Post-total abdominal hysterectomy pain experience of patients at academic hospitals with and without a pain service

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

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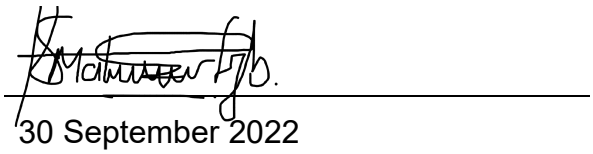
Declaration

I, Utshudi Joe Malumalu, declare that this research report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



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Abstract

Background

Acute post-operative pain management remains sub-optimal despite introducing acute pain services. Not all hospitals have an acute pain service, and where they do exist, there is wide variability in efficiency. This study aimed to compare the pain experience on Day 1 post-total abdominal hysterectomy (TAH) of patients exposed to a pain service at Rahima Moosa Mother and Child Hospital (RMMCH) and those at Chris Hani Baragwanath Academic Hospital (CHBAH) with no pain service.

Methods

A comparative cross-sectional research design was followed using convenience sampling. The PAIN-OUT questionnaire was used to collect data. There were 72 patients from RMMCH and 70 from CHBAH enrolled in the study.

Results

There were no significant differences between the worst and least pain scores and time in severe pain between the patients at RMMCH and CHBAH with median scores of 7 versus 8 (p=0.6490), 3 versus 4 (p=0.064) and 40% versus 45% (p=0.195), respectively. There were also no significant differences in pain scores for in-bed activities 4 versus 5 (p=0.166) or the incidence of nausea, drowsiness, itching and dizziness 0 versus 1 (p=0.089), 3 versus 3 (p=0.498), 0 versus 0 (p=0.441) and 2 versus 2 (p=0.626), respectively. Satisfaction with pain management was not significantly different between the patients at the two hospitals, 9 versus 8 (p=0.123).

Conclusion

Although post-operative pain management is regarded as a fundamental human right, TAH post-operative pain was poorly managed in this study. There was no significant difference between the pain scores and the side effects experienced between patients at the two hospitals, despite an office-hours acute pain service at one of the hospitals. Patients at RMMCH experienced significantly less pain with out of bed activities, deep breathing or coughing and sleeping and felt less anxious and helpless. Patients at both hospitals were satisfied with pain management.

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I am extremely grateful to my parents for their love, prayers, caring and sacrifices for educating and preparing me for my future. I am very much thankful to my wife, my daughter and son for their love, understanding, prayers, you all have remained the reason for my life.

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Abbreviations

APS	Acute pain service
CHBAH	Chris Hani Baragwanath Academic Hospital
IASP	International Association for the Study of Pain
IV-PCA	Intravenous patient-controlled analgesia
NRS	Numerical rating scale
NSAIDS	Nonsteroidal anti-inflammatory drugs
PCA	Patient controlled analgesia
RMMCH	Rahima Moosa Mother and Child Hospital
SASA	South African Society of Anaesthesiologists
TAH	Total abdominal hysterectomy
TAP	Transversus abdominis plane
TRPV1	Transient receptor potential vanilloid type1
WFSA	World Federation of Societies of Anaesthesiologists
WHO	World Health Organization
Wits	University of the Witwatersrand

Statement

The Research Report consists of a literature review, draft article, study proposal and appendices. The study proposal is included for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The formatting of the draft article may differ from the author guidelines of the Southern Africa Journal of Anaesthesia and Analgesia, the journal to which it is intended to be submitted, in order to comply with the University's style guide.

Section 1: Review of the literature

1.1 Introduction

A total abdominal hysterectomy (TAH) is considered a major surgical procedure and is associated with moderate to severe pain post-operatively (1-3). TAH is one of the most common surgical procedures performed in gynaecology, and the severity of pain is often underestimated (2, 4-6)

This section briefly discusses the definition, classification and physiology of pain, assessment of acute post-operative pain, and post-operative pain management following hysterectomy.

1.2 Definition, classification and physiology of pain

Pain is defined by the International Association for the Study of Pain (7) as “an unpleasant sensory and emotional experience associated with or resembling that associated with actual or potential tissue damage”. The Association states the following six keynotes.

- “Pain is always a personal experience that is influenced to varying degrees by biological, psychological, and social factors.
- Pain and nociception are different phenomena. Pain cannot be inferred solely from activity in sensory neurons.
- Through their life experiences, individuals learn the concept of pain.
- A person’s report of an experience as pain should be respected.
- Although pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being.
- Verbal description is only one of several behaviours to express pain; inability to communicate does not negate the possibility that human or nonhuman animal experiences pain” (7).

Pain can be referred to as a normal defence mechanism aiming to protect the human tissue from damage, further damage or a translation of actual damaged tissue (8, 9). Pain might also be a disease whereby the protective mechanism is defective or simply dysfunctional, and nociception is not the cause (7, 9, 10).

Traditionally, pain is classified as acute or chronic based on the time course of three months, nociceptive, inflammatory or neuropathic according to the pathophysiology and mild, moderate or severe based on the assessment score (7, 8). This arbitrary classification is subject to criticism as all types of pains may coexist (8). Clinically, acute post-operative pain is suggested to be the pain experienced after a surgical procedure due to an identifiable cause such as trauma, inflammation or procedure-related complications and does not persist disproportionately long following the surgery (8). Should pain persist, it is considered chronic (3, 4, 8, 11, 12).

The neural mechanisms of acute post-operative pain after TAH are mainly nociceptive, thermal-mechanical and inflammatory (3, 4, 13) but occasionally neuropathic (8). Acute neuropathic pain in the post-operative period often results from peripheral nerve damage (8, 14). Four physiological processes are involved in the nociceptive pain pathway: transduction, transmission, modulation, and perception (15, 16). Transduction refers to the process by which tissue-damaging stimuli activate nerve endings, generating an electrical impulse (8, 17). During TAH, tissue damage associated with the incision of the abdominal wall and the dissection of the viscera leads to the release of nociceptive chemical mediators that activate the nociceptors directly or reduce their activation threshold (17, 18). The heat produced by the diathermy during incision and dissection also sensitises the nociceptors, which, by direct activation of the transient receptor potential vanilloid type1 or via the oxidative metabolites of linoleic acid, represents the thermal component of nociception (8, 18, 19). The stretching and pulling of muscle and viscera during the surgical procedure also sensitise the nociceptors and represent the mechanical component of nociception (18). The molecular receptors that respond to noxious mechanical stimuli have not yet been identified (20). This process requires the initial stimuli to be of significant magnitude, and the distribution across the nociceptors needs to be sufficient for the electrical potential to be transformed into an action potential to allow transmission to the central nervous system (15-17).

During transmission, the electrical impulse is relayed to the central nervous system by the axon of the primary afferent fibre (17). Nociception from TAH has

two aspects, namely somatic and visceral (21, 22). The somatic aspect is superficial and deep (23). The superficial somatic nociception arises from the skin and subcutaneous tissues of the abdominal wall. It is transmitted to the dorsal horn of the spinal cord via Aδ nerve fibres and myelinated C fibres (23). Glutamate is the main neurotransmitter involved (15). This transmission is fast and often perceived as sharp, well-localised pain when activated (15, 17). The deep somatic nociception arises from the abdominal wall muscles and fascia, transmitted to the dorsal horn via unmyelinated C fibres (23) and is responsible for a burning, slow, poorly localised pain (15, 16). Substance P is the main neurotransmitter in this pathway (8, 15). These fibres run through thoracoabdominal nerves (T7 – T11), subcostal nerve (T12) and iliohypogastric-ilioinguinal nerves (L1) between the internal oblique and the transversus abdominis muscle (23). Transversus abdominis plane (TAP) block may successfully suppress this nociception (15).

