events or circumstances to attempt to draw conclusions about the various outcomes observed at the time of enrollment (85). A retrospective study design was utilised here as the patients' medical records were examined and a set of questionnaires were completed by both the researcher and patients at the time of their enrolment in the study, drawing back on events over the preceding day of surgery.

A contextual study explores characteristics from a population in a specific social and environmental setting, with unique traits (86). This study only focused on the experiences of patients following TAH at RMMCH and is therefore contextual.

Study population

The study population included all women presenting for elective TAH at RMMCH.

Sample method

A non-probability method of consecutive convenience sampling was used to select patients to be included in this study's sample, as every patient who underwent a TAH at RMMCH in a three-month period was approached post-operatively. Convenience sampling is also referred to as "accidental" or "availability" sampling, and as such is considered a weaker method of acquiring cases as it limits the ability to the control bias over which cases are included or excluded by chance. Consecutive convenience sampling however is considered a slightly stronger form

of sampling, as all of the patients in the accessible population over a specific time period are included. (85)

Sample size

The sample size was realised by the number of patients recruited during a three-month period of the researcher's rotation at RMMCH.

Inclusion and exclusion criteria

Inclusion criteria used in this study were:

- patient equal to or older than 18 years of age
- post-operative patients, following elective TAH or vaginal hysterectomy cases converted to abdominal hysterectomy approach intra-operatively
- voluntary consent obtained by the patient to participate in the study
- able to communicate in English.

Exclusion criteria used in this study were:

- not within the prescribed time periods for data collection, on POD1 between 08:00 to 17:00

Data collection

The study methods that were followed were those according to PAIN-OUT.

The researcher alone collected all the data during the three-month period at RMMCH. In order for the data collected to be of the highest possible standard, the researcher had to pass an online assessment test that described the standard operating procedures (SOPs) in great detail and ensured that adherence to the PAIN-OUT study methods was maintained. The researcher was not involved in the anaesthetic management, nor did they have any clinical responsibilities with these patients in the wards.

The PAIN-OUT IPO questionnaire was accompanied by detailed SOPs (11).

- Patients on POD1 post-TAH were approached between 08:00 and 17:00 to ensure uniformity, provided that they had been in the wards for at least six hours (since arriving from theatre).
- If the patient did not meet the criteria for inclusion, or if refused study participation, the patient was excluded at this stage. However, the

demographic data collected thus far was still added to the online database to gauge the extent of “attrition” of datasets during the study.

- The PQ and POQ were completed at the same time in order to be able to associate the interventions and outcomes temporally.
- The patient needed to complete the POQ independently, without assistance from other staff, family or friends. If the patient was otherwise consenting, but unable to physically complete the questionnaire themselves, and understood English, for example: illiterate, was too ill or too weak, they were able to request assistance from the researcher to perform an interview following precise guidelines and instructions. If an interview was conducted, this was recorded, with the reasons, on the questionnaire. Once the questionnaire had been completed, the researcher would ensure that all the questions were answered. If some of the questions were left blank, the researcher could offer assistance for completion, which would simply involve the repetition of the question without additional explanation, but if it remained unclear, the question would be left blank and was entered as “unanswered” on the online database.
- The questionnaire had three options for entering data: “Yes” denoting that the information was available and accessible from the file, “No” if there was missing data in a section of the patient’s file typically used to record this data, and “Not possible to obtain the information” was selected when there was no section of the hospital file found that would be used to record the specific information sought by the questionnaire. The patient was not asked to provide missing information.
- The surgical procedure was recorded using ICD-9 codes, this study looked at patients undergoing TAH only and therefore reflected the same coding for all cases.

Patients were invited to participate voluntarily in the study. An informatory cover letter was given to each patient and if they were agreeable, they would sign a written consent form documenting this.

The following data was collected on a data collection sheet (Appendix A and B).

- demographics (age, weight, height, nationality, country of birth, co-morbidities, type of anaesthesia, duration of surgery)
- medication (sedatives and analgesia) prescribed pre-surgery
- the intra-operative pain management

- pain management in recovery room
- pain management in the ward
- the pain intensities, using the NRS:
    - the worst pain since surgery
    - the least pain since surgery
    - the percentage of time in severe pain
- the pain interference with the following functions:
    - mobility (in and out of bed)
    - breathing and coughing
    - sleeping
- the pain interference with the following emotions:
    - anxiety
    - helplessness
- side-effects experienced (nausea, drowsiness, itching and dizziness)
- the patients' perception of pain treatments:
    - amount of pain relief
    - adequacy of pain relief offered
    - adequacy of pain relief information offered
    - involvement in pain relief decisions
    - overall satisfaction
- any alternative pain relief methods used;
- the impact of chronic pain on pain relief.

The questionnaires' data were entered online into the PAIN-OUT database using unique log-in details and passwords generated for each active participating site and research assistant. The data were additionally entered into a Microsoft Excel™ spreadsheet to allow for analysis of the data separately.

Data analysis

Data were analysed using Microsoft Excel™. Descriptive and inferential statistics were used. Categorical variables were summarised using frequencies and percentages and continuous variables using means and standard deviations or medians and inter-quartile ranges, as appropriate. Comparisons were made between groups, if possible, using the appropriate statistics depending on the number of groups involved in the analysis and the distribution of the data.

Chapter 4: Results

Information was collected from a total of 76 patients during a three-month period, starting at the beginning of September through to the end of November 2015. A total of 87 patients who were undergoing elective TAH cases, performed over 44 elective surgical slates, were approached. At RMMCH, four potential elective gynaecology slates are booked each week (Monday, Tuesday, Thursday and Friday). During the study period, only five days' worth of elective slates had no TAH cases booked and one day was a public holiday, where no data could be obtained. The gynaecologists book vaginal hysterectomies and other gynaecological procedures on these slates as well, however, one still sees a high rate of TAH cases being performed– given the gynaecology registrar training requirements. This frequency would be typical for this secondary-level hospital site. Eleven patients did not meet the inclusion criteria. Four patients refused participation in the study; two patients were not willing to participate - without wanting to give any reasons. Two declined participation due to their own estimation of high levels of post-operative pain and discomfort on the ward, requiring intervention and (as per the PAIN-OUT SOPs) were excluded on the basis of "too much pain experienced" - which was appropriately addressed in each case. Seven patients were not included as they were unable to communicate in the language of the questionnaire - either unable to read, write or speak English adequately. Strict inclusion criteria had to be met in order to complete the Process (PQ) and Patient- Outcomes Questionnaires (POQ), following signed informed consent by the patient.

Participant demographics

The demographics of the study patients is shown in Table 4.1.

Table 4.1 Patient demographics

Demographic	Mean (Standard Deviation)	Median (Interquartile Range)
Age (years)	46.14 (8.82)	
Weight (kilograms)	76.76 (15.55)	
Surgical duration (hours)		1.89 (1.52 – 2.54)
Time on ward post-op (hours)		22.46 (20.46 – 25.04)

Table 4.1 Patient demographics (continued)	
Demographic	**Number (Percentage)**
Nationality:	
South African	66 (86)
Other	8 (10)
Not recorded	2 (2)
Co-morbidities:	
Nil recorded illness	24 (31)
Asthma	4 (5)
Chronic Obstructive Airways Disease	1 (1)
Chronic Kidney Disease	1 (1)
Diabetes Mellitus	5 (6)
Human Immunodeficiency Virus	17 (22)
Hypertension	21 (27)
Obstructive Sleep Apnoea	1 (1)
Peptic Ulcer Disease	5 (6)
Rheumatoid Arthritis	1 (1)
	Number (Percentage)
Indications for hysterectomy:	
Not recorded in file at time of review	56 (73)
Abnormal uterine bleeding	1 (1)
Atypical endometrial hyperplasia	1 (1)
High-grade cervical changes	4 (5)
Micro-invasion of Squamous Cell Carcinoma	1 (1)
Multi-fibroid uterus	12 (15)
Persistent low-grade cervical changes	1 (1)

The average age of the sample population was 46.14 years (SD 8.82), ages ranged from 31 to 80 years.

The majority of the patients were South African. Two patients (2%) had no recorded nationality in their files and due to PAIN-OUT Standard Operating Procedures this could not be ascertained by direct questioning. Countries of birth were not reliably recorded.

Surgical duration varied greatly. The quickest recorded surgical time was 30 minutes while the longest case was 4 hours and 55 minutes. Median surgical duration was 1.89 hours (IQR 1.52 to 2.54 hours).

Medication prescribed pre-operatively

Seventeen of the patients received sedation pre-operatively. Twelve patients were given intravenous Midazolam prior to induction by the anaesthesiologist (exact timing not clearly indicated in every case), either 1 mg intravenously (92% of these cases) or 2 mg intravenously (8%). The remaining five cases received oral sedative pre-medication, usually the night before surgery: Midazolam 7.5 mg (one case), Diazepam 5 mg (two cases) or Diazepam 10 mg (two cases). One patient was prescribed both Diazepam 10 mg orally and Lorazepam 4 mg orally pre-operatively for sedation and anxiolysis. No patients received any additional relevant non-opioid or opioid pre-medication prior to their TAH. [Table 4.2]

Table 4.2 Medication prescribed pre-operatively by anaesthetist

Premedication	Number of patients (Percentage)
Intravenous Midazolam	12 (15)
Oral Midazolam	1 (1)
Oral Diazepam	4 (5)
Oral Lorazepam	1 (1)

Anaesthetic technique

Intra-operative general anaesthetic techniques varied slightly between anaesthesiologists. The majority of cases had intravenous inductions, with Propofol and inhalational maintenance with Sevoflurane. Eleven cases were anaesthetised using target-controlled infusions (TCIs) or intravenous anaesthetics, with Propofol and Remifentanil. [Table 4.3]

Table 4.3 Choice of anaesthetic

Anaesthetic maintenance	Number of patients (Percentage)
Intravenous Target-Controlled Infusions (TCIs)	11 (14)
Volatile anaesthetic (Sevoflurane)	65 (85)

Intra-operative pain management

Details of the medication administered for analgesia is shown in Table 4.4.

Table 4.4 Pain management intra-operatively

Anaesthetic / analgesic	Number of patients (Percentage)
REGIONAL ANAESTHESIA	
Transversus Abdominis Plane blocks	38 (50)
Bupivacaine 50 mg	4 (5)
Bupivacaine 100 mg	29 (38)
Bupivacaine 120 mg	1 (1)
Bupivacaine 150 mg	4 (5)
Single-shot wound infiltration	
Bupivacaine 100 mg	19 (25)
NON-OPIOID MEDICATIONS	
Ketamine intravenous bolus	38 (50)
Paracetamol intravenously (1g)	39 (51)

Table 4.4 Pain management intra-operatively (continued)	
Anaesthetic / analgesic	**Number of patients (Percentage)**
Diclofenac intravenously (75 mg)	4 (5)
Diclofenac per rectal suppository (100 mg)	2 (2)
OPIOID MEDICATIONS	
Remifentanil Target-Controlled Infusion (TCI)	13 (17)
Alfentanil intravenous bolus	4 (5)
100 mcg	2 (2)
150 mcg	1 (1)
200 mcg	1 (1)
Fentanyl intravenous boluses	42 (55)
100 mcg	1 (1)
150 mcg	1 (1)
200 mcg	32 (42)
250 mcg	1 (1)
300 mcg	6 (7)
450 mcg	1 (1)
Sufentanil intravenous boluses	17 (22)
10 mcg	8 (10)
15 mcg	1 (1)
20 mcg	5 (6)
30 mcg	2 (2)
40 mcg	1 (1)
Morphine intravenous boluses	73 (96)
1 – 3 mg	2 (2)
4 – 6 mg	15 (19)
7 – 9 mg	35 (46)
10 – 12 mg	17 (22)
13 – 15 mg	4 (5)

In 38 (50%) cases transversus abdominus plane (TAP) blocks were performed, all ultrasound-guided. One patient with obstructive sleep apnoea had an epidural insertion attempt (prior to general anaesthesia) which was unfortunately unsuccessful and abandoned. When TAP blocks were performed, a total volume of 40 ml solution was consistently prepared. Variable bupivacaine dosing was used: 100 mg (diluted to 40ml solution; 0.25%) in the majority of cases. Four patients received only 50mg. If TAP blocks were not performed a quarter of the patients (19 of 76) received wound infiltration by the surgeon. Bupivacaine 100mg was used in all instances.

