Reassessment of acute postoperative pain in a resource limited burns unit after the implementation of an analgesic management plan

A dissertation presented by

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to

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Faculty of Medicine and Health Sciences

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Master of Medicine
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Supervisor : Dr AC Senekal
Co – Supervisor : Dr AA Murray

DECLARATION

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own original work, that I am the author and owner thereof (unless explicitly stated otherwise) and that I have not previously submitted it in its entirety or in part to obtain any qualification.

Signature

Date 18 December 2017

Abstract

Background

Tygerberg Academic Hospital is the referral centre for all major burn wounds in adult patients in the Western Cape. Patients who underwent surgery for burns related injuries at Tygerberg Academic Hospital were identified as having a high incidence of moderate to severe postoperative pain in an audit done in 2012 when there was no fixed protocol for postoperative analgesia.[1]

In an attempt to reduce the incidence of moderate to severe postoperative pain, the Department of Anaesthesiology and Critical Care at Tygerberg Academic Hospital introduced a new postoperative analgesia protocol in the burns unit in November 2016. This is, according to our knowledge, the first unit in Tygerberg Academic Hospital where pain scores were introduced as part of routine vitals.

Methods

A five month interval after the introduction of the new protocol was allowed before an audit of patients' pain experience was commenced. A sample of 64 patients that underwent burns related surgery was evaluated. Patients were asked to indicate on a printed visual analogue scale (VAS) the worst pain experienced in the first 24 hours postoperatively, as well as the amount of pain experienced at the time of the interview at 24 hours postoperatively.

These values were compared to the data collected during the audit of 2012 to establish whether any improvement had been made. We considered a reduction in median VAS score of at least 18mm to be significant.

Results

In this study we could not prove a statistically significant difference between the control group of Murray and Retief from 2012 and the post-intervention group of 2017 in terms of pain outcome.

Opsomming

Agtergrond

Tygerberg Akademiese Hospitaal is die verwysingsentrum vir alle ernstige brandwonde van volwasse pasiënte in die Wes Kaap. Pasiënte wat chirurgie vir brandwondverwante beserings gehad het was geïdentifiseer om ‘n hoë insidensie van matig tot ernstige postoperatiewe pyn te hê in ‘n oudit wat gedoen was in 2012.[1] Daar was op daardie stadium geen vasgestelde protokol vir postoperatiewe pynverligting nie.

In ‘n poging om die insidensie van matig tot ernstige postoperatiewe pyn te verlaag, het die Departement van Anestesiologie en Kritieke Sorg in November 2016 ‘n nuwe protokol vir postoperatiewe pynverligting geloods in Tygerberg Akademiese Hospitaal se brandwonde eenheid. Hierdie is, sover ons kennis strek, die eerste eenheid in Tygerberg Akademiese Hospitaal waar pyntellings as deel van roetine observasies begin is.

Metodes

‘n Vyf maande interval was toegelaat na die bekendstelling van die nuwe protokol voor ‘n oudit van pasiënte se pynervaring begin is. ‘n Steekproef van 64 pasiënte wat brandwondverwante chirurgie ondergaan het is geëvalueer. Pasiënte het op ‘n uitgedrukte Visuele Analoog Skaal (VAS) die ergste pyn ondervind in die eerste 24 uur na chirurgie, asook die pyn ervaar ten tye van die onderhoud teen 24 uur na chirurgie aangedui.

Hierdie waardes is vergelyk met die waardes verkry tydens die vorige oudit in 2012 om te bepaal of enige verbetering plaasgevind het. Ons het ‘n verlaging in die mediaan VAS telling van ten minste 18mm aanvaar as noemenswaardig.

Uitslae

Ons was nie daartoe in staat om ‘n statisties noemenswaardige verskil tussen die kontrole groep van Murray en Retief van 2012 en die post-ingreepgroep van 2017 te bewys in terme van pynuitkomste nie.

Acknowledgements

I wish to thank my Creator for the opportunity to advance my talents and make a difference in other people's lives.