The visceral aspect arises mainly from the uterus and is transmitted to the dorsal horn via the unmyelinated C fibres within afferent nerves (23). Impulses from the intraperitoneal uterus run through lower thoracic and upper lumbar splanchnic nerves along with sympathetic nerves to reach the cell bodies in the spinal ganglia (23). Nociception from the subperitoneal uterine cervix and visceral vagina follow the parasympathetic fibres through the uterovaginal and hypogastric plexuses and the pelvic splanchnic nerves to reach the spinal sensory ganglia at S2 – S4 level (23). Caudal and saddle blocks will suppress the subperitoneal nociception only. Epidural or spinal blocks may suppress intra- and subperitoneal nociception, including the abdominal somatic impulses. Lastly, a pudendal block only affects the lower vagina, which is somatic by nature and supplied by the pudendal nerve (15).

Modulation is a peripheral and central process of inhibiting or facilitating the pain sensation (16). Central mechanisms of facilitation and inhibition involve several neurotransmitters and opioid receptors and explain why cyclooxygenase inhibitors, opioids, selective serotonin reuptake inhibitors, tricyclic agents and α2 agonists have central analgesic action (15, 22, 24).

Perception is the subjective awareness of nociception. It is a complex process in the central nervous system involving the integration of many sensory impulses into

a relevant message perceived as pain (25). Perception has a physiological neural basis but is highly dependent on subjective genetic, environmental and psychological factors such as attention and expectation (8, 24). Therefore, the interpretation of pain cannot be directly and objectively measured (18, 25).

Pain must always be seen in the context of mixed matrix interactions between biological and psychological processes. Attempting pain management without considering these interactions will lead to frustration and failure (16).

1.3 Assessment of acute post-operative pain

Regular, individual assessment of pain may lead to improved management of acute pain (8). Pain is a subjective experience, making pain assessment challenging for clinical or research purposes (26). It has long been known that the severity of pain post-operatively may not correlate with the severity of tissue damage or surgical incision size (18, 27, 28). The severity of post-operative pain is determined by patient factors such as individual pain modulation, individual response to analgesia (29-31), expectations, previous pain experience, cultural beliefs, mood and psychological factors and certain surgical factors such as the type and location of surgery (8).

Pain is considered the fifth vital sign (8, 12, 32). Several pain assessment scales have been validated for accurately detecting the presence and severity of pain and tested for reliability (32). Guidelines recommend using these tools, although there is inadequate evidence that the tools change post-operative pain outcomes (28, 32). There are various scales in common use, and they can be classified as:

- Numerical rating scales (NRS)
- Visual analogue scales
- Qualitative-categorical scales.

The selection of a particular tool is based on factors such as age, developmental status, cognitive status, level of consciousness, education level, language and cultural differences (8, 32). No single pain scale is considered ideal or better than the other for every situation (8, 12).

Acute pain, such as TAH post-operative pain, requires only unidimensional assessment and measurement. It is not practical or efficient to employ questionnaires addressing qualitative aspects of pain (12). An example of a unidimensional assessment and measurement tool is the PAIN-OUT patient outcomes questionnaire (33).

PAIN-OUT (33) is an international project of the International Association for the Study of Pain based in Europe that provides a web-based information system intended to improve the treatment of patients with post-operative pain. Participating hospitals worldwide collect patient-reported outcome data as well as clinical data in a standardised way using a questionnaire available in more than 20 languages. After the input of data, hospitals receive online feedback and can compare their results with other participating hospitals. This helps to identify deficits in pain management, allowing for improvements to be made (33).

1.4 Post-operative pain management following hysterectomy

Background

International guidelines (8, 28, 32, 34-36) and the 2017 South African Acute Pain Guidelines (12) recommend multimodal analgesia whenever possible to manage acute post-operative pain. The Guidelines for Perioperative Care in Gynaecology and Oncology: Enhanced Recovery After Surgery (ERAS) recommendations (37) also recommend multimodal analgesia emphasising opioids sparing strategies. Avoiding opioid use in multimodal post-operative analgesia improves patient experience and functional recovery after surgery (38). Multimodal analgesia aims to provide the best possible pain relief to minimise the multi-systemic deleterious effects caused by the stress response with minimal side effects from each group of therapy used in combination (28, 34-37, 39).

Multimodal analgesia is defined as the use of various analgesic medications and techniques sometimes combined with non-pharmacological interventions to target different mechanisms of action in the peripheral or central nervous system or both and have additive or synergistic effects and more effective pain relief compared to single modality interventions (28, 32, 36). Multimodal analgesia can be achieved by combining neuraxial techniques or regional blocks with systemic agents like

opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), paracetamol, N-methyl-d-aspartate receptor antagonist drugs, alpha-2 adrenomimetic drugs, alpha-2 delta agonists, corticosteroids and local anaesthetics, among others (4, 28, 32, 36). Multimodal analgesia also includes physical modalities such as transcutaneous electrical nerve stimulation, cold therapy, massage, localised heat, passive motion, acupuncture (32) and cognitive-behavioural modalities such as relaxation methods, guided imagery, hypnosis and music (32).

An epidural is regarded by experts as the gold standard for acute post-operative pain management after major abdominal surgery such as TAH by providing excellent pre-emptive and preventive analgesia (4, 11, 28, 32, 34-36). The South African 2017 Acute Pain Guidelines (12) support epidural insertion wherever possible. This, however, depends on the availability of trained professionals and adequate monitoring. Intravenous patient-controlled analgesia (IV-PCA) using opioids is an alternative technique for managing moderate to severe post-operative pain and is combined with paracetamol, NSAIDs and other analgesic adjuvants to decrease the side effects of opioid-only treatment (4, 40).

The International Association for the Study of Pain guidelines (7) state that acute post-operative pain must be treated immediately and there should be no “wait time”. Various practical multimodal approaches to acute pain management are suggested (41, 42) based on intensity, physiopathology of pain, complexity of symptoms, presences of comorbidities and psychological factors in the social context. One of the suggested approaches is the revised four-step World Health Organization’s (WHO) Analgesic Ladder (43) as a foundation for chronic cancer pain that can be adapted to any acute pain treatment. However, the WHO approach has drawbacks, as it addresses mainly the pharmacological aspect of pain rather than including other aspects such as psychological, cultural and emotional aspects of pain as well (43). The approach consists of the following main principles.

- “Oral prescription of analgesic drugs whenever possible as opposed to other routes of administration (rectal, intravenous, or any other).
- Around the clock prescription of drugs rather than per demand, integrating pharmacokinetics of the prescribed drugs.

- Analgesics must be prescribed based on pain intensity as recorded by a scale of pain severity and tailored in such a way that the strongest analgesics must be considered rather than the traditional stepwise approach. In this regard, a clinical examination must combine an adequate assessment of pain.
- Individualised therapy must address patients concerns balancing analgesic desired level and possible occurrence of side effects.
- Accessibility and adherence to appropriate guidelines for dosage to avoid pain recurrence" (43).

Successful management of acute post-operative pain requires a multidisciplinary team (7) involving all personnel taking care of the patient and will be determined by the education of patients, personnel executing the pain treatment plan and organisational structures for pain treatment such as an acute pain service and the use of appropriate guidelines rather than analgesic techniques themselves . The level of institutional engagement is important for the effective implementation of an acute pain service (8, 44, 45). Functional outcomes with appropriate patient education rather than pain scores alone should guide pain management (32).

Severe post-operative pain is associated with decreased patient satisfaction, delayed post-surgery ambulation, delayed hospital stay, unplanned hospital admissions, delayed wound healing, impaired sleep, impaired physical function, reduced quality of life development of chronic pain, increased incidence of severe cardio-pulmonary complications, high post-operative mortality and morbidity and increased cost of care (11, 46).

Reported pain management following hysterectomy

Acute post-operative pain management remains sub-optimal despite introducing acute pain services (34, 47, 48). Not all hospitals have an acute pain service, and where they do exist, there is wide variability in efficiency (34, 47, 49-51). PAIN-OUT studies in different types of surgeries in both developed and developing countries show the worst post-operative pain scores varying from moderate to severe (52-55). Evaluating post-operative pain management literature following

hysterectomy is challenging as different anaesthetic and surgical approaches and research methodologies are used.