Non-opioids used intra-operatively varied between cases. Thirty-eight (50%) patients received Ketamine intravenously as a synergistic analgesic drug and in 18 (23%) of these cases, it was the only non-opioid drug administered intra-operatively.

Paracetamol, when it was intermittently available, was administered intravenously in 39 (51%) of the cases.

Four (5%) patients received Diclofenac 75 mg intravenously as an infusion intra-operatively, whilst two patients received a per rectum suppository of 100 mg Diclofenac immediately post-operatively while still under anaesthesia. Poor stock medication levels at the hospital limited the availability – this was observed to be a factor at the time of the study by the single researcher collecting data.

Opioid analgesic combinations also varied between cases. Forty (52%) of the cases received a combination of Fentanyl and Morphine intra-operatively. Seventeen (22%) cases had a combination of Sufentanil and Morphine administered intravenously while four patients (5%) received Alfentanil and Morphine. Thirteen (17%) received a TCI method with Remifentanil running intra-operatively and the Morphine dosing just before wake-up. Two cases that received Remifentanil as a TCI had a volatile anaesthetic maintenance delivered with Sevoflurane.

Pain management in recovery

No patients received regional anaesthesia or top-ups via catheters post-operatively in this study. One participant received Paracetamol 1000 mg intravenously in recovery, since she had not received it intra-operatively. Two (2%) patients were given intramuscular Diclofenac 75 mg in the recovery room. One patient received Ketamine 15 mg intravenously. Two patients were given intravenous Morphine in recovery. One received 2 mg (25% of total dose), another was given 3 mg (43% of total Morphine dose) post-operatively. One patient was given Pethidine 25 mg intravenously post-operatively. [Table 4.5]

Table 4.5 Pain management in the recovery room	
Anaesthetic / analgesic	**Number of patients (Percentage)**
REGIONAL ANESTHESIA	0
NON-OPIOID MEDICATIONS	
Ketamine intravenous bolus (15 mg)	1 (1)
Paracetamol intravenously (1 g)	1 (1)
Diclofenac intramuscular injection (75 mg)	2 (2)
OPIOID MEDICATIONS	
Morphine intravenous bolus	2 (2)
Pethidine intravenous bolus	1 (1)

Pain management in the ward

Eighteen participants (23% of cases) did not receive any kind of adjuvant medication on the wards, despite it being prescribed by doctors before the time of assessment on POD1. Twelve of these patients were utilising a Morphine PCA pump. Those patients who did receive non-opioid medication were given various combinations of oral Paracetamol (1000 mg per dose), oral Ibuprofen (400 mg per dose), Indomethacin or Diclofenac suppositories (100 mg PR per dose, up to three maximum) or Diclofenac 75 mg intramuscularly in very few cases. Medication issued on the ward was often received late, or inconsistently. Missed doses, "refused" doses and stock issues were a problem across both wards for the duration of the study, despite reports of poorly treated pain from the patients.

Patients were sometimes given oral Tramadol (5 patients, 6%) in either 50 mg, 75 mg or 100 mg dose increments. Of those who did not receive a Morphine PCA, the gynaecologists prescribed either Morphine or Pethidine intramuscularly, the majority of these patients (29 of 42, 69%) received Pethidine intramuscularly, in 100mg doses six-hourly, up to a maximum of three to four doses. The remainder (18 of 42, 43%) received intramuscular Morphine, 10 mg or 15 mg at a time on the wards. There was no clear division or patient-factor that distinguished those that received Morphine as opposed to Pethidine, as evidenced by the anaesthetic charts, however, no statistical analysis was performed to confirm or refute this as the study was not adequately powered.

Morphine patient-controlled analgesia (PCA) pumps were established post-operatively in the recovery room or the immediate post-operative period on the ward in 34 patients (44% of cases). A median of 21.5 mg of Morphine was used per patient with PCA, ranging from 3 mg to 54 mg. The dosing offered was 1 mg (per 1 ml) with a seven-minute lockout time and maximum of 8mg potentially issued per hour. [Table 4.6]

No record was made in the hospital files of patients' level of pain reported or any note of review of pain levels post-administration of analgesia as per the SOPs, by the nursing or medical staff.

Table 4.6 Pain management in the ward post-operatively

Anaesthetic / analgesic	Number of patients (Percentage)
REGIONAL ANAESTHESIA	0
NON-OPIOID MEDICATIONS	
Prescribed analgesia not administered	18 (23)
Paracetamol per os (1 g 6 hourly)	49 (64)
Received once	19 (25)
Received twice	18 (23)
Received three doses	8 (10)
Received four doses	4 (5)
Ibuprofen per os (400 mg 8 hourly)	25 (32)
Received once	12 (15)
Received twice	11 (14)
Received three doses	2 (2)
Indomethacin per rectal suppository (100 mg 12 hourly x 3)	11 (14)
Received once	5 (6)
Received twice	5 (6)
Received all doses	1 (1)
Diclofenac intramuscular injection (75 mg)	2 (2)

Table 4.6 Pain management in the ward post-operatively (continued)	
Anaesthetic / analgesic	**Number of patients (Percentage)**
OPIOID MEDICATIONS	
Morphine PCA (patient-controlled analgesia) pump	34 (44)
Pethidine intramuscular injection	29 (38)
Tramadol per os	5 (6)
Morphine intramuscular injection	18 (23)

Pain intensity scales

The worst pain experienced post-operatively since the surgery was assessed using a numerical rating scale (NRS) with a score of 0 meaning no pain and 10 the worst pain possible. The maximum score of 10 was chosen for 17 of the cases (22%). The lowest score given was 1, selected twice (2%). There was a median score rating of 8, interquartile range (IQR) 5 to 9.

Patients used the same scale above to indicate the least pain experienced since the surgery. The maximum score of 10 was chosen twice (2%) and the minimum allocated score being 0, reached in 7 cases (9%). The median was 4 (IQR 2 – 6). Scores greater than 4 are considered in international research and academic discussions to be too high, reflecting unacceptable levels of pain and suggesting poor control of post-operative pain in our study group. A score above 6 would generally be considered as severe pain. [Figures 4.1 and 4.2]

Figure 4.1

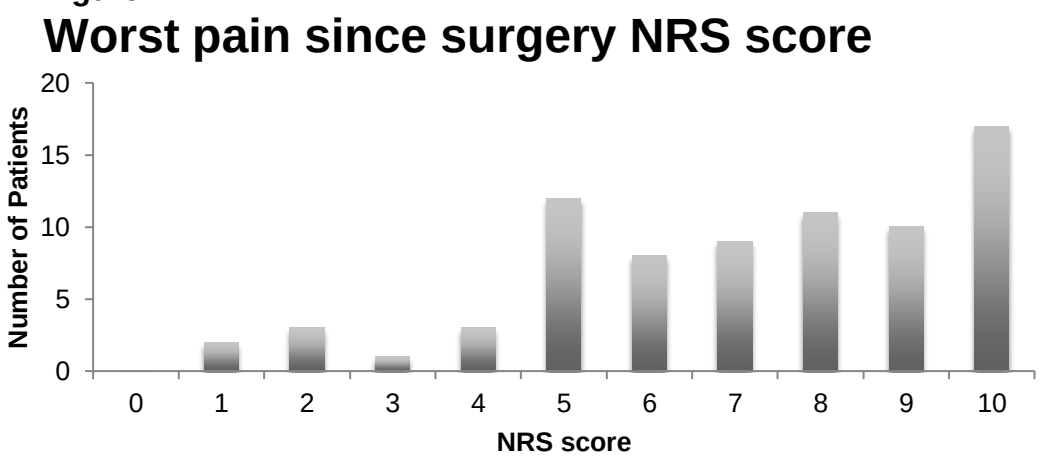


Figure 4.2

Least pain since surgery NRS score

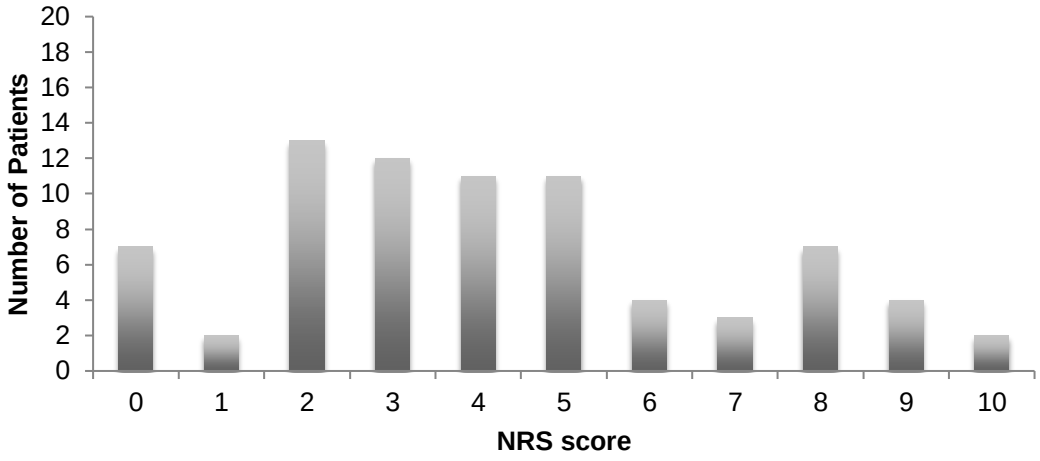
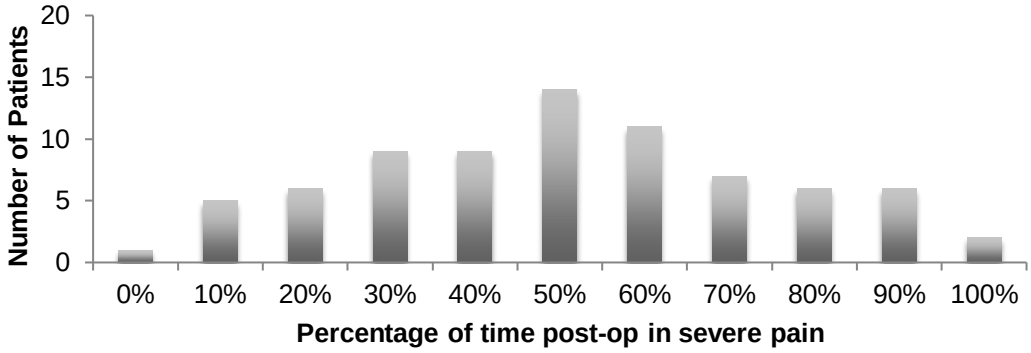