To my wife, Tessa, and children, Rivkah, Anja and Gustav. Thank you for allowing me to spend so much time on a project in order to build a better future for all of us.

Dr AA Murray deserves special mention for his contribution. He was the original promoter for this thesis prior to leaving the service of the University of Stellenbosch for a change in career early in 2017. Dr Murray provided data from his 2012 thesis to use as reference for this follow-up study. He helped with the design of this follow-up study as well as the stationery used in the evaluation of patients. He also gave immense input in the statistical design of the study as well as the eventual analysis of collected data. He continued to avail time from his busy schedule to give input after he had left the service of the University. His contribution has been most valuable and without his assistance the completion of this dissertation would have been much harder.

A consultant at the Biostatistics Unit within the Centre for Evidence Based Health Care (CEBHC), Stellenbosch University assisted with the design and analysis of this study through support from the Faculty of Medicine and Health Science's dean's fund.

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List of Abbreviations

BMI	Body Mass Index
CI	Confidence Interval
CRF	Case Report Form
DALY	Disability Adjusted Life Years
DVT	Deep Venous Thrombosis
ED	Emergency Department
GABA	Gamma Aminobuturic Acid
h	hour
IASP	International Association for the Study of Pain
ICU	Intensive Care Unit
IM	Intramuscular
IV	Intravenous
kg	kilogram
MCSD	Minimum Clinically Significant Difference
mg	milligram
mm	millimeters
n	number
NFkB	Nuclear Factor kappa B
NMDA	N-methyl-D-aspartate
NSAIDS	Non-steroidal Anti-inflammatory Drugs
PAG	Peri-aquaductal Grey
PAINAD	Pain Assessment in Advanced Dementia
PCA	Patient Controlled Analgesia
SD	Standard Deviation
VAS	Visual Analogue Scale
VNRS	Verbal Numeric Rating Scale
VRS	Verbal Rating Scale

Chapter 1

1.1 Hypothesis

The null hypothesis states that there is no difference in the postoperative pain experience of patients after the implementation of a comprehensive analgesic management plan in patients that had debridement or skin grafting after a burns injury.

The alternative hypothesis is that there is a significant difference in the experience of postoperative pain in burns patients following debridement or skin grafting between the post-interventional group and the control group.

1.2 Aim of the Investigation

Tygerberg Academic Hospital is the referral centre for all adult burns patients in the Western Cape. The burns unit is a busy specialist unit with 16 ward beds as well as a 6 bed ICU with ventilators. An audit of all elective post-operative patients in Tygerberg Academic Hospital by Murray and Retief in 2012 revealed that the patients of the burns unit had a high incidence of moderate to severe pain.[1]

Members of the Department of Anaesthesiology and Critical Care at Stellenbosch University developed a new protocol for post-operative pain relief for the burns unit of Tygerberg Academic Hospital which was implemented in November 2016.

Nursing staff of different shifts were educated about the new protocol. The practical application of the new protocol was explained to them and there were opportunities for questions to be asked. The unit manager was present in most of these discussions. All the stationery that were to be used were available and explained to the staff. Nursing staff members participated very well during the contact sessions. Many questions were answered and uncertainties explained. Education regarding the specific drugs to be used and their possible benefits were given. The concept of pain scores as well as the interpretation thereof was explained.

Nursing staff had been very excited about the new protocol. They were particularly impressed with the introduction of ketamine as a rescue analgesic because they were apprehensive of giving morphine too frequently in fear of promoting tolerance and addiction in patients.

The aim of this study was to determine whether any progress had been made in terms of the severity of postoperative pain experienced by patients in the burns unit of Tygerberg Academic Hospital since the previous audit done in 2012.

The primary objective was to measure the severity of postoperative pain and the incidence of moderate or severe pain 24 hours after a burns injury related procedure at Tygerberg Academic Hospital burns unit. These results were then compared with the results of a previous similar study in the same setting.