Following TAH, on a scale of 0 – 10, Dougall (56) in South Africa reported a median score of 8 for worst pain experience and 4 for least pain. Participants stated that they spent 50% of the time in severe pain during the first 24 hours post-operatively. TAH patients in a study in Egypt by Hendawy and Abuelnaga (57) received spinal anaesthesia and morphine plus other analgesia in the post-operative period. Furthermore, half the patients also received ear acupuncture and reported significantly lower mean pain scores, 2.5 versus 5 out of 10 (57). In Turkey, TAH patients in a study by Suner et al (58) received morphine intravenously via a PCA pump and other analgesia post-operatively. In addition, one group also received a TAP block immediately following surgery. Those receiving the TAP block reported significantly lower median pain scores, 2 versus 4 out of 10, compared to those with no TAP block (58). Ciobotaru et al (59) reported post-operative pain after TAH according to the type of anaesthesia received in Romania. Of the patients,45.6% experienced severe pain with a mean worst pain score of 8.3. There was a significant difference between the number of patients in severe pain who received spinal anaesthesia than those who received general anaesthesia (28.1 versus 62%). The authors found that 33.5% of the patients experienced moderate pain, with the majority of these having received spinal anaesthesia (46.9%) compared to those that received general anaesthesia (19%) (59). Ismail et al (34) in Pakistan evaluated the effectiveness of post-operative pain management practices following major gynaecological procedures in an acute pain management service. The authors found no significant differences in the occurrence of mild, moderate or severe pain among those receiving intravenous IV-PCA, epidurals or opioid infusions. The severity of pain scores decreased to mild pain by 24 hours post-operatively (34).

Dougall (56) reported a low incidence of side effects with drowsiness, dizziness, nausea and itching receiving a median score of 0 – 2 (56). Lockat (60) in South Africa reported a higher side effect incidence in the same hospital. The side effect most commonly reported was sedation. Other side effects documented were pruritus, nausea and vomiting, 38.1% in the TAP block group versus 33.3% in the

non-TAP block group (60). Suner et al (58) reported a low incidence of side effects. In the TAP block group, nausea and vomiting were reported in one patient requiring the PCA to be stopped at 18 hours and two patients in the non-TAP block group (58). Ismail et al (34) reported a significantly higher rate of vomiting,16.7% in the iv opioid group compared to 6.6% in those who received IV-PCA and none in the epidural group. Nausea was observed in 14.3%, 11% and 4.8% of patients in these groups, respectively. Sedation (1.1%), anxiety (2.2%) and hypotension (1.1%) were observed in only the IV-PCA group (34). A randomised controlled trial by Hendawy and Abuelnaga (57) reported a high rate of nausea in the control group (71.4%) and none in the ear acupuncture group 12 hours post-operatively and no nausea in either group at 24 hours post-operatively.

In the study by Dougall (56), 56 % of patients could mobilise within 24 hours of surgery. Regarding pain interference with function, the median score for in and out of bed activities was 5 out of 10. The median pain score for interference with coughing and deep breathing was 4 and for interference with sleeping was 3. Regarding the effect of pain on emotions, a median score of 2 was reported for anxiety and 1 for pain-related helplessness (56).

1.5 Summary

This section briefly discussed the definition, classification and physiology of pain, assessment of acute post-operative pain, and post-operative pain management following hysterectomy.

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All abbreviations should be spelt out when first used and thereafter used consistently, e.g. ‘intravenous (IV)’ or ‘Department of Health (DoH)’.

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Section 3: Draft article

Post-total abdominal hysterectomy pain experience of patients at academic hospitals with and without a pain service

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Keywords: PAIN-OUT, total abdominal hysterectomy, post-operative pain, acute pain service

Abstract

Background

Acute post-operative pain management remains sub-optimal despite introducing acute pain services. Not all hospitals have an acute pain service, and where they do exist, there is wide variability in efficiency. This study aimed to compare the pain experience on Day 1 post-total abdominal hysterectomy (TAH) of patients exposed to a pain service at Rahima Moosa Mother and Child Hospital (RMMCH) and those at Chris Hani Baragwanath Academic Hospital (CHBAH) with no pain service.

Methods

A comparative cross-sectional research design was followed using convenience sampling. The PAIN-OUT questionnaire was used to collect data. There were 72 patients from RMMCH and 70 from CHBAH enrolled in the study.

Results

There were no significant differences between the worst and least pain scores and time in severe pain between the patients at RMMCH and CHBAH with median scores of 7 versus 8 (p=0.6490), 3 versus 4 (p=0.064) and 40% versus 45% (p=0.195), respectively. There were also no significant differences in pain scores for in-bed activities 4 versus 5 (p=0.166) or the incidence of nausea, drowsiness, itching and dizziness 0 versus 1 (p=0.089), 3 versus 3 (p=0.498), 0 versus 0 (p=0.441) and 2 versus 2 (p=0.626), respectively. Satisfaction with pain management was not significantly different between the patients at the two hospitals, 9 versus 8 (p=0.123).

Conclusion

Although post-operative pain management is regarded as a fundamental human right, TAH post-operative pain was poorly managed in this study. There was no significant difference between the pain scores and the side effects experienced between patients at the two hospitals, despite an office-hours acute pain service at one of the hospitals. Patients at RMMCH experienced significantly less pain with out of bed activities, deep breathing or coughing and sleeping and felt less anxious and helpless. Patients at both hospitals were satisfied with pain management.

Introduction

It has been reported that over 300 million people undergo surgery each year, and the numbers are increasing globally (1). The majority of these people experience acute post-operative pain, with more than half rating the intensity as moderate, severe, or extreme (1-4). The South African Acute Pain Guidelines Consensus Group (5) highlights the concern from the South African Society of Anaesthesiologists (SASA), the World Federation of Societies of Anaesthesiologists (WFSA) and the International Association for the Study of Pain (IASP) that pain is poorly managed in all parts of the world, but particular attention needs to be given to pain management in developing countries.

Acute post-operative pain is a complex, multifactorial concept, and the severity is often underestimated (1, 4). Studies and guidelines have been published attesting to the complexity of pain management (1, 2). Therefore, post-operative pain management remains a challenge despite the introduction of multimodal pain management approaches and the development of acute pain services (APS) worldwide. Anaesthetists play an important role in acute pain management internationally (2, 4). A total abdominal hysterectomy (TAH) is considered a major and common surgical procedure performed in gynaecology. TAH is associated with moderate to severe pain post-operatively (3, 6) and the severity of pain is often underestimated (6).

PAIN-OUT (7) is an international project based in Europe that provides a web-based information system intended to improve the treatment of patients with post-operative pain. Participating hospitals worldwide collect patient-reported outcome data as well as clinical data in a standardised way using a questionnaire available in more than 20 languages. After the input of data, hospitals receive online feedback and can compare their results with other participating hospitals. This helps to identify deficits in pain management, allowing for improvements to be made (7)

APS units have been instituted in many hospitals since the early 1990s and have been shown to improve, albeit not eliminate post-operative pain (8). Anecdotally, in South Africa, it is known that the majority of hospitals do not have an APS. None

of the University of the Witwatersrand (Wits) affiliated hospitals has a dedicated 24-hour APS. At Chris Hani Baragwanath Academic Hospital (CHBAH), anaesthetists are responsible for intraoperative and immediate post-operative (recovery room) pain management, leaving the post-operative management to the surgeons once the patient has left theatre. However, Rahima Moosa Mother and Child Hospital (RMMCH) offers an office-hours pain service managed by the anaesthetist on duty for acute pain and the consultant anaesthesiologist in theatre. The pain service offers electronic patient-controlled analgesia (PCA) post-operatively to every patient scheduled for a TAH or any major gynaecological procedure. After hours, PCA pumps are managed by nurses in the ward. Any complications are reported to the anaesthetist on call. It was unknown how effectively post-TAH pain at RMMCH and CHBAH was being managed and the impact the pain service has on managing post-TAH pain. This study aimed to compare the pain experience on Day 1 post-TAH of patients exposed to a pain service at RMMCH and those at CHBAH with no pain service.