Table 4.7 Percentage of time spent in severe pain	
Score	**Number (Percentage)**
0%	1 (1)
10%	5 (6)
20%	6 (7)
30%	9 (11)
40%	9 (11)
50%	14 (18)
60%	11 (14)
70%	7 (9)
80%	6 (7)
90%	6 (7)
100%	2 (2)

All but one patient reported spending some time in “severe pain”, which was self-interpreted, however the scores given for the worst pain experienced post-operatively in another question revealed that only fifty-five (72%) patients rated their maximal pain as 6 out of 10 or greater. For the percentage of time spent in severe pain (as per the NRS scores), the mean duration was 50% (SD 24%) of the postoperative time. [Table 4.7 and Figure 4.3]

Figure 4.3

Time spent in severe pain

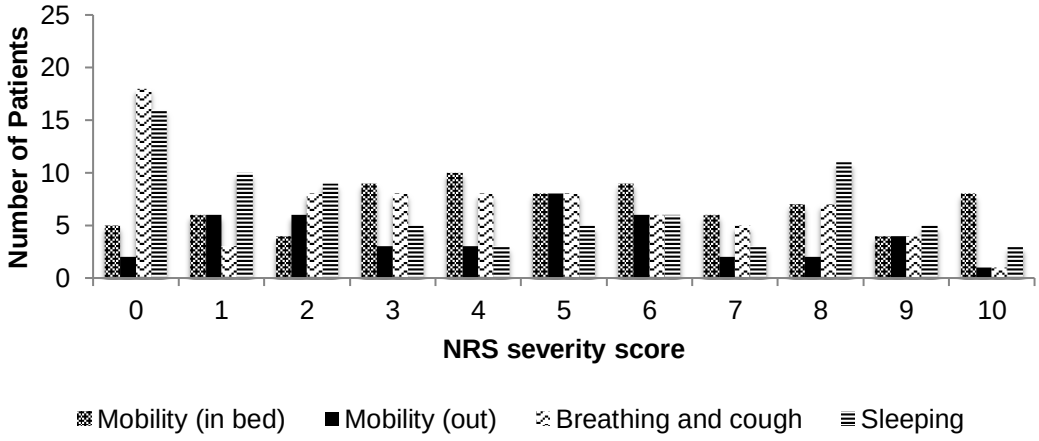


Pain interference with function

Indications were made by the patients on a scale from 0 (did not interfere) to 10 (completely interfered) for the activities listed in the PAIN-OUT Questionnaire. [Figure 4.4]

Figure 4.4

Pain interference with function



Mobility in bed - turning, sitting up, changing position: five patients (6%) chose a score of 0 (no interference), whereas eight patients (10%) reflected a score of 10, meaning that their pain post-operatively interfered completely with these activities. The median score rated was 5 (IQR 3 - 8).

Forty-three (56%) patients had mobilised out of bed by the time of assessment on POD1. Two patients reported no interference (score of 0) and one patient gave a score of 10 (complete interference) with activities performed out of bed such as walking, sitting in a chair and standing at the sink (as per the questionnaire). Median score allocated for those who mobilised was also 5 (IQR 2 - 6).

When assessing the pain's interference with deep breathing and coughing, eighteen patients reported no interference (score of 0), whereas only one patient gave a maximum score of 10. The median score selected was 4 (IQR 1 - 6).

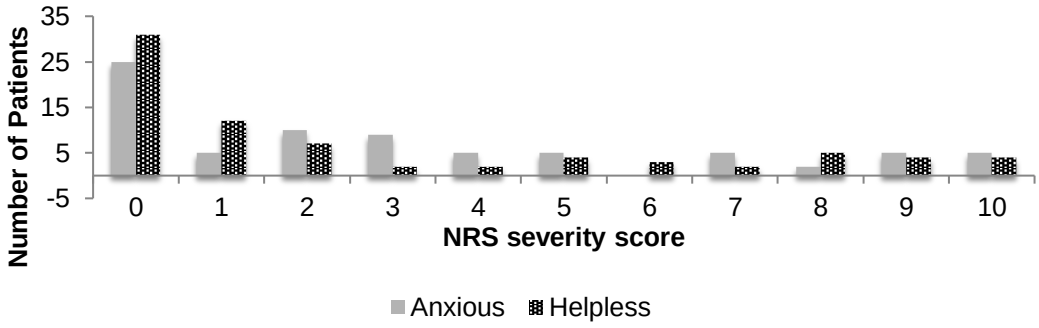
Seventeen patients reported no interference (score of 0), whilst three gave a maximum score of 10, describing the effect of their pain on the quality of their sleep. The median score given was 3 (IQR 1 - 8) for interference with sleeping.

Pain interference with emotions

The patients had to indicate on the questionnaire, utilising a scale from 0 (not at all) to 10 (extremely) whether they had experienced either of the two emotions, anxiety or helplessness. [Figure 4.5]

Figure 4.5

Pain interference with emotions



Five patients (6%) indicated that they felt extremely anxious due to pain (score of 10), whilst 25 (32%) patients reported no feelings of anxiety. Pain-related anxiety had a low median score of 2 (IQR 0 - 5) in this population.

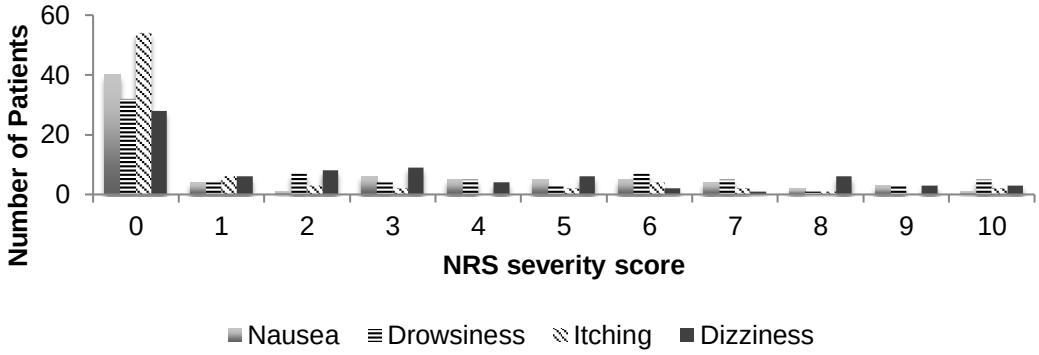
With regards to helplessness associated with pain, a median score of 1 (IQR 0 - 5) was reported by the group. A maximum score of 10 was selected by 4 patients (5%), whilst a minimum score of 0 (not at all) was selected by 31 patients (40%).

Side-effects experienced

Indications were made of the intensity of side effects, from 0 (none) to 10 (severe). Overall, the incidence of side-effects of analgesic medication reported in the study were very low. This may be a reflection of patients not receiving medication predictably or regularly on the wards and thus having less exposure to the potential for experiencing side-effects. Predominant side-effects reported by the study patients were drowsiness and dizziness, although the mean scores were also low. [Figure 4.6]

Figure 4.6

Side-effects experienced

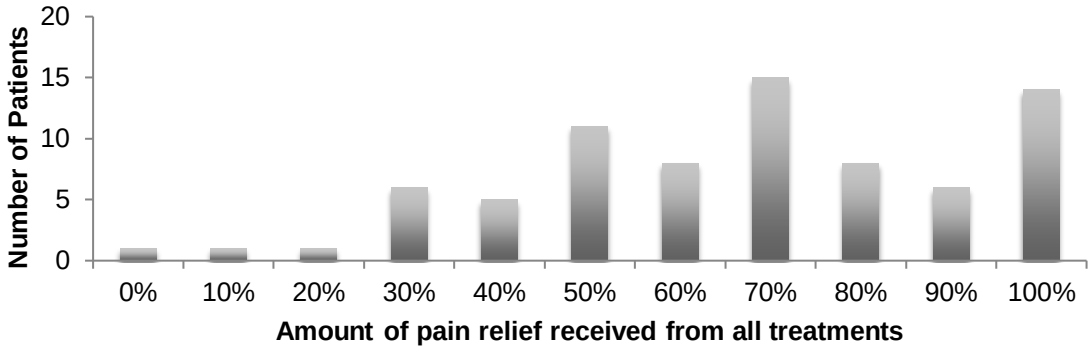


Patients' perception of pain treatments

The percentage of relief received from all pain treatments combined, both medicine and non-medicine, from 0% (no relief) to 100% (complete relief) was assessed. Median percentage allocated was 70% (IQR 50% - 90%), indicating high levels of relief across the population. Fourteen patients described having complete relief, whilst one patient reported no relief (0% relief). [Figure 4.7]

Figure 4.7

Amount of pain relief received

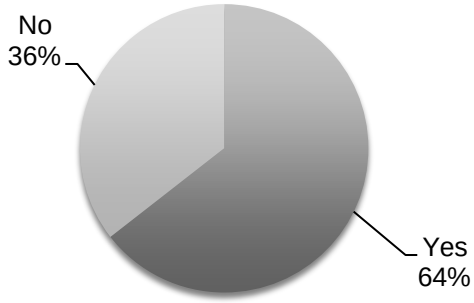


Patients were asked whether they would have liked more pain treatment than they had received, answering either 'Yes' or 'No'.

Forty-nine patients (64%) would have liked to receive more pain treatment than they got during their admission until the point of assessment on the ward. This was expected as medication issuing was erratic on the wards and the reported pain levels were high. [Figure 4.8]

Figure 4.8

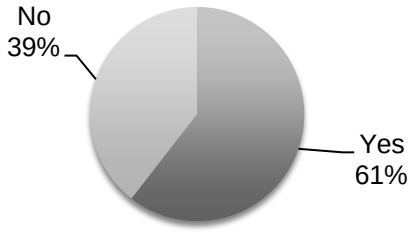
Would you have liked more pain treatment?



Patients were asked whether or not they had received any information about their pain treatment options. Thirty patients (39% of cases) had not received any information about their pain treatment options. This level is unacceptably high. [Figure 4.9]

Figure 4.9

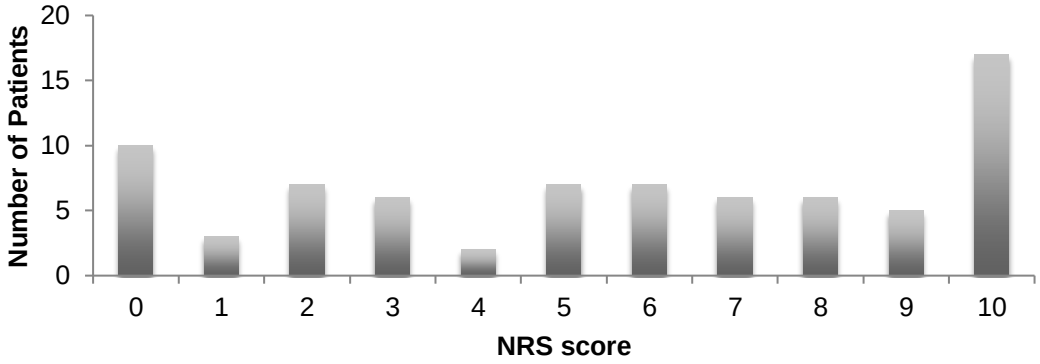
Any information about pain treatment options received?