The secondary objective was to audit the frequency of analgesia administered during the first 24 hours after surgery for a burns related injury.

1.3 Ethics Approval Letter

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Approval Notice
New Application

08-Mar-2017
Greyling, Adriaan AJ

Ethics Reference #: S17/02/028

Title: **Reassessment of acute postoperative pain in a resource limited burns unit after the implementation of an analgesic management plan.**

Dear Dr Adriaan Greyling,

The **New Application** received on **08-Feb-2017**, was reviewed by members of **Health Research Ethics Committee 1** via Expedited review procedures on **02-Mar-2017** and was approved.
Please note the following information about your approved research protocol:

Protocol Approval Period: **08-Mar-2017 -07-Mar-2018**

Please remember to use your **protocol number** (**S17/02/028**) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:
Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired.
The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.
Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel:

+27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at .

Included Documents:
Appendix Timeline.docx
Appendix post-operative pain management plan.docx
Child Assent Form(Eng).doc
Appendix Data dictionary.docx
Application form page 6 SIGNED.pdf
Application form.doc
Appendix variables.docx
Appendix Peri-operative pain plan Poster.pdf
CV Dr Murray.pdf
Protocol Synopsis
Appendix Pain scale and survey.docx
Appendix Budget.docx
Full research proposal.docx
Informed consent Eng.doc
CV Dr Greyling.doc
Child Assent Form(Afr).doc
Investigator Declaration dr Murray.pdf
Informed consent Afr.doc
Investigator declaration dr Greyling.pdf
General Checklist.doc

Sincerely,

Franklin Weber
HREC Coordinator
Health Research Ethics Committee 1

Investigator Responsibilities

Protection of Human Research Participants

Some of the responsibilities investigators have when conducting research involving human participants are listed below:

1.Conducting the Research. You are responsible for making sure that the research is conducted according to the HREC approved research protocol. You are also responsible for the actions of all your co-investigators and research staff involved with this research.

2.Participant Enrolment. You may not recruit or enrol participants prior to the HREC approval date or after the expiration date of HREC approval. All recruitment materials for any form of media must be approved by the HREC prior to their use. If you need to recruit more participants than was noted in your HREC approval letter, you must submit an amendment requesting an increase in the number of participants.

3.Informed Consent. You are responsible for obtaining and documenting effective informed consent using **only** the HREC-approved consent documents, and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Please give all participants copies of the signed informed consent documents. Keep the originals in your secured research files for at least fifteen (15) years.

4.Continuing Review. The HREC must review and approve all HREC-approved research protocols at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period.** Prior to the date on which the HREC approval of the research expires, **it is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in HREC approval does not occur.** If HREC approval of your research lapses, you must stop new participant enrolment, and contact the HREC office immediately.

5.Amendments and Changes. If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of participants, participant population, informed consent document, instruments, surveys or recruiting material), you must submit the amendment to the HREC for review using the current Amendment Form. You **may not initiate** any amendments or changes to your research without first obtaining written HREC review and approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to participants and the HREC should be immediately informed of this necessity.

6.Adverse or Unanticipated Events. Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research-related injuries, occurring at this institution or at other performance sites must be reported to the HREC within **five (5) days** of discovery of the incident. You must also report any instances of serious or continuing problems, or non-compliance with the HRECs requirements for protecting human research participants. The only exception to this policy is that the death of a research participant must be reported in accordance with the Stellenbosch Universtiy Health Research Ethics Committee Standard Operating Procedures www.sun025.sun.ac.za/portal /page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/Application_package All reportable events should be submitted to the HREC using the Serious Adverse Event Report Form.

7.Research Record Keeping. You must keep the following research-related records, at a minimum, in a secure location for a minimum of fifteen years: the HREC approved research protocol and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence from the HREC

8.Reports to the MCC and Sponsor. When you submit the required annual report to the MCC or you submit required reports to your sponsor, you must provide a copy of that report to the HREC. You may submit the report at the time of continuing HREC review.

9.Provision