Methods

A comparative cross-sectional research design was followed. At the time of this study, the PAIN-OUT study was being conducted at CHBAH. Permission to use the CHBAH data for this study and the patient outcome questionnaire at RMMCH was obtained from the project manager of PAIN-OUT. Approval to conduct the study was further obtained from the University of the Witwatersrand Human Research Ethics Committee (Medical) (M191186).

The study population consisted of adult patients presenting for elective TAHs at RMMCH and CHBAH. The sample size was determined in consultation with a biostatistician using STATA® version 15 (StataCorp, USA) based on the means and standard deviations of pain scores 24 hours after surgery in similar studies (9, 10). A minimum sample size of 68 patients per group was determined. This was calculated at a 95% confidence level, a significance level of 0.05 and a power of 80%. Convenience sampling was used. Patients were excluded if they:

- had persistent painful conditions meeting chronic pain criteria lasting more than three months

- had cognitive impairment, for example, Down syndrome, dementia, Alzheimer's disease, cerebral palsy and post-operative delirium,
- were unable to communicate, for example, those who were deaf or did not read or write English,
- refused consent, and
- questionnaires missing essential data, that is worst and least pain and time in severe pain.

RMMCH had an office-hours pain service. After hours, the nursing staff and the anaesthetist on-call maintained the service. The RMMCH patient group received morphine via PCA electronic pumps (1 mg/1 ml) after discharge from the recovery room, with a lockout time adjusted to the patients' requirements but with a minimum lockout period of five minutes. CADD Solis® (Smith Medical) pumps were used. Non-steroidal anti-inflammatories (if available) and paracetamol were also given as standard pain management. The CHBAH patient group was managed after discharge from the recovery room by the surgeons, and received conventional pain management that included opioids, non-steroidal anti-inflammatories (if available) and paracetamol.

The English version of the patient outcomes questionnaire of PAIN-OUT (7) was used to collect data. Demographic data were collected in addition to the questionnaire. The patient outcomes questionnaire consisted of 13 questions relating to pain intensity and interference, affective impairment, side effects of treatment (nausea, drowsiness, itchiness and dizziness), perceptions of care, non-pharmacologic methods of pain treatment and chronic pain. Affective impairment was assessed regarding in bed activities such as turning and changing position, breathing deeply or coughing and sleeping, and out of bed activities such as walking, sitting in a chair and standing at the sink (7).

Data were collected on day one post-operative – this was the day following surgery, with data being collected between 08:00 and 18:00 as per the PAIN-OUT protocol (7). At CHBAH, anaesthetists involved in the PAIN-OUT study collected data following training and accreditation as data collectors. At RMMCH, one author (UJM), who had also received the training and been accredited as a data collector, collected data.

Patients completed the patient outcomes questionnaire independently without assistance from staff, family or friends on the day following surgery between 08:00 and 18:00. If the patients were unable to complete the questionnaire themselves (for example, they did not have their spectacles) but understood and could write English, they were allowed to receive assistance from the data collector to follow precise guidelines and instructions. Once the questionnaires were completed, the data collector ensured that all questions had been answered. If some questions were left blank, the data collector could offer assistance with completion by repeating the question but offering no additional explanation. However, if the question remained unclear to the patient, this was noted and left unanswered. An 11-point numeric rating scale was used, and patients rated their pain on a continuum of numbers from 0 – 10 or percentages from 0 – 100%. For questions asking about pain severity, selective activities, anxiety, helplessness and side effects, a higher score indicates worse pain or severity of the condition. A higher score indicated better pain relief or satisfaction for the questions regarding pain relief, participation in decisions in pain treatment, and satisfaction with pain treatment.

Data were analysed in consultation with a statistician using STATA® version 13.1 (Stata Corp, USA). Categorical variables were described using frequencies and percentages, and associations between the two groups were made using Chi-square tests. NRS scores were summarised using means and standard deviations or medians and interquartile ranges and compared between the two groups using independent t-tests or Mann-Whitney tests depending on the data distribution. A p-value of <0.05 was considered statistically significant.

Results

One hundred and forty-two patients participated in the study, 72 from RMMCH and 70 from CHBAH. Six patients were excluded from the CHBAH group as they did not meet the inclusion criteria. Thirty-one patients from CHBAH did not have a height charted. The characteristics of the patients are shown in Table 1.

Table 1: Characteristics of patients

Characteristic	RMMCH	CHBAH
	Mean (SD)	
Age (years)	48 (9.63)	49.76 (9.84)
Weight (kg)	75.08 (15.72)	74.16 (14.59)
	Median (IQR)	
Height (cm)	165 (162 – 170)	165 (160 – 165)

The worst and least pain and the percentage of time in severe pain were compared between the two hospitals and are shown in Table 2. No significant differences were found.

Table 2: The worst, least and percentage of time in severe pain

Item	RMMCH	CHBAH	p-value
	Median (IQR)		
Worst pain	7 (5 – 9)	8 (5 – 9)	0.649
Least pain	3 (2 – 5)	4 (2 – 5)	0.064
Time in severe pain (%)	40 (20 – 50)	45 (30 – 60)	0.195

The extent to which pain interfered with or prevented patients from doing selected activities was compared between the two hospitals. The level of anxiety and helplessness and the side effects experienced were also compared. This is shown in Table 3. Where significant differences were found between the two groups, those at the hospital with a pain service fared better. Significantly more patients at RMMCH, 69 (95.8%) versus 59 (84.3%) patients at CHBAH, had been out of bed by day one (p=0.021).

Table 3: The effect of pain on movement, anxiety and helplessness and side effects

Item		RMMCH	CHBAH	p-value
		Median (IQR)		
Physical	Activities in bed	4 (2 – 6.8)	5 (3 – 7.3)	0.166
	Deep breathing or coughing	1 (0 – 4)	2 (0 – 4)	0.046
	Sleeping	1 (0 – 4.3)	2 (0 – 6.3)	0.029
	Out of bed activities	4 (2 – 5)	5 (3 – 6)	0.026
Mental	Anxious	1 (0 – 3)	3 (0 – 6)	<0.0005
	Helpless	0 (0 – 2)	1 (0 – 5)	0.013
Side effects	Nausea	0 (0 – 2)	1 (0 – 3)	0.089
	Drowsiness	3 (1 – 5)	3 (0 – 6)	0.498
	Itching	0 (0 – 1)	0 (0 – 0)	0.441
	Dizziness	2 (1 – 5)	2 (0 – 6)	0.626

The comparisons between the two hospitals for the mean (SD) percentage of how much pain relief was received by the patients from both pharmacological and non-pharmacological methods, the number (%) of patients who would have liked more pain treatment and who had received information about pain treatment options and lastly, the median (IQR) for the extent to which patients were allowed to participate in their pain treatment decisions is shown in Table 4.

Table 4: Comparison between pain relief, treatment, information, participation and satisfaction

Item	RMMCH	CHBAH	p-value
	Mean (SD) %		
Pain relief received	65.7 (21.2)	57.0 (24.4)	0.025
Would have liked more pain treatment	n (%)		
	17 (23.6)	42 (60.0)	<0.0005
Received information about pain treatment	61 (84.7)	31 (44.3)	<0.0005
Allowed to participate in pain treatment decisions	Median (IQR)		
	8.0 (5.0 – 9.0)	2.0 (0.0 – 8.0)	<0.0005
Satisfaction with pain treatment	9.0 (7.0 – 9.8)	8.0 (5.0 – 9.0)	0.123

Significantly more patients from CHBAH, 44 (61.1%), versus 28 (38.9%) from RMMCH used or received non-pharmacological pain relief (p=0.004). Where only 1 patient indicated an option, these were combined with the “other” category. Four (5.7%) patients from CHBAH and 3 (4.2%) patients from RMMCH had selected either the application of heat, transcutaneous electrical nerve stimulation, massage, imagery or visualisation or other. No participants selected the application of cold or acupuncture. The non-pharmacological methods of pain relief used or received by patients at the two hospitals are shown in Figure 1.