Decisions about their pain management participation - with 0 being not at all to 10 being very much so - was assessed. Patients rated a median score of 6 (IQR 2 - 9), implying that they were partially involved in the decisions regarding their pain management. [Figure 4.10]

Figure 4.10

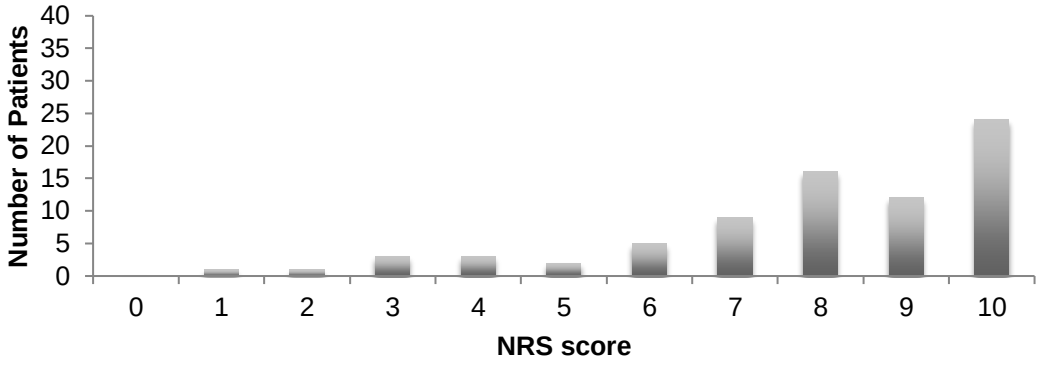
Adequacy of involvement in pain relief decisions



Satisfaction with pain treatment since their surgery (0 being extremely dissatisfied to 10 being extremely satisfied) showed a median result of 8 (IQR 7 - 10) This correlates poorly to the reported scores of pain levels and vocalised desire for more analgesia during the post-operative period in this sample. This may reflect the complex nature of interacting forces affecting patient satisfaction and the achievement of healthcare targets. It does however follow the general trend in the literature. [Figure 4.11]

Figure 4.11

Overall satisfaction with pain treatment



Alternative pain relief methods used

Twenty-two patients utilised other methods of pain relief (often unknowingly at the time). Popular choices included prayer, talking to relatives and staff, walking or distraction. None of these alternative methods were suggested to them by the treating team and were patient-initiated. [Table 4.8]

Table 4.8 Non-medicine pain relief methods utilised

Methods	Number of patients (Percentage)
Cold pack	1 (1)
Walking	9 (11)
Talking to medical staff	7 (9)
Talking to friends or relatives	5 (6)
Deep breathing	4 (5)
Prayer	10 (13)
Distraction (watching TV, music, Internet)	5 (6)
Meditation	1 (1)

Impact of chronic pain on pain relief

Patients were asked to consider whether or not they had a persistent painful condition for three months or longer before being admitted for this elective surgery. The severity of the chronic pain had to be rated from 0 (no pain) to 10 (worst pain possible) and the location of the chronic pain indicated. Forty-six patients (60%) had chronic pain before this surgery, with a median score of 8 out of 10 (IQR 6 - 10). Only 9 of these patients were referring to pain elsewhere (not related to the site of surgery). [Table 4.9]

Table 4.9 Chronic pain present pre-operatively

Location of pain	Number (Percentage)	Median NRS pain severity score (IQR)
Site of surgery	23 (30)	8 (5 - 10)
Elsewhere	9 (11)	7 (6 - 9)
Both (surgical site and elsewhere)	13 (17)	7 (6 - 10)

Chapter 5: Discussion

The study population interviewed on the first post-operative day following elective TAH at RMMCH was non-homogeneous. The majority of patients were of South African descent, with a mean age of 46.14 years (SD 8.82 years). The majority of patients (68%) had a pre-existing medical illness requiring treatment. Hypertension was most prevalent, found in 27% of the study group. In our study, conducted over a three-month period, the median surgical time for the TAH procedure was 1.89 hours (IQR 1.52 to 2.54 hours). Most cases (73%) had no recorded indication for the TAH in their file, however, of those whose indications were explicit, the majority (15%) were for multi-fibroid uterus, this reflects the findings in the literature (61, 87).

Only six (7%) patients were prescribed oral sedatives pre-operatively on the ward. A further twelve (15%) patients received intravenous sedatives immediately pre-operatively in theatre, administered by the anaesthetist. There is thought to be a link between states of pre-operative anxiety and levels and experience of post-operative anxiety and pain. In a study by Kain et al (88) looking at elective hysterectomy patients, their levels of acute state anxiety correlated well to the degree of post-operative pain, both immediately and once discharged home a week later. Those patients who were more anxious experienced worse post-operative pain. Their suggestion was to actively address anxiety both pre- and post-operatively, thus helping to reduce pain. Median NRS scores for the worst post-operative pain in the subset of patients who received pre-operative sedation in this study population were the same as the rest of the group – 8 out of 10 (IQR 5 – 10), but the study was limited by size to show a potential difference or effect.

The majority (85%) of the study population received volatile anaesthetic maintenance, following an intravenous induction with a short-acting opioid and Propofol. Eleven (14%) of the patients received TCI anaesthesia for the procedure, utilising Propofol and Remifentanil. Remifentanil is known to induce hyperalgesia in the post-operative period if there is inadequate dosing of additional long-acting opioids or NMDA-receptor antagonists, such as Ketamine, before emergence. A study examining the difference between TIVA and inhalational maintenance anaesthesia with Sevoflurane in liver surgery, it was observed that the TIVA group reported less pain on the first two post-operative days, but not the third, compared with the Sevoflurane group. They appeared to require less opioids post-operatively, but with comparable patient satisfaction in the two groups (89). Not all studies examining the post-operative pain outcomes following these two techniques have

been in agreement. Individual sub-group analysis could not be undertaken in this study owing to the small numbers enrolled.

Half of the study participants received TAP blocks as a regional anaesthetic technique, after induction and before skin incision. A further nineteen (25%) patients received a single-shot local anaesthetic wound infiltration administered post-operatively by the surgeon. The literature demonstrates that TAP blocks performed for TAH cases showed improved post-operative pain for the first 24 hours, at rest and activity compared with no block, however the opioid requirements were similar in both groups by 48 hours post-operatively once the block had worn off (68). Similar comparisons up to 48 hours could not be made in my study as the point of interview for my patients on the first post-operative day fell between 20 to 30 hours after surgery.

Half the patients were given analgesic doses of Ketamine intra-operatively. Intravenous Paracetamol was administered in 51% of the cases. Six (7%) patients received Diclofenac, either intravenously or per rectal suppository. All patients received a short-acting opioid agent. Ninety-six percent of the cases were administered Morphine intravenously during the procedure, the remaining four percent received Morphine post-operatively in recovery or in the ward. This is in line with the WHO analgesic ladder for acute pain and incorporates the idea of multimodal analgesia as advocated by the World Federation of Societies of Anaesthesiologists (9). Multimodal analgesia refers to the simultaneous administration of two or more agents with differing mechanisms of action and, usually different pain pathway receptor targets. This allows for synergistic action with the potential to reduce each agents' inherent side-effect profile, which is usually dose-related, and was originally intended to be 'opioid-sparing'.

Recovery room medication administration was rare. Of these recorded episodes, two (2%) patients were given intravenous Morphine. It is assumed, but not clear, that patients were discharged from recovery to the ward when pain control was satisfactory. There is no indication of these pain levels in the study. There needs to be a clear indication at each time point in the post-operative period of the patient's pain control and analgesic requirements, especially prior to discharge from recovery room to the ward. Either due to poor record-keeping or inadequate levels of vigilance and care, there is inconsistent and sparse noting of the measures instituted (when required) or of the responses to such measures on the anaesthetic record or post-operative recovery chart. The presumption is that some patients possibly leave recovery room already in some discomfort without their pain being fully addressed. In this particular unit, nursing staff ran the recovery area and

involved doctors from the relevant theatre if there was a concern. Perhaps looking at good coverage of the recovery area by an assigned acute pain team doctor or anaesthetist would be valuable in ensuring no patient is in undue levels of acute pain before leaving. Acute untreated pain can develop into a spiral of difficult-to-treat pain and the development of hyperalgesia, allodynia or even chronic pain syndromes.(1, 5)

At the time of review it was noted that despite clear prescriptions, patients were not receiving regular analgesia in 23% of cases. The IASP has set out guidelines on the management of pain, and some particularly relating to “wait-times” for analgesic medication suggesting that acute post-operative pain be dealt with immediately (44).

There was some observable resistance from the nursing staff with requests for analgesia to be issued outside of the usual dosing / medication round times, this was personally identified by the researcher when queried about at the time of review. If a patient had unusually high requirements without a PCA, they simply had to go without. There were clear gaps in analgesia administration from the patient records – either given but not signed for, but presumably, not given at all – as per accounts directly from the patients who were experiencing pain upon review. Nursing staff appeared (from the viewpoint of the researcher), at the time of the study, reluctant to change practice and not follow usual protocol, and gynaecology doctors (often junior interns) are hesitant to prescribe more analgesia with the fear of oversedation and respiratory depression in the patients on their wards – this was directly observed during the course of the study.

Post-operative analgesic regimens prescribed by the unit gynaecologists were variable. There was little consensus as to what patients received, and when. This large variability may add to the confusion of the nurses administering analgesia on the wards. There has been shown to be improved outcomes with pain protocol implementation with improved communication and collaboration between disciplines. With standardised algorithms on the management of pain, the nursing staff and managing doctors have a way of initiating best practice care earlier and more consistently (84). Not enough good quality studies have been performed as yet looking at outcomes of various surgery-specific analgesic-protocols and their implementation, but it is expected that utilizing multimodal approaches designed at fast-tracking recovery and improving outcomes after surgery will benefit patients and allow for more cost-effective and consistent care. (90)

Morphine PCA pumps were given to thirty-four (44%) patients. Those on the patient-controlled pumps, at review on the first post-operative day, had used a median value of 21.5 mg of Morphine (IQR 12.75 mg to 30 mg). If a patient requires three to

four opioid bolus doses, within an hour, to control pain on the ward post-operatively, they are likely to benefit from a PCA pump according to previous studies (5). This may be prudent in our setting given the medication administration delays and omissions witnessed on the wards post-operatively in this study.

There was no standardised recording of levels of patients' self-reported pain or pain-interference in the files. In fact, this was often not enquired about or highlighted by staff on the ward, as indicated by the patients themselves. In most of the interviews during the study period, it was the first occasion that patients had been exposed to a concept of numeric rating scales for the quantification of subjective levels of pain. The South African Acute Pain Guidelines support the use of some quantification tool to elicit the subjective degree of the pain experienced by the patient (1). The interpretation of these pain scales can be influenced by level of education and patient cultural norms. A study undertaken in Ireland by Mohan et al (91) examining the effectiveness of using the Visual Analogue Scale or the Verbal Numerical Rating Scale to assess pain over time in the emergency department, found that there were discrepancies in interpretation based on the patient's level of education. Particularly, when looking at the way in which the two different scales were congruent with each particular patient's interpretation and reporting of pain, they found inconsistencies. It was noted that there was improved consistency based on higher levels of education and that patients generally preferred the Numerical Rating Scale compared to the Visual Analogue Scale, when offering a preference (91). Whichever method is used, it needs to be translatable and acceptable to the population being studied or cared for. Explanation of the various tools used to grade the severity of pain should be undertaken with the patient involved, in all circumstances. In cases where patients are perhaps illiterate, alternative representations, for example facial expressions, should be explored instead of relying upon a numbered ranking or language-based system. Perhaps even more meaningful is the degree to which the pain is limiting the patient's function, which could be explored instead of a simple number or grade.

Pain intensities, as recorded by the patients for the purposes of the study showed that patients experienced a median post-operative maximal NRS pain score of 8 (IQR 5 - 9), ranging from 0 to 10 on the scale. The median score for the least pain experienced since surgery was 4 (IQR 2 - 6). Patients reported to have spent an average of half the time post-operatively in severe pain. This reflects the data in the literature quoting inadequate post-operative pain control across all surgery types in developed countries, with between 50% to 80% of patients investigated reporting moderate to severe pain (13).

Pain interfered with function variably. Mobility in and out of bed was affected to a median reported score of 5 (IQR 3 – 8; 2 - 6) on the severity scale. Deep breathing and coughing were affected to a median report of 4 (IQR 1 - 6) on the scale, and sleeping to a median of 3 (IQR 1 - 8).

Most patients did not report any overt effect of the pain experienced by them on their emotions. A median score of 2 (IQR 0 - 5) was assigned to the severity of anxiety experienced and a median score of 1 (IQR 0 - 5) was reported for feeling helpless as a result of the pain. The international literature is in agreement regarding the additional burden placed on the experience of pain by emotions such as fear, anxiety, low mood and various patient coping strategies that may allow for “pain catastrophising” and further negative pain interpretation by patients (1, 4, 35, 92). It is unclear whether the lack of similar findings in this study points to a difference in population characteristics or is reflective of the small sample studied. Further research would need to be undertaken to explore this.

The majority of patients did not report experiencing any side-effects of nausea, drowsiness, itching or dizziness as a result of their pain treatments. Median NRS severity scores for these ranged between 0 and 2. This is out of keeping with the international trend, where there is often a high incidence of post-operative nausea and vomiting, particularly prevalent with gynaecological procedures. Usual rates of post-operative nausea and vomiting following a general anaesthetic are currently around 30% of patients, but the incidence starts to approach 70% to 80% with “high-risk” cases in the literature, where female gender, volatile anaesthetic and opiate use and gynaecological procedures are a few of the known risk factors. These factors were all present in our study population, but with much lower rates of reported nausea post-operatively. One would have expected higher reported rates of nausea in our patients, in line with international literature, but this was not the case. (93, 94)

One patient reported no relief (0%) of pain “from all treatments”. She may have been in the group of patients not receiving adequate and timeous dosing of analgesia on the ward, although it is possible that the question was misinterpreted or she may have taken the question to mean the degree of pain relief at that singular point in time post-operatively. The median score reported was 70% relief (IQR 50% - 90%), with 18% of the study participants indicating 100% relief obtained. Forty-nine (64%) patients indicated that they would have liked more pain treatment than they received. This is much higher than that found by the PAIN-OUT study conducted with over 5000 patients across Europe, following various procedures, where 16% of patients wished that they had received more pain treatment (72). This

implies that we are managing acute post-operative pain very poorly at present in this unit with the current inconsistencies in drug prescribing, issuing, lack of protocols and insufficient multidisciplinary teamwork in managing the problem. The effective and timely relief of pain is a “fundamental human right” as much as it is a concept of “good clinical and ethical practice” in medical care (6, 27, 45, 60, 95).

Forty-six (60%) patients report having received information about pain treatment options, with the rest indicating that no information or education was offered to them. It was not explored in the context of the PAIN-OUT questionnaire what patients meant by this response. It is not clear whether the inadequate peri-operative counseling was due to patient misunderstanding or whether the information was not conveyed by the treating team at all. Either way, this is a concerning finding in terms of optimising patient care.

Participation in pain treatment decisions with the team showed a median score of 6 (IQR 2 - 9). Seventeen (22%) patients reported a maximal involvement of 10. Involvement in the decisions regarding care post-operatively and discussion with the patient of the expected pain levels after the procedure has been shown in the literature to improve patient satisfaction with care and has improved overall pain management as rated by the patients themselves, in multiple settings (35, 60).

Overall satisfaction regarding pain treatment was also rated from 0 to 10. A median score of 8 was given by the study patients, interquartile range of 7 to 10. No one assigned a minimal score of 0. Twenty-four (31%) patients gave a maximal score of 10 in terms of overall satisfaction. Patient satisfaction is fast-becoming one of the more important measures of the quality of medical care delivered, especially in the field of Anaesthesiology, as supported by the current literature (6, 96).

Patient satisfaction is difficult to predict as the factors associated with it vary among population groups, and with individual patient characteristics and beliefs. The issues surrounding patient satisfaction are “numerous and complex” (78), and one may find that patients are satisfied despite high pain intensity scores (2, 6, 7).

One proposed reason for this, as set out by the American Pain Society, is that the “caring attitude of the staff’ may play a large role in the satisfaction reported by patients suffering from under-treated pain (6, 78, 97). A significant sample containing 16 868 patients, collated from reviewed findings of the PAIN-OUT study in 42 centres consistently demonstrated that satisfaction with post-operative pain treatment is not “associated with the patient’s actual pain experience, but more strongly with impressions of improvement and appropriateness of care”. They found improved satisfaction in cases with better pain relief and increased involvement in

decision-making about care. (80)

Patients who receive information about their hospital stay, surgery and analgesic plan and feel as though they are involved in their management will often report better satisfaction overall compared with those that do not (82).

Only a few patients reported utilising alternative pain-relief methods during the study. The majority of these (13%) used prayer. A Cochrane meta-analysis looking at alternative pain therapies for women in labour found that hypnosis and acupuncture could be effective however there appears to be limited scientific study investigating the effectiveness of other therapies. (98)

Forty-six (60%) patients had chronic pain for at least three months, pre-dating the TAH, with a median NRS score of 8 out of 10 (IQR 6 - 10) for this pain. Of these cases, 23 patients (30%) had pre-existing pain in the region of the site of surgery. It is important to recognise cases where there is a chronic or pre-existing pain component involved, as management may be more focused toward eliminating the occurrence of untoward levels of post-operative pain to prevent further debilitation. The literature supports the theory that the adequate treatment or prevention of acute pain episodes decreases the burden of chronic pain (5, 69)

Summary: Main findings

A total of 76 patients were included in the study. The study size was therefore relatively small, allowing very limited conclusions to be made about the greater population it represented. The study demonstrated the relative similarity of technique of anaesthetic administered for this type of procedure by the anaesthetists at RMMCH.

The study highlighted the unacceptably high levels of post-operative pain reported by patients. It also showed that analgesic medication administration was not prioritised by the staff in the post-operative ward by the time the patients were interviewed on the first post-operative day. Staff were not documenting pain levels of the patients, nor enquiring about these. There was very little or no interdisciplinary collaboration in management. Medication was often not being administered to patients as prescribed, highlighting the need for good teamwork and ongoing staff education and buy-in to deliver satisfactory levels of care from all parties caring for the patient. The study highlights that integrated care with collaboration across specialties is required to manage pain better.

Patients were not uniformly informed about their pain management options or counseled regarding what they might expect post-operatively and indicated that they wished that they had received more pain treatment. Not many patients utilised non-medicine methods of pain relief in this study, and when they had, it had been of their own accord and not suggested or always supported by medical staff. There is room to improve the staff's education and understanding of non-pharmacological methods of pain relief and to work toward a more holistic approach with patients directing care options.

Patients still reported relatively high satisfaction levels with the care received, despite inadequately addressed post-operative pain. This suggests what the literature proposes about the complex and multifaceted nature of patient satisfaction. More work would have to go in to addressing the various components that drive patient satisfaction, particularly with regards to the care and information offered and delivered by healthcare workers, in agreement with patient wishes, to better understand where the areas are for improvement.

Limitations

There were numerous limitations encountered, some were foreseen before the introduction of the study to the population at RMMCH.

The information was collected, in part, directly from the hospital files and anaesthetic charts - in accordance with the PAIN-OUT SOP. This relied on accurately completed medical records at RMMCH during the study period. Some information was therefore not available according to the standard record-keeping observed at the hospital. This information could not be supplemented from direct questioning of the participants either, and therefore when unavailable, it had to be left unrecorded.

The SOPs of PAIN-OUT limited the collection of data to working hours between 08:00 and 17:00, thus restricting possible data collection blocks to a period when the researcher was able to rotate back to RMMCH for three months, more than a year after initial research proposal. In the interim, some of the issues of ineffective pain management post-operatively were addressed, as an Acute Pain Service was initiated at the hospital to offer post-operative Morphine PCA pumps and to fill some of the gaps in service delivery. This may have had an influence on the outcome of the study's results and placed the service delivery in a more positive light. There is still much room for improvement however, as the offer of PCA pumps was not universal due to limited resources and concurrent pain management studies running at the hospital - which utilised the pumps and staff resources.

The method of sampling employed may also result in misrepresentation of the actual population, as convenience consecutive case sampling had to be utilised to make the study practical with other work commitments.

English questionnaires proved to be challenging for some of the patients - they struggled to understand the meaning or context adequately in quite a few parts of the questionnaire. Some patients, for example, scored a low score for worst pain on the NRS and vice versa. This was corrected without too much additional explanation upon review. Seven patients had to be excluded from the initial sample because they were not able to understand English or were illiterate and could not participate in a researcher interview either. The SOPs did not allow for any translation or explanations on the part of the researcher. This was done in order to help minimise bias, but it limited the overall application to our population.

The patients who were placed on Morphine PCA pumps by the acute pain doctor in the wards had additional monitoring, follow-up and counseling. There was however a trend for these patients to not receive any additional prescribed analgesia such as

paracetamol and NSAIDs from the ward nursing staff. This influenced the efficacy of the treatment modality with potentially losing the benefit of synergistic effects with multimodal analgesia and minimising adverse effects. This problem was not easily addressed and resolved, despite clear and repeated discussions with the nursing staff. Explanations for this could be due to incorrect perceptions or protocol limitations on the part of the ward nurses or treating unit's gynaecology medical staff.

Satisfaction is complex and not clearly or directly related to reduced pain levels and improved analgesia, even in the setting of reduced adverse drug effects. There is likely a myriad of interacting forces at work which influence the patient's overall perception of care and quality of healthcare experience. This occurs from the time of opening a hospital file through to basic care and personal understanding on the wards post-operatively and involves many role-players, not simply the anaesthetic doctors and support nursing staff in theatre (or the wards).

The recurrent lack of certain analgesic medications and limited armamentarium available in the state sector had a considerable effect on the availability of what could be offered to patients intra- and post-operatively. The cases in the study were not able to uniformly receive the same multimodal regimens over the course of the study owing to lack of stock availability. This would limit the conclusions that could be drawn from the group, as non-opioid interventions were not always similar.

Any intervention cannot be interpreted to have produced the final NRS of patient satisfaction outcome observed. Therefore, further investigation with more structured controls may reveal the individual impact of each intervention on the patient's level of satisfaction. This study, as observed via the questionnaires completed as such, offers little evidence for each particular drug or intervention but rather suggests more favourable combinations of applied interventions over others. Limited conclusions can thus be drawn from this information.

A multivariate analysis would have been useful to determine which specific factors or interventions employed lead to more favourable reports from the patients regarding overall satisfaction with care, however the study was not adequately powered to draw these conclusions.

The study was undertaken at a single hospital site in Johannesburg, therefore the results may not be generalised accurately to other sites or units.