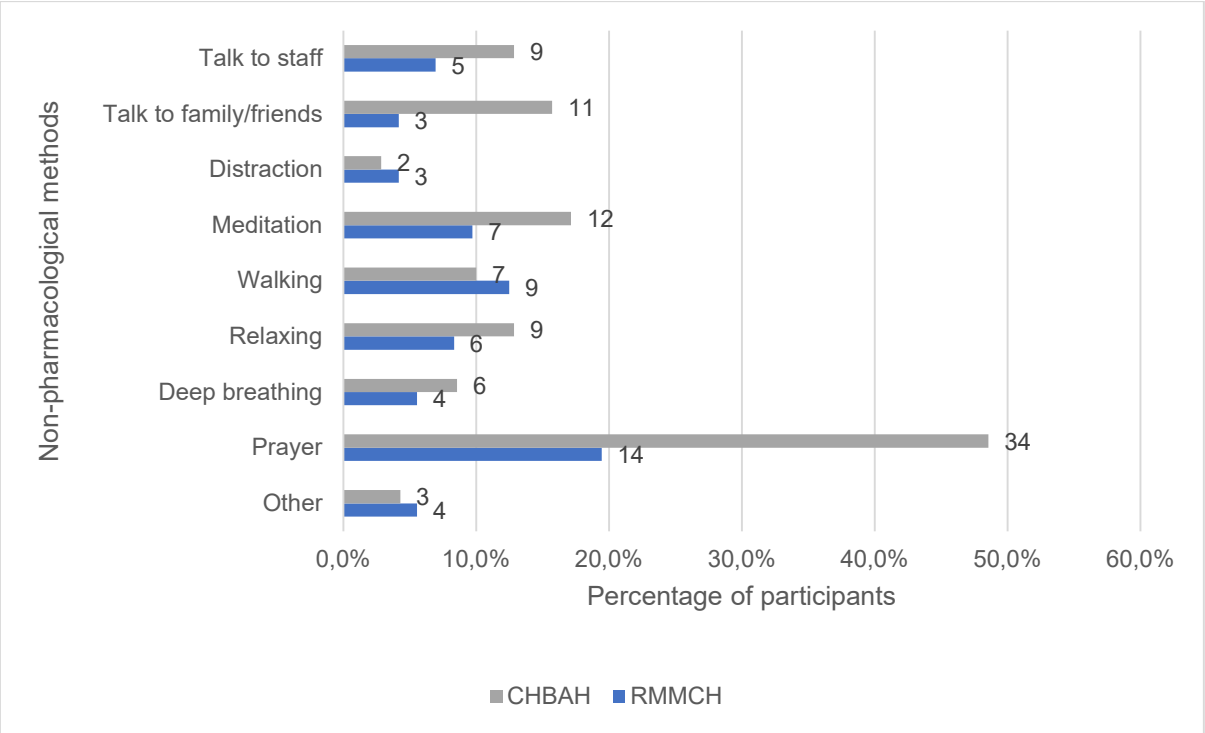

Figure 1: Non-pharmacological methods of pain relief used or received by patients at the two hospitals

The number of patients who responded that they had a persistent painful condition (not fulfilling the criteria of chronic pain) for three months or more before coming to hospital for their surgery, and the site and the severity of the pain is shown in Table 5. There was no significant difference between the number of patients who had persistent painful conditions between the two groups (p=0.375).

Table 5: Persistent painful condition, site and severity of pain

Item	RMMCH	CHBAH	Total
	n (%)		
Persistent painful condition	6 (8.3)	10 (14.3)	16 (11.3)
Pain at site of surgery	5 (6.9)	8 (11.2)	13 (9.2)
Pain elsewhere	1 (1.4)	1 (1.4)	2 (1.4)
Missing information	0	1 (1.4)	1 (0.7)
	Range		
Pain severity	3 – 10	4 – 10	

Discussion

Pain is considered the fifth vital sign (5, 11) and pain management as a fundamental human right (12, 13). Regular, individual assessment of pain may lead to improved management of acute pain (11). Pain is a subjective experience, making pain assessment for clinical or research purposes difficult (14). Evaluating post-operative pain management literature following hysterectomy is challenging as different anaesthetic and surgical approaches and research methodologies are used.

Acute post-operative pain management remains sub-optimal despite introducing acute pain services (15-17). Not all hospitals have an acute pain service, and where they do exist, there is wide variability in efficiency (15, 17-19). In this study, there were no significant differences between the pain scores of CHBAH, which has no pain service and RMMCH, which has an office-hour pain service.

In this study at RMMCH and CHBAH, worst pain scores were 7 and 8, least were 3 and 4 and time in severe pain was 40% and 45%, respectively. Following TAH, on a scale of 0 – 10, Dougall (20), also at RMMCH in 2018 when there was a full time acute pain service, reported a median score of 8 for worst pain experience and 4 for least pain. The author also reported that patients spent 50% of the time in severe pain during the first 24 hours post-operatively. TAH patients in the study by Hendawy and Abuelnaga (21) received spinal anaesthesia and morphine plus other analgesia in the post-operative period. Furthermore, half the patients also received ear acupuncture and reported significantly lower mean pain scores, 2.5 versus 5 out of 10 (21). TAH patients in a study by Suner et al (22) received morphine intravenously via PCA pump and other analgesia post-operatively. In addition, one group also received a TAP block immediately following surgery. Those receiving the TAP block reported significantly lower median pain scores, 2 versus 4 out of 10, compared to those with no TAP block (22). Ciobotaru et al (23) reported post-operative pain after TAH according to the type of anaesthesia received. Of the patients,45.6% experienced severe pain with a mean worst pain score of 8.3. There was a significant difference between the number of patients in severe pain who received spinal anaesthesia than those who received general anaesthesia (28.1 versus 62%). The authors found that 33.5% of the patients

experienced moderate pain, with the majority of these having received spinal anaesthesia (46.9%) compared to those that received general anaesthesia (19%) (23). The severity of post-operative pain is determined by patient factors such as individual pain modulation, individual response to analgesia (24-26), expectations, previous pain experience, cultural beliefs, mood and psychological factors and certain surgical factors such as the type and location of surgery (11).

The highest score for side effects in this study was for drowsiness, with a median score of 3 at both hospitals. Dougall (20) reported a low incidence of side effects with drowsiness, dizziness, nausea and itching receiving a median score of 0 – 2 (20). Lockat (27) reported a higher side effect incidence at RMMCH in 2019 following TAHs with and without TAP Blocks. The side effect most commonly reported was sedation. Other side effects documented were pruritus, nausea and vomiting, 38.1% in the TAP block group versus 33.3% in the non-TAP block group (27). Suner et al (22) reported a low incidence of side effects. In the TAP block group, nausea and vomiting were reported in one patient requiring the PCA to be stopped at 18 hours and two patients in the non-TAP block group. Hendawy and Abuelnaga (21) reported a high rate of nausea in the control group (71.4%) and none in the ear acupuncture group 12 hours post-operatively and no nausea in either group at 24 hours post-operatively.

Significantly more patients at RMMCH, 95.8% versus 84.3% at CHBAH, had been out of bed by Day1. There was a small but significant difference in the pain score for out of bed activities with patients at CHBAH experiencing more pain. There was no significant difference between activities in bed between the two hospitals. However, there was a small but significant difference between deep breathing or coughing and sleeping, with CHBAH reporting slightly more pain. Patients at RMMCH also experienced significantly less feelings of anxiety and helplessness. Dougall (20) reported that 56 % of patients could mobilise within 24 hours of surgery. Regarding pain interference with function, the median score for in and out of bed activities was 5 out of 10. The median pain score for interference with coughing and deep breathing was 4 and for interference with sleeping was 3. Regarding the effect of pain on emotions, a median score of 2 was reported for anxiety and 1 for pain-related helplessness (20).