Recommendations

Clinical practice

Investigating patient satisfaction following certain interventions or the degree to which patients are involved in treatment decisions in a unit may be useful to reflect upon the ongoing clinician-patient interaction in the unit. It is useful to monitor baseline performance and subsequent changes following interventions or altered practice standards implemented. It is imperative for training anaesthetists to question the degree to which their care could improve and which aspects may contribute to improved patient outcomes. It is useful to look at the overall satisfaction of patients regarding their care, even if it may not be clear initially how to directly improve this. If one were to implement a standard of care that included appropriate and adequate counseling of patients pre-operatively, perhaps on more than one occasion by different healthcare providers, communication of management goals and expectations would improve. Where there is improved communication and collaboration with patients, they are more able to be key role-players in managing their pain levels and recovery and this would usually translate into improvements in perceptions of care. Offering the patient a “clear plan for analgesia will improve satisfaction, even though pain is not completely avoided” - incorporates a balanced biopsychosocial approach and is supported by the literature (5). Improvements in delivery of prescribed analgesic medication post-operatively needs to be adequately ensured and staff trained in the importance of managing pain appropriately.

It may be of benefit to institute “acute pain teams” in hospitals to address the problem of post-operative pain and direct attention to “continuous” monitoring and adequate, early treatment of pain whilst also striving for the ongoing education of both staff and patients regarding the benefits of and options for analgesia. (1, 26, 84)

Patients could be encouraged by the team to attempt utilising various other methods for pain relief, in consultation with them about what would work best.

Further research

A study comparing the outcomes of patient satisfaction levels with routine anaesthetic care for other routine procedures in RMMCH and other hospitals on the Johannesburg WITS circuit may help draw meaningful comparisons.

A similar study could be repeated after a period of staff training and education followed by a follow-up study looking at pain scores and satisfaction. Implementation of evidence-based programmes like ERAS (Enhanced Recovery After Surgery) have been shown to improve outcomes in patient care. (99)

Conclusion

Acute pain management in the South African context is still poorly managed. We as clinicians need to better understand the challenges our patients face, in various facets of their care. We need to appreciate the role of the patient as the most important member of the acute pain team. Pain should be managed holistically, effectively, timeously and wherever and whenever it is reported. Departments should strive to undertake best-evidence practice guidelines and protocols of care to manage their patients wherever possible. This will eliminate the potential for poor clinical outcomes and complications.

Discussion with the patient regarding the potential acute pain outcomes following a procedure is essential, whilst also incorporating their personal wishes.

We need to understand how we are currently performing in terms of acute pain management in our units, with our unique patients' needs and expectations in order to improve upon the shortcomings, where identified. Self-examined practice with the hope and aim of continual positive advancement is the only way one can begin to improve clinical service delivery, with the help of the entire clinical team.

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APPENDIX A: PAIN-OUT Process Questionnaire

PAIN OUT

A DATE OF DATA COLLECTION:	2 0 1 Y M M D D	D RESEARCH ASSISTANT CODE:	
B TIME OF DATA COLLECTION:	H H M M	PATIENT CODE:	
C WARD WHERE DATA IS COLLECTED:		ROOM NUMBER:	

SCREENING - INCLUSION CRITERIA

	yes	no
S1 Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward **End surgery:** Date: 2 0 1 Y M M D D Time: H H M M POD1? **Back in ward:** Date: 2 0 1 Y M M D D Time: H H M M 6HRS?	☐	☐
S2 Patient is consenting age or over	☐	☐
S3 Patient has given his assent (or consent) to participate	☐	☐

If **yes** to 1 and 2 and 3
- Give the Outcomes questionnaire to the patient
- Complete the Process questionnaire

If **no** to 1 or 2 or 3:
- Do not fill in the rest of the Process questionnaire
- Do not give the Outcomes questionnaire to the patient
- Input the screening data (up to the point you have reached) into the web mask

Special case: If **yes** to 1 and 2 and 3f and you have permission from the Ethics Committee in your hospital:
- Complete the Process questionnaire

If **no** to S3, mark the reason(s):

- ☐ a. Patient is not on the ward
- ☐ b. Patient does not wish to participate[1]
  - ☐ b1. too ill
  - ☐ b2. too much pain
  - ☐ b3. other
- ☐ c. Patient is asleep
- ☐ d. Patient has visitors
- ☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
- ☐ f. Patient is cognitively impaired (e.g., Downs syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
- ☐ g. Other, specify: _____

[1] Remember: You may interview patients who need help, e.g., are too ill or in too much pain or illiterate

DEMOGRAPHIC INFORMATION

D1 Gender	☐ Male ☐ Female	**D2 Year of birth**	1 9 Y Y
D3 Weight	_____ kg	**D4 Height**	_____ cm
D5 Nationality (check records)		**D6 Country of birth** (check records)	

D7 Language of Outcome questionnaire (select one)

☐ Albanian	☐ Arabic	☐ Bahasa Malaysia	☐ Danish	☐ Dutch	☐ English	☐ Filipino
☐ Finnish	☐ French	☐ German	☐ Hebrew	☐ Hindustani	☐ Italian	☐ Korean
☐ Mandarin	☐ Romanian	☐ Russian	☐ Serbo-Croatian	☐ Spanish	☐ Swedish	

BLANK FIELDS

Blank field 1: _____

Blank field 2: _____

Blank field 3: _____

Blank field 4: _____

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Page 2

Mark medications *given* to patient; record *cumulative* doses.

PATIENT CODE: ☐☐☐☐☐☐

MEDICAL HISTORY

H1 Comorbidities

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (check all that apply):

Cancer	☐ **Cancer**
Renal	☐ **Renal** insufficiency or disease **without dialysis** ☐ **Renal** disease **requiring dialysis**
Psychiatric	☐ **Affective disorders** (depression, anxiety, phobia, PTSD, bipolar disorder) ☐ **Schizophrenia** ☐ **Alcohol** use disorder ☐ Current **smoker** ☐ **Substance abuse** of drugs (legal and illegal)
Cardiovascular	☐ **Hypertension** ☐ **Coronary artery** disease or **myocardial infarction** or **cerebral vascular accident**
Hematology	☐ **Sickle cell disease**
GI disease	☐ **Liver Cirrhosis** ☐ History or current upper or lower **GI ulcer** (peptic or duodenal ulcer disease) ☐ **Irritable bowel disease** (Crohn's disease, ulcerative colitis)
Pulmonary disease	☐ **Asthma** ☐ **Sleep apnea** ☐ Chronic Obstructive Pulmonary Disease (**COPD**)
Neurologic	☐ **Fibromyalgia**
Steroid use	☐ Regular administration of **oral or parenteral corticosteroid** medications
Multiple trauma	☐ At least 1 **fracture**(s) / **laceration**(s) / **tissue damage** in addition to the current reason for surgery
Other surgery	☐ Patient has already undergone **another surgery** during current hospitalization
	☐ **Other**, specify:

H2 Existing condition (check medical record)

☐ Pregnancy, Week: ☐☐ ☐ not relevant ☐ not possible to obtain the information

☐ Lactation ☐ not relevant ☐ not possible to obtain the information

H3 Did the patient receive any opioid(s) before the current admission?

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	Immediate release (PO & other)	Controlled release; (PO & other)
Buprenorphine	☐ mg\day	☐ µg\hr transdermal
Codeine	☐ mg\day	☐ mg\day
Fentanyl	☐ µg\hr transmucosal / intranasal	☐ µg\hr transdermal
Hydrocodone	☐ mg\day	☐ mg\day
Hydromorphone	☐ mg\day	☐ mg\day
Morphine	☐ mg\day	☐ mg\day
Oxycodone	☐ mg\day	☐ mg\day
Oxycodone (with Naloxon)	☐ mg\day	☐ mg\day
Pethidine (Meperidine)	☐ mg\day	☐ mg\day
Tapentadol	☐ mg\day	☐ mg\day
Tilidin (w\wo Naloxon)	☐ mg\day	☐ mg\day
Tramadol	☐ mg\day	☐ mg\day
Other, specify:	☐	☐
Other, specify:	☐	☐

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Mark medications *given* to patient; record *cumulative* doses.

PATIENT CODE:

PRE - MEDICATION

M1 Sedatives (pre-medication)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	p.o.	i.v.
Diazepam	☐ mg	☐ mg
Clorazepate dipotassium	☐ mg	☐ mg
Haloperidol	☐ mg	☐ mg
Lorazepam	☐ mg	☐ mg
Midazolam	☐ mg	☐ mg
Promethazine	☐ mg	☐ mg
Other, specify:	☐ mg	☐ mg

M2 Non-opioids (pre-medication)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	p.o.	i.v.	i.m.	supp.
Celecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Diclofenac	☐ mg	☐ mg	☐ mg	☐ mg
Etoricoxib	☐ mg	☐ mg	☐ mg	☐ mg
Gabapentin	☐ mg	☐ mg	☐ mg	☐ mg
Ibuprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketoprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketorolac	☐ mg	☐ mg	☐ mg	☐ mg
Metamizol	☐ mg	☐ mg	☐ mg	☐ mg
Naproxen	☐ mg	☐ mg	☐ mg	☐ mg
Nefopam	☐ mg	☐ mg	☐ mg	☐ mg
Paracetamol (Acetaminophen)	☐ mg	☐ mg	☐ mg	☐ mg
Parecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Pregabalin	☐ mg	☐ mg	☐ mg	☐ mg
Other, specify:	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐

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Mark medications *given* to patient; record *cumulative* doses.

PATIENT CODE:

PRE - MEDICATION

M3 Opioids (pre-medication)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	Immediate release (PO & other)	Controlled release (PO & other)	i.v.	i.m.	supp.	s.c.
Buprenorphine	☐ mg	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr
Codeine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Fentanyl	☐ µg\hr transmucosal	☐ µg\hr transdermal	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr
Hydrocodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Hydromorphone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Morphine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Nalbuphine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Oxycodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Oxycodone (with Naloxon)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Pethidine (Meperidine)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Piritramide	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Sufentanil	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg
Tapentadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Tilidin (w\wo Naloxon)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Tramadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg
Other, specify:	☐	☐	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐	☐	☐

SURGICAL PROCEDURE(S)

P1 Surgical procedure(s)

use ICD-9 codes link **http://icd9cm.chrisendres.com/index.php?action=procslist**

	ICD-9 Procedure Code		Text (only for your notes, not necessary for mask)
1		1	
2		2	
3		3	
4		4	

P2 Duration of surgery

Start surgery: Date: 2 0 1 Y M M D D Time: H H M M

End surgery: Date: 2 0 1 Y M M D D Time: H H M M

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Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE:

INTRA-OPERATIVE

M4 General anaesthesia (intra-op)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☐ Inhalational	☐ IV

M5 Regional anaesthesia (RA) (intra-op)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☐ Epidural	☐ Spinal	☐ Brachial plexus	☐ Femoral
☐ Sciatic	☐ Paravertebral	☐ Other:	☐ Other:

In M8: Mark the RA medication(s) given in the RA column

M6 Non-opioids (intra-op)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	i.v.	i.m.	supp.
Clonidine	☐ mg	☐ mg	☐ mg
Diclofenac	☐ mg	☐ mg	☐ mg
Ibuprofen	☐ mg	☐ mg	☐ mg
Ketamine	☐ mg	☐ mg	☐ mg
Ketoprofen	☐ mg	☐ mg	☐ mg
Ketorolac	☐ mg	☐ mg	☐ mg
Metamizol	☐ mg	☐ mg	☐ mg
Naproxen	☐ mg	☐ mg	☐ mg
Nefopam	☐ mg	☐ mg	☐ mg
Paracetamol (Acetaminophen)	☐ mg	☐ mg	☐ mg
Parecoxib	☐ mg	☐ mg	☐ mg
Other, specify:	☐	☐	☐
Other, specify:	☐	☐	☐
	i.v.	i.m.	supp.

Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE:

INTRA-OP

M7 Wound infiltration (intra-op)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible; analgesic is not recorded):

☐ Single shot by surgeon ☐ Indwelling catheter ☐ Other, specify: ☐ Other, specify:

M8 Opioids & local anaesthetics (intra-op)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	RA (see M5)	i.v.	i.m.	s.c.
Alfentanil	☐ mg	☐ mg	☐ mg	☐ mg
Buprenorphine	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr
Codeine	☐ mg	☐ mg	☐ mg	☐ mg
Fentanyl	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr
Hydrocodone	☐ mg	☐ mg	☐ mg	☐ mg
Hydromorphone	☐ mg	☐ mg	☐ mg	☐ mg
Morphine	☐ mg	☐ mg	☐ mg	☐ mg
Nalbuphin	☐ mg	☐ mg	☐ mg	☐ mg
Oxycodone	☐ mg	☐ mg	☐ mg	☐ mg
Pethidine (Meperidine)	☐ mg	☐ mg	☐ mg	☐ mg
Piritramid	☐ mg	☐ mg	☐ mg	☐ mg
Remifentanil	☐ mg	☐ mg	☐ mg	☐ mg
Sufentanil	☐ µg	☐ µg	☐ µg	☐ µg
Tramadol	☐ mg	☐ mg	☐ mg	☐ mg
Bupivacaine	☐	☐	☐	☐
Levobupivacaine	☐	☐	☐	☐
Lidocaine	☐	☐	☐	☐
Prilocaine	☐	☐	☐	☐
Ropivacaine	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐
	RA	i.v.	i.m.	s.c.

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Mark medications *given* to patient; record *cumulative* doses.

PATIENT CODE:

REGIONAL ANAESTHESIA

M7 Regional analgesia

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☐ yes ☐ no ☐ not possible to obtain the information

If yes, please specify:

1 Type

☐ Epidural	☐ Spinal (Intrathecal)	☐ Brachial plexus ☐ interscalene ☐ supraclavicular ☐ intraclavicular ☐ axillary	☐ Femoral	☐ Sciatic nerve ☐ subgluteal ☐ popliteal	☐ Other ☐ Intercostal ☐ Paravertebral ☐ Psoas ☐ Transabdominus planar block (TAP)

2 Technique

☐ Single shot	☐ Continuous catheter	☐ PCA (continuous + bolus)	☐ PCA (only bolus)	☐ Implanted pump

3 Phase of care initiated

☐ Preop	☐ Intraop	☐ Recovery room	☐ Ward

4 Local anaesthesia

1. If catheter and single shot were used: document local anaesthetic of catheter
2. If PCA bolus + continuous: document cumulative dose of boli in mL and continous dose in mL/h
3. If PCA bolus: document cumulative dose in mL

☐ Bupivacaine	☐ Levobupivacaine	☐ Lidocaine	☐ Prilocaine	☐ Ropivacaine	☐ Other, specify:
____ %	____ %	____ %	____ %	____ %	____ %
No cath / PCA: ____ mL	No cath / PCA: ____ mL	No cath / PCA: ____ mL	No cath / PCA: ____ mL	No cath / PCA: ____ mL	No cath / PCA: ____ mL
Catheter: ____ mL/h	Catheter: ____ mL/h	Catheter: ____ mL/h	Catheter: ____ mL/h	Catheter: ____ mL/h	Catheter: ____ mL/h

5 Opioids and others

If catheter and single shot were used: document drugs of catheter

☐ Clonidine	☐ Epinephrine	☐ Fentanyl	☐ Hydromorphone	☐ Morphine	☐ Sufentanil
____ %	____ %	____ %	____ %	____ %	____ %
No cath / PCA: ____ µg	No cath / PCA: ____ µg	No cath / PCA: ____ µg	No cath / PCA: ____ µg	No cath / PCA: ____ µg	No cath / PCA: ____ µg
Catheter: ____ µg/h	Catheter: ____ µg/h	Catheter: ____ µg/h	Catheter: ____ µg/h	Catheter: ____ µg/h	Catheter: ____ µg/h

6 Catheter (dis)continued

☐ Catheter continued

☐ Catheter discontinued

- ☐ From beginning no effect (probably never in right place)
- ☐ Stopped following protocol for this surgery
- ☐ Other reason, specify: ____
- ☐ Catheter dislocated
- ☐ Not possible to obtain reason

Time when catheter was discontinued: H H M M

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Mark medications *given* to patient; record *cumulative* doses.

PATIENT CODE:

RECOVERY ROOM

M9 Non-opioids (recovery room)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	p.o.	i.v.	i.m.	supp.
Celecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Clonidine	☐ mg	☐ mg	☐ mg	☐ mg
Diclofenac	☐ mg	☐ mg	☐ mg	☐ mg
Etoricoxib	☐ mg	☐ mg	☐ mg	☐ mg
Gabapentin	☐ mg	☐ mg	☐ mg	☐ mg
Ibuprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketamine	☐ mg	☐ mg	☐ mg	☐ mg
Ketoprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketorolac	☐ mg	☐ mg	☐ mg	☐ mg
Metamizol	☐ mg	☐ mg	☐ mg	☐ mg
Naproxen	☐ mg	☐ mg	☐ mg	☐ mg
Nefopam	☐ mg	☐ mg	☐ mg	☐ mg
Paracetamol (Acetaminophen)	☐ mg	☐ mg	☐ mg	☐ mg
Parecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Pregabalin	☐ mg	☐ mg	☐ mg	☐ mg
Other, specify:	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐
	p.o.	i.v.	i.m.	supp.

M10 Regional analgesia (recovery room)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☐ Epidural	☐ Spinal	☐ Brachial plexus	☐ Femoral
☐ Sciatic	☐ Paravertebral	☐ Other:	☐ Other:

In M11: (1) Mark the RA medication(s) given in the RA column
(2) If the medication was given as PCA, tick appropriate box in the PCA column

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Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE:

RECOVERY ROOM

M11 Opioids & local anaesthetics (recovery room)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible)

	Immediate release (PO & other)	Controlled release (PO & other)	RA (see M10)	i.v.	i.m.	supp.	s.c.	PCA (see M10)
Buprenorphine	☐ mg	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐
Codeine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Fentanyl	☐ µg\hr transmucosal	☐ µg\hr transdermal	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐
Hydrocodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Hydromorphone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Morphine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Nalbuphin	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Oxycodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Oxycodone (with Naloxone)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Pethidine (Meperidine)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Piritramid	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Sufentanil	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐
Tapentadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Tilidin (w\wo Naloxon)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Tramadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Bupivacaine	☐	☐	☐	☐	☐	☐	☐	☐
Levobupivacaine	☐	☐	☐	☐	☐	☐	☐	☐
Lidocaine	☐	☐	☐	☐	☐	☐	☐	☐
Prilocaine	☐	☐	☐	☐	☐	☐	☐	☐
Ropivacaine	☐	☐	☐	☐	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐	☐	☐	☐	☐
Naloxone (only as an antagonist for respiratory depression)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
	Immediate release (PO & other)	Controlled release (PO & other)	RA	i.v.	i.m.	supp.	s.c.	PCA

Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE: ☐

WARD

M12 Non-opioids (ward)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	p.o.	i.v.	i.m.	supp.
Celecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Clonidine	☐ mg	☐ mg	☐ mg	☐ mg
Diclofenac	☐ mg	☐ mg	☐ mg	☐ mg
Etoricoxib	☐ mg	☐ mg	☐ mg	☐ mg
Gabapentin	☐ mg	☐ mg	☐ mg	☐ mg
Ibuprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketamine	☐ mg	☐ mg	☐ mg	☐ mg
Ketoprofen	☐ mg	☐ mg	☐ mg	☐ mg
Ketorolac	☐ mg	☐ mg	☐ mg	☐ mg
Metamizol	☐ mg	☐ mg	☐ mg	☐ mg
Naproxen	☐ mg	☐ mg	☐ mg	☐ mg
Nefopam	☐ mg	☐ mg	☐ mg	☐ mg
Paracetamol (Acetaminophen)	☐ mg	☐ mg	☐ mg	☐ mg
Parecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Pregabalin	☐ mg	☐ mg	☐ mg	☐ mg
Other, specify:	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐
	p.o.	i.v.	i.m.	supp.

M13 Regional analgesia (ward)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☐ Epidural	☐ Spinal	☐ Brachial plexus	☐ Femoral
☐ Sciatic	☐ Paravertebral	☐ Other:	☐ Other:

In M14: (1) Mark the RA medication(s) given in the RA column
(2) If the medication was given as PCA, tick appropriate box in the PCA column

Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE:

WARD

M14 Opioids & local anaesthetics (ward)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	Immediate release (PO & other)	Controlled release (PO & other)	RA (see M13)	i.v.	i.m.	supp.	s.c.	PCA (see M13)
Buprenorphine	☐ µg	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐
Codeine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Fentanyl	☐ µg\hr transmucosal	☐ µg\hr transdermal	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐
Hydrocodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Hydromorphone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Morphine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Nalbuphin	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Oxycodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Oxycodone (with Naloxone)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Pethidine (Meperidine)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Piritramid	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Sufentanil	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐ µg	☐
Tapentadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Tilidin (w\wo Naloxon)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Tramadol	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Bupivacaine	☐	☐	☐	☐	☐	☐	☐	☐
Levobupivacaine	☐	☐	☐	☐	☐	☐	☐	☐
Lidocaine	☐	☐	☐	☐	☐	☐	☐	☐
Prilocaine	☐	☐	☐	☐	☐	☐	☐	☐
Ropivacaine	☐	☐	☐	☐	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐	☐	☐	☐	☐
Other, specify:	☐	☐	☐	☐	☐	☐	☐	☐
Naloxone (only as an antagonist for respiratory depression)	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
	Immediate release (PO & other)	Controlled release (PO & other)	RA	i.v.	i.m.	supp.	s.c.	PCA

M15 Measurement of pain: Was pain documented as defined in the SOPs?

☐ yes ☐ no ☐ not possible to obtain the information

APPENDIX B: PAIN-OUT Patient Outcomes Questionnaire

PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

The following questions are about pain you experienced since your surgery.

P1. On this scale, please indicate the **worst pain** you had since your surgery:

0	1	2	3	4	5	6	7	8	9	10

no pain **worst pain possible**

P2. On this scale, please indicate the **least pain** you had since your surgery:

0	1	2	3	4	5	6	7	8	9	10

no pain **worst pain possible**

P3. How often were you in **severe pain** since your surgery?
Please circle your best estimate of the percentage of time you experienced **severe pain**:

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

never in severe pain **always in severe pain**

P4. Circle the one number below that best describes how much, since your surgery, **pain interfered with or prevented you from** ...

a. doing **activities in bed** such as turning, sitting up, changing position:

0	1	2	3	4	5	6	7	8	9	10

did not interfere **completely interfered**

b. **breathing deeply** or **coughing**:

0	1	2	3	4	5	6	7	8	9	10

did not interfere **completely interfered**

c. **sleeping**:

0	1	2	3	4	5	6	7	8	9	10

did not interfere **completely interfered**

d. Have you been **out of bed** since your surgery?