Patients at both hospitals were satisfied with their pain management despite having high worst pain scores, and 23.6% and 60.0% would have liked more pain management. Dougall (20) also reported satisfaction with pain management with a median score of 8 and 64% would have liked more pain management. This is not surprising as Boring et al (28), Gordon (29) noted that patients tend to rate the overall service and experience during their stay in hospital rather than quantifying actual pain experience.

A limitation of this study was that it was done at two Wits affiliated hospitals, and the results may not be generalisable to other hospitals. A further limitation was that the study only reflects the patients' pain experience within the first 24 hours post-operatively. It is recommended that the PAIN-OUT study should be undertaken in other South African hospitals to render a more comprehensive view of post-operative pain management following TAH.

Conclusion

Although post-operative pain management is regarded as a fundamental human right, TAH post-operative pain was poorly managed in this study. There was no significant difference between the pain scores and the side effects experienced between patients at the two hospitals, despite an office-hours acute pain service at one of the hospitals. Patients at RMMCH experienced significantly less pain with out of bed activities, deep breathing or coughing and sleeping and felt less anxious and helpless. Patients at both hospitals were satisfied with pain management.

Conflict of interest

The authors declare that we have no financial or personal relationships, which may have inappropriately influenced us in writing this paper.

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Section 4: Proposal

Post total abdominal hysterectomy pain experience of patients at academic hospitals with and without a pain service

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4.1 Introduction and problem statement

It has been reported that over 300 million people undergo surgery each year, and the numbers are increasing globally (1, 2). The majority of these people experience acute post-operative pain, with more than half rating the intensity as moderate, severe, or extreme (2-5). Authors (6) highlight that the South African Society of Anaesthesiologists (SASA), the World Federation of Societies of Anaesthesiologists (WFSA), and the International Association for the Study of Pain (IASP) state that pain is poorly managed in all parts of the world, but particular attention needs to be given to pain management in developing countries.

Acute post-operative pain is a complex, multifactorial concept, and the severity is often underestimated (2, 5, 7, 8). Studies and guidelines have been published attesting to the complexity of pain management (2, 3, 9). Therefore, post-operative pain management remains a challenge despite the introduction of multimodal pain management approaches and the development of acute pain services (APS) worldwide. Anaesthetists play an important role in acute pain management internationally (3, 5, 10-12).

A total abdominal hysterectomy (TAH) is considered a major surgical procedure and is associated with moderate to severe pain post-operatively (4, 13, 14). TAH is one of the most common surgical procedures performed in gynaecology, and the severity of pain is often underestimated (13, 15-17).

APS units have been instituted in many hospitals since the early 1990s and have been shown to improve, albeit not eliminate post-operative pain (18). In South Africa, the majority of hospitals do not have APSs.

PAIN-OUT (19) is an international project based in Europe that provides a web-based information system intended to improve the treatment of patients with post-operative pain. Participating hospitals worldwide collect patient-reported outcome data as well as clinical data in a standardised way using a questionnaire available in more than 20 languages. After the input of data, hospitals receive online feedback and can compare their results with other participating hospitals. This helps to identify deficits in pain management, allowing for improvements to be made.

None of the affiliated hospitals at the University of the Witwatersrand (Wits) have a dedicated 24-hour APS. At Chris Hani Baragwanath Academic Hospital (CHBAH) anaesthetists are responsible for intraoperative and immediate post-operative (recovery room) pain management, leaving the post-operative management to the surgeons once the patient has left theatre. However, Rahima Moosa Mother and Child Hospital (RMMCH) offers an office-hours pain service managed by the anaesthetist on duty for acute pain, and the consultant anaesthesiologist in the theatre. The pain service offers electronic patient-controlled analgesia (PCA) postoperatively to every patient scheduled for a TAH, or any major gynaecological procedure. After hours, PCA pumps are managed by nurses in the ward. Any complications are reported to the anaesthetist on call.

It is unknown how effectively post-TAH pain at CHBAH and RMMCH is managed and the impact the pain service plays in managing post-TAH pain.

4.2 Aim and objectives

4.2.1 Aim

The aim of this study is to compare the pain experience on day one post-TAH of patients exposed to a pain service at RMMCH and those at CHBAH where there is no pain service.

4.2.2 Objectives

The primary objective of this study is to compare the Numeric Rating Scale (NRS) post-surgery between the two groups for:

- worst pain
- least pain
- time in severe pain.

The secondary objectives of this study are to:

- compare the NRS post-surgery between the two groups for:
    - selective activities
    - anxiety and helplessness

    - selective side-effects
- compare the NRS between the two groups for
    - pain relief received
    - need for more pain treatment
    - received information regarding pain treatment
    - participation in pain treatment decision
    - satisfaction with pain treatment
- document non-pharmacological methods of pain relief used or received
- document occurrence of persistent pain for three or more months and the severity and site of the pain.

4.3 Research assumptions

The following definitions will be used in this study.

Adult: is a person 18-years and older.

CHBAH patient group: after discharge from recovery room these patients are managed by the surgeons and receive conventional pain management that includes opioids, non-steroidal anti-inflammatories (if available), and paracetamol.

RMMCH patient group: after discharge from recovery room these patients receive morphine via PCA electronic pumps (1 mg/1 ml) with a lockout time adjusted to the patients' requirements, but with a minimum lockout period of five minutes. CADD Solis® superscript (Smith Medical) pumps are used. Non-steroidal anti-inflammatories (if available) and paracetamol are also given as standard pain management. This hospital has an office-hours pain service. After hours, the nursing staff and the anaesthetist on-call maintain the service.

NRS: is a numeric rating scale where patients rate their pain. In this study, it will be used as a continuum of numbers from 0 – 10 or percentages from 0 – 100%.

Day one post-operative: this is the day following surgery, with data being collected between 08:00 and 18:00 on the first post-operative day as per the PAIN-OUT protocol (19).

Selected activities: will include the following activities (19).

- in bed activities such as turning and changing position
- breathing deeply or coughing
- sleeping
- out of bed activities such as walking, sitting in a chair and standing at the sink.

Selected side effects: will include nausea, drowsiness, itchiness and dizziness (19).

Essential information: worst and least pain and time in severe pain.

4.4 Demarcation of study field

This study will be conducted in the post-operative gynaecology wards at CHBAH and RMMCH. Both hospitals are affiliated with the Faculty of Health Sciences of the University of the Witwatersrand.

CHBAH is a 2888-bed central hospital with 25 theatres, and approximately 65 000 theatre cases are performed per year. One elective theatre is allocated to gynaecology, and an average of 12 TAHs are done per week. There are two post-operative wards.

RMMCH is a 338-bed regional hospital with four theatres, and approximately 6600 theatre cases are performed per year. One elective theatre is allocated to gynaecology, and an average of 12 TAHs are done per week. There are two post-operative wards.

4.5 Ethical considerations

Approval to conduct the study will be obtained from:

- The Human Research Ethics Committee (Medical) and the Graduate Studies Committee at Wits
- RMMCH Research Committee (Appendix 1).

Approval has been obtained from:

- The Medical Advisory Committee at CHBAH (Appendix 2)

- The Head of the Department of Anaesthesiology at RMMCH (Appendix 3)
- The Head of the Department of Obstetrics and Gynaecology at RMMCH (Appendix 4).

Consent will be obtained by approaching patients on day one post-operatively in the ward. The study will be explained to the patients, and they will be invited to take part. Should they agree to participate, they will be given the information letter (Appendix 5) and will be asked to sign a consent form (Appendix 6) before addressing the questionnaire (Appendix 7). Any patient who is unable to consent due to severe pain will be referred to the attending practitioner for pain management.

Anonymity will be ensured as the questionnaire will not contain any identifying information and will only be allocated a study number. Lists with the patient names, hospital and study numbers will be compiled and stored separately. Confidentiality will be maintained as only the researcher and supervisors will have access to the raw data.

The collected data will be stored securely for six years after completion of the study in locked cupboards. The study will be conducted according to the principles of the Declaration of Helsinki (20) and the South African Guidelines for Good Clinical Practice (21).

4.6 Research methodology

4.6.1 Research design

A comparative cross-sectional research design will be followed.
A comparative study is used to compare differences between variables in two or more groups in a natural setting (22). This study is comparative as it compares the pain experience between two groups.

A contextual study refers to research in specific groups, defined by de Vos et al (23) as a “small scale world”. This study will be done contextually at CHBAH and RMMCH.

4.6.2 Study population

The study population will consist of adult patients presenting for elective TAHs at CHBAH and RMMCH.

4.6.3 Study sample

Sample size

The sample size was determined in consultation with a biostatistician using STATA® version 15 (StataCorp, USA) based on the means and standard deviations of pain scores at 24 hours after surgery in similar studies (24, 25). A minimum sample size of 68 patients per group was determined. This was calculated at a 95% confidence level, a significance level of 0.05 and a power of 80%.

Sampling method

In this study, a convenience sampling method will be used. This is also referred to as “accidental or availability” sampling and involves the choice of readily available participants or objects for the study. Participants are included in the sample because they happen to be in the right place at the right time (26). Patients who have TAHs at the time of data collection will be approached for inclusion in the study.

Inclusion and exclusion criteria

The inclusion criteria for this study are:

- adult patients presenting for TAHs
- patients who consent to take part in the study.

The exclusion criteria in this study are:

- patients with persistent painful conditions lasting more than three months
- patients with cognitive impairment, for example, Down syndrome, dementia, Alzheimer’s disease, cerebral palsy and post-operative delirium

- patients who are unable to communicate, for example, those who are deaf or do not read or write English
- essential information not documented.

4.6.4 Data collection

Questionnaire development

The English version of the patient outcomes questionnaire of PAIN-OUT (19) will be used to collect data (Appendix 7). Permission to use the questionnaire at RMMCH was obtained from the project manager of PAIN-OUT (Appendix 8). The following demographic data will be collected: age, weight and height. The outcome questionnaire consists of 13 questions which relate to:

- pain intensity
- pain interference
- affective impairment
- side effects of treatment
- perceptions of care
- non-medicine methods of pain treatment
- chronic pain.

Data collection

Patients will complete the patient outcomes questionnaire independently without assistance from staff, family or friends on the day following surgery between 08:00 and 18:00. If the patient is unable to physically complete the questionnaire themselves (for example, they do not have their spectacles) but understand and can write English, they may receive assistance from the researcher to complete the questionnaire following the precise guidelines and instructions.

Once the questionnaires have been completed, the researcher will ensure that all questions have been answered. If some questions were left blank, the researcher may offer assistance with completion by repeating the question but offering no additional explanation. However, if the question remains unclear to the patient, this will be noted, and the question left unanswered.

At CHBAH, anaesthesiologists involved in PAIN-OUT are currently collecting data following training and accreditation as data collectors. Ethics approval has been received for this ongoing project at CHBAH.

At RMMCH, the researcher, who has also received the training and been accredited as a data collector, will be collecting the data after all the permissions have been obtained.

4.6.5 Data analysis

A Microsoft Excel® spreadsheet will be used to capture data. Data will be analysed in consultation with a biostatistician using STATA® version 13.1 (StataCorp, USA). Categorical variables will be described using frequencies and percentages, and comparisons between the two groups will be done using Chi-squared or Fishers exact tests. NRS scores will be summarised using means and standard deviations or medians and interquartile ranges and compared between the two groups using independent t-tests or Mann-Whitney tests depending on the distribution of the data. A p-value of less than 0.05 will be considered statistically significant.

4.6.6 Significance of the study

The results of this study will give insight into the effectiveness of the management of pain following TAH at CHBAH, where anaesthetists are responsible only for intra-operative and immediate post-operative (recovery room) pain management in comparison to RMMCH that offers an office-hours pain service. Furthermore, the result will indicate the role that the pain service plays and whether or not there is a need to establish more formalised pain services at other Wits affiliated hospitals.

4.7 Validity and reliability of the study

Validity of an inference is defined as the degree to which the measured value approximates the true value of the inference, and reliability represents the consistency of the measure achieved (27).

Validity and reliability will be ensured in this study by the following measures.

- Using an appropriate research design and data collection technique.

- Determining a sample size in consultation with a biostatistician.
- Using the validated patient outcome questionnaire of PAIN-OUT (19).
- Using trained and accredited data collectors to collect data
- Analysing data in consultation with a biostatistician.

4.8 Potential limitations

Data will be contextually collected at CHBAH and RMMCH, and the results may therefore not be generalisable to other hospitals.

Convenience sampling will be used, and this may lead to under- or over-representation of certain elements (26).

4.9 Project outline

4.9.1 Time frame

Activity	Oct 2019	Nov 2019	Jan 2020	Feb 2020	Mar 2020	Apr 2020	May 202	Jun 2020	Jula 2020	Aug 2020
Proposal preparation										
Literature review										
Proposal submission										
Ethics approval										
Post-graduate approval										
Data collection										
Data analysis										
Draft article										
Submission										

4.9.2 Budget

	Price per page	Number of pages	Copies	Total
Proposal	1	27	10	R 270
Post graduate form	1	2	6	R 12
Information letters	1	1	80	R 80
Consent forms	1	1	80	R 80
Questionnaires	1	5	80	R 400
Complete report	1	100	4	R 400
Grand total				**R 1242**

The Wits Department of Anaesthesiology will incur the costs of paper and printing.

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4.11 Appendices

Appendix 1 Information sheet

Dr Utshudi Joe Malumalu

Department of Anaesthesiology

University of the Witwatersrand

10 October 2019

Attention: Rahima Moosa Mother and Child Research Committee

Re: Post total abdominal hysterectomy pain experience of patients at academic hospitals with and without a pain service

I am conducting a research study for my M Med. I aim to compare the pain experience of patients post total abdominal hysterectomy at Rahima Moosa Mother and Child Hospital where there is a pain service to those at Chris Hani Baragwanath Academic Hospital where there is no pain service. At this stage, it is not known whether the pain service makes any difference to patients' postoperative pain in our community. The results may indicate whether or not there is a need to establish more formalised pain services at other Wits affiliated hospitals.

The study will use the PAIN-OUT questionnaire to assess the effectiveness of pain management in both hospitals and will not add or remove any treatment from the current treatment prescribed to the patients.

Only my supervisors and I will have access to the raw data, ensuring confidentiality. A copy of the final report can be available to you after completion of the study.

The study will not add any additional cost to the hospital or to the Department of Anaesthesiology.

Utshudi Joe Malumalu (0714944001)

Appendix 2: Approval Medical Advisory Committee Chris Hani Baragwanath Academic Hospital

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 18th March 2019

TITLE OF PROJECT: PAIN OUT: an international quality improvement and research network for optimizing management of post operative pain, subproject ASPIRE

UNIVERSITY: Witwatersrand

Principal Investigator: Dr D Lines

Department: Anaesthesia

Supervisor : N/A

Permission Head Department (where research conducted): Yes

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Academic Hospital. The CEO / management of Chris Hani Baragwanath Academic Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- The Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- The MAC will be informed of any serious adverse events as soon as they occur
- Permission is granted for the duration of the Ethics Committee Approval.