☐ Yes ☐ No

If yes, how much did **pain interfere or prevent you from doing activities out of bed** such as walking, sitting in a chair, standing at the sink:

0	1	2	3	4	5	6	7	8	9	10

did not interfere **completely interfered**

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PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

P5. Pain can affect our mood and emotions.
On this scale, please circle the one number that best shows how much, since your surgery, **pain caused you to feel** ...

a. **anxious**

0	1	2	3	4	5	6	7	8	9	10
not at all										**extremely**

b. **helpless**

0	1	2	3	4	5	6	7	8	9	10
not at all										**extremely**

P6. Have you had any of the following **side effects** since your surgery?
Please circle "0" if no; if yes, circle the one number that best shows the severity of each:

a. **Nausea**

0	1	2	3	4	5	6	7	8	9	10
none										**severe**

b. **Drowsiness**

0	1	2	3	4	5	6	7	8	9	10
none										**severe**

c. **Itching**

0	1	2	3	4	5	6	7	8	9	10
none										**severe**

d. **Dizziness**

0	1	2	3	4	5	6	7	8	9	10
none										**severe**

P7. Since your surgery, how much **pain relief** have you received?
Please circle the one percentage that best shows how much relief you have received from all of your **pain treatments** combined (medicine and non-medicine treatments):

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
no relief										**complete relief**

P8. Would you have liked **MORE pain treatment** than you received?

☐ Yes ☐ No

P9. Did you receive any **information** about your **pain treatment** options?

☐ Yes ☐ No

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PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

P10. Were you **allowed to participate in decisions** about your **pain treatment** as much as you wanted to?

0	1	2	3	4	5	6	7	8	9	10

not at all **very much so**

P11. Circle the one number that best shows how **satisfied** you are with the results of your **pain treatment** since your surgery:

0	1	2	3	4	5	6	7	8	9	10

extremely dissatisfied **extremely satisfied**

P12. Did you use or receive any **non-medicine methods** to relieve your **pain**?

☐ Yes ☐ No

If yes, **check all** that apply:

☐ cold pack ☐ meditation ☐ deep breathing
☐ heat ☐ acupuncture ☐ prayer
☐ talking to medical staff ☐ walking ☐ massage
☐ talking to friends or relatives ☐ relaxation ☐ imagery or visualization
☐ TENS (Transcutaneous Electrical Nerve Stimulation)
☐ distraction (like watching TV, listening to music, reading)
☐ other (please describe):

P13. Did you have a **persistent painful condition for 3 months** or more before coming into hospital for this surgery?

☐ Yes ☐ No

a. If yes, **how severe** was the **pain** most of the time?
Please circle the number that indicates this.

0	1	2	3	4	5	6	7	8	9	10

no pain **worst pain possible**

b. If yes, **where** was this **persistent pain** located?

☐ site of surgery ☐ elsewhere ☐ both (site of surgery and elsewhere)

Thank you for your time and feedback

To be filled in by the research assistant Research assistant code:

Patient was interviewed: ☐ Yes ☐ No

If yes, please mark the reason(s):

☐ Too ill / weak ☐ Too much pain ☐ Requested assistance ☐ Did not understand scales
☐ Technical reasons (patient has no eyeglasses / is blind; can not sit up; is illiterate; arm is in cast; etc)

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APPENDIX C: Letter to CEO Rahima Moosa Hospital

Rahima Moosa Mother and Child Hospital

Cnr. Fuel & Oudtshoorn Streets, Coronationville, Randburg, 2093

Private Bag 20

Newclare

Randburg, Johannesburg

2112

July 2014

Attention: Chief Executive Officer Rahima Moosa Mother and Child Hospital

RE: Permission to conduct research at RMMCH

Dear Ms Jordaan,

I am a registrar in the Department of Anaesthesiology of the University of the Witwatersrand and I am registered for the Master of Medicine degree. The title of my proposed research is “The peri-operative pain management of total abdominal hysterectomy patients at an academic hospital”. This has been approved by the Postgraduate Committee and the Human Research Ethics Committee (HREC) of the University of the Witwatersrand (Certificate number: M140843).

I hereby apply for permission to collect prospective data on the incidence of acute postoperative pain and satisfaction levels in our patients presenting for elective total abdominal hysterectomies with the aim of conducting a three-month performance audit of our anaesthetic department functions in this field. We will be utilising the PAIN-OUT international database methods for data collection and interpretation.

There will be no financial implications for the hospital in order for us to conduct this study.

Should you require any further information, kindly contact me.

Attached please find a copy of my MMed proposal and HREC clearance.

Thanking you in advance for your assistance.

Kind regards,

_____

Dr Lauren Dawn Dougall

MBBCH (Wits) DA (SA)

Registrar in the Department of Anaesthesiology

University of the Witwatersrand

APPENDIX D: Patient information letter for participation in study

July 2014

Dear patient,

Hello, my name is Lauren Dougall and I am a doctor specialising in the care of patients at the time of their surgery. I am a registrar undergoing further training at the University of the Witwatersrand in order to become a qualified anaesthetist (the doctor who makes you sleep during an operation and treats your pain afterwards).

I would like to invite you to be a part of a study I am conducting at this hospital for all patients having had a hysterectomy to remove their womb with a cut made on their abdomen. I am trying to find out how much pain our patients are feeling after they have had this type of operation and how well we are doing as doctors and nurses to make your stay as comfortable and as pain-free as possible. This research will be handed in to the Department of Anaesthesiology at Wits University as part of my Masters degree.

It will take about ten minutes for you to complete the questionnaire. You may ask for my assistance in order to complete the questions. If there is a question that is unclear to you or that you do not wish to answer, you may leave it blank.

If you choose to take part in this research, your information will be kept completely anonymous and there will be no way for others to link the questionnaires back to you. The information shared by you and taken from your file will be confidential at all times, none of the information will be shared with others. The doctors and nurses looking after you in the ward will not have access to your answers. Only my supervisors and myself will see the answers.

The answers you give will not affect the way in which you are cared for during your stay in this ward. Every patient will still receive the same care after their operation as if this research were not taking place. Your involvement in this research is completely voluntary and you may decide to change your mind and not be included at any time, by simply informing us, without needing to give a reason. There may be no direct benefit to you for taking part in this study but the information will be used to help improve the care of future patients coming to RMMCH for hysterectomies. There is no penalty for choosing not to be involved. If you have unsatisfactorily high pain levels, I will contact your treating doctors to assist you and ensure that you are receiving the best care.

Please ensure that you have read and understood the information contained in this letter before completing the questionnaire. I, as the researcher, will complete another questionnaire using information from your hospital file about treatments you were given to help with pain before, during and after your operation.

If you choose to assist us with collecting information about your experience, please sign the separate consent form provided (you will be given a copy of this letter and your signed consent form).

Thank you for taking the time to read this letter. If you have any questions or concerns, please contact the researchers on (011) 488-4397 or the chairman of the Human Research Ethics Committee at Wits University on (011) 717-1234.

Yours Sincerely,

_____

Dr Lauren Dawn Dougall - MBBCh (Wits) DA (SA)

Registrar, RMMCH Department of Anaesthesiology

APPENDIX E: Patient written consent for study inclusion

July 2014

MMed Study: “The peri-operative pain management of total abdominal hysterectomy patients at an academic hospital”

The details and purpose of the MMed study has been discussed as per the information letter given to each potential participant.

Participation is completely voluntary and can be withdrawn at any time.

Contact details of the researchers have been provided to each patient.

I, _____ (insert name) hereby voluntarily consent to be involved in this study to assess patient care and pain levels after abdominal hysterectomy at RMMCH. I understand that my information will be kept completely anonymous and confidential and will be analysed in order to help doctors offer patients better care in this field. I understand that I can withdraw my involvement at any time, without reason.

I undertake to complete the Patient Outcomes Questionnaire provided by the researcher, to the best of my ability, to assist with data collection.

_____ _____

Patient’s Signature Date

APPENDIX F: UCT HREC Clearance Letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 404 7682
Email: nosi.tsama@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

28 August 2017

HREC REF: 616/2017

Dr J van Nugteren
D23 Anaesthesia & Periop Medicine
NGSH

Dear Dr van Nugteren

PROJECT TITLE: THE PERI-OPERATIVE PAIN MANAGEMENT OF TOTAL ABDONIMAL HYSTERECTOMY PATIENTS AT AN ACADEMIC HOSPITAL-MMeD-candidate-Dr L Dougall)

Thank you for submitting study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th August 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student Dr L Dougall will be involved in this study.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical

APPENDIX G: Wits University HREC Clearance Letter

R14/49 Dr Lauren Dawn Dougall et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140843

NAME: (Principal Investigator)	Dr Lauren Dawn Dougall et al
DEPARTMENT:	Anaesthesiology Rahima Moosa Mother and Child Hospital
PROJECT TITLE:	The Peri-Operative Pain Management of Total Abdominal Hysterectomy Patients at an Academic Hospital
DATE CONSIDERED:	29/08/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Ms Helen Perrie
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	08/04/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX H: Permission from Wits to complete research at UCT

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | FACULTY OF HEALTH SCIENCES

6 January 2017

Dr Lauren Dougall
Student No: 0500146A

Dear Dr Dougall

Requesting permission to use Wits Research report towards MMed marking at UCT

Thank you for your request to use research started at the Wits Faculty of Health Sciences towards completion of your MMed degree at the University of Cape Town. Thank you also for forwarding the communication indicating support from your supervisors, the Academic Head of the Department of Anaesthesiology and the Head of School of Clinical Medicine.

This letter serves to grant you permission to pursue the research for the completion and awarding of the degree by UCT.

We wish you well with your studies and look forward to hearing of your progress.

Yours sincerely

Martin Veller
Dean, Faculty of Health Sciences

Cc: Professor Maria Papathanasopoulos: Assistant Dean, Research & Postgraduate Support
Professor Mkhululi Lukhele – Head, School of Clinical Medicine

Office of the Dean
Phillip V Tobias Health Sciences Building | 29 Princess of Wales Terrace (cnr York Road), Parktown 2193, Johannesburg, South Africa
T +27 11 717 2555 | **E** poovy.govender@wits.ac.za | www.wits.ac.za

APPENDIX I: Permission letter from RMMCH CEO to conduct study

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

RAHIMA MOOSA MOTHER AND CHILD HOSPITAL

RAHIMA MOOSA MOTHER AND CHILD HOSPITAL
Enquiries: Mrs. S. Jordaan
Tel: (011) 470 9030/4
Fax: (011) 477 4117
Email: sjordaan@icon.co.za

University of Witwatersrand
Department of Anaesthesiology
Faculty of Humanities
JOHANNESBURG
2001

Re:"The Peri-Operative Pain management of Total Abdominal Hysterectomy patients at an Academic Hospital"

Dear Dr. Lauren D. Dougall

Permission is granted for you to conduct the research as indicated in your request as per the title above.

The terms under which this permission is granted is contained in the Researcher Declaration form that you signed. Failure to comply with these conditions will result in the withdrawal of such permission.

Note that it is imperative that you notify the hospital of the actual start and end dates of your study by notifying the CEO's secretary preferably by email or fax.

Should the study commence more than 12 months from receipt of this letter then the Researcher Declaration form needs to be re-signed prior to commencement of the research. Your are strongly advised to keep a signed copy of the declaration form so as to ensure that the terms of this agreement are complied with at all times.

Yours sincerely,

Sjordaan

CHIEF EXECUTIVE OFFICER
SJ/cj. 2015 - 02-02

ADDRESS: cnr. FUEL & OUDSTHOORN STREET CORONATIONVILLE 2093 / PRIVATE BAG X20 NEWCLARE 2112 JHB