Recommended
(On behalf of the MAC)
Date: 18/03/2019

Approved/~~Not Approved~~
Hospital Management
Date: 19/03/2019

Appendix 3: Approval from Head of Department of Anaesthesiology, RMMCH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Department of Anaesthesiology
Rahima Moosa Mother and Child Hospital

Tel: (011) 470-9303
Fax: 0865194183
E-mail: kleyenstuber@hotmail.com

8 October2019

Attention: The Chair of the Human Research Ethics Committee

Permission to collect data in the Department of Anaesthesia at Rahima Moosa Mother & Child Hospital

I hereby grant permission for data to be collected in the Department of Anaesthesia at Rahima Moosa Mother & Child Hospital for the following MMED research project:

" Post total abdominal hysterectomy pain experience of patients at academic hospitals with and without an acute pain service".

Kind Regards

Dr T Kleyenstuber

Head: Clinical Unit - Anaesthesiology
Rahima Moosa Mother and Child Hospital

Appendix 4: Approval from Head of Department of Obstetrics and Gynaecology, RMMCH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Rahima Moosa Mother and Child Hospital
Department of Obstetrics and Gynaecology
Private Bag x20
Newclare
2121
12th October 2019

Dr. Joe Malumalu

Re.: Permission to conduct research

Dear Dr Malumalu

I hereby give you permission to conduct your research project at Rahima Moosa Mother and Child Hospital.

The permission is under the condition that the CEO and the relevant Research Ethics Committees provide permission for the project.

Regards

Prof Hennie Lombaard
Adjunct Professor
Head of Department: Obstetrics and Gynecology
Rahima Moosa Mother and Child Hospital
Tel.: 011 470 9090
Fax.: 011 470 9092

Appendix 5: Patient information letter

Hello! My name is Joe. I am a qualified doctor studying further to become a specialist anaesthetist at the University of the Witwatersrand. Anaesthetists are doctors who make you sleep during your operation and make sure you have no pain or minimum pain during and after your operation. I am conducting a research study about the pain you experience after your operation, and I would like to invite you to participate.

Pain you feel after your operation is different for different people. The purpose of this study is to compare the pain experience in patients at Rahima Moosa Mother and Child Hospital, where there is an office hours service for following up patients' pain and at Chris Hani Baragwanath Academic Hospital, where there is no pain service but the ward doctors and nurses treat the pain. My research study will not add or remove any treatment that is prescribed for you or any other patient.

You may choose if you want to take part in this study or not. If you do not want to be part of the study, you will still get all the same care that you receive if you do take part. If you do take part, I will ask you to fill in a pain questionnaire asking you about any pain you have felt. The questionnaire should not take you more than 15 minutes to fill in. All information you provide in the questionnaire will be confidential, meaning that we will not share it with others. When I report the result of the study, your name will not appear anywhere. I appreciate that you will not benefit directly from participation in this study. However, I hope that the results of the study will better help us understand and possibly improve the services that we deliver.

This study has been approved by the Human Research Ethics Committee at the University of the Witwatersrand (M191186).

Should you wish to contact me, or require any further information, please do not hesitate to contact me on 011 489 0084 or the chairperson of the Human Research Ethics Committee, Professor CB Penny on 011 717 1234 or by email: clement.penny@wits.ac.za. The secretariats of the committee can also be contacted: Zanele Ndlovu, Rhulani Mkansi, Charmaine Khumalo or Josh Ndkingumandla on 0117172700/1234 or by e-mails: Zanele.ndlovu@wits.ac.za; Rhulani.mkansi@wits.ac.za; Charmaine.khumalo@wits.ac.za; josh.ndkingumandla@wits.ac.za

Thank you for taking the time to read this information letter.

Yours sincerely

Joe Malumalu

Appendix 6: Informed Consent form

I_____ hereby confirm that I have read and understood the information letter regarding the study entitled: “Post total abdominal hysterectomy pain experience of patients at academic hospitals with and without a pain service”, and I am satisfied with all the information provided.

I am aware that the information provided by me will be treated in a confidential manner, will not be used to discriminate against me, and will be used anonymously when the study is reported.

Participant

I hereby give consent to take part in this study.

_____ _____ _____

(Participant name) (Participant signature) (Date)

Researcher

I_____ hereby confirm that the above participant has been fully informed about the nature and benefits of this study.

Appendix 7: Questionnaire

Study number: …….

Patient demographic data

Age in years	
Weight in Kg	
Height in cm	

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**

Version2.6 110225

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

Version2.6 110225

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)

Version2.6 110225

Appendix 8: Consent to use PAIN-OUT questionnaire and data collected at CHBAH

Weinmann, Claudia Claudia.Weinmann@med.uni-jena.de
To: 'joe malumalu'
Cc : 'lines@pixie.co.za'
8 Oct 2021 15:33

Dear Joe,

Thank you for your e-mail. I'm not sure I understand your request.

As your hospital is a PAIN OUT participant, you can use the data you collect at Witwatersrand University for any analysis you deem useful as long as you respect our publication strategy.

So if it's okay for Dr. Lines, you can use your hospital's data for your MMED.

Using the PAIN OUT questionnaire in an additional hospital is more difficult. From our side, you may use it (provided you obtain ethics approval from your local authorities of course), but as this additional hospital is not part of the PAIN OUT network, you cannot enter this data into our database. You'd need to do your analysis independently.

Kind regards,

Claudia

Section 5: Annexures

5.1 Ethics approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Utshudi Joe Malumalu

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M191186

NAME: (Principal Investigator)	Dr Utshudi Joe Malumalu
DEPARTMENT:	Anaesthesiology Rahima Moosa Mother and Child Hospital
PROJECT TITLE:	Post total abdominal hysterectomy pain experience of patients at academic hospitals with and without an acute pain service
DATE CONSIDERED:	29/11/2019
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof J Scribante, Mrs H Perrie and Dr D Lines
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	30/06/2020

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 Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. 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.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore be due in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.2 Graduate studies approval

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

20 May 2020
Person No: 1822516
PAG

Dr MJ Utshudi
Po Box 6526
Cresta
2118
South Africa

Dear Dr Malumalu Utshudi

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *Post total abdominal hysterectomy pain experience of patients at academic hospitals with and without a pain service*. has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

5.3 Approval Research Committee Rahima Moosa Mother and Child Hospital

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

RAHIMA MOOSA MOTHER AND CHILD HOSPITAL

Enquiries : Karen Marshall
Tel : (011) 470 9284
Fax : 086 553 4623
Email : Karen.Marshall@wits.ac.za

TITLE OF RESEARCH PROJECT:
"POST TOTAL ABDOMINAL HYSTERECTOMY PAIN EXPERIENCE OF PATIENTS AT ACADEMIC HOSPITALS WITH AND WITHOUT PAIN SERVICE"

NAME OF RESEARCHER:
Dr U Malumalu
Department of Anaesthesiology
University of the Witwatersrand

NHRD REF NO: GP_202008_049

Dear Dr Malumalu,

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

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

It is crucial for you to inform the Research Coordinator, Karen Marshall of the actual start and end dates of your study. This could be done by e-mail.

Should the study commence more than 12 months after receipt of this approval letter you will have to go through the process of applying again.

You 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,

ACTING CHIEF EXECUTIVE OFFICER
2020:09:09

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

5.4 Turnitin report

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | FACULTY OF HEALTH SCIENCES

18 January 2021

The Chairperson
Graduate Studies Committee
Faculty of Health Sciences
University of the Witwatersrand

Dear Professor Papathanasopoulos

Re: M Med: **Post total abdominal hysterectomy pain experience of patients at academic hospitals with and without a pain service.**

Dr Utshudi Joe Malumalu, student number: 1822516, has submitted his research report to Turnitin, which revealed a similarity index of 14%. These similarities appear not to be plagiarism but mainly the use of common terminology and phrases specific to the topic of the research.

Yours sincerely,

Juan Scribante
Supervisor

1

article pre submission for plagiarism-1.docx

ORIGINALITY REPORT

14%	8%	8%	4%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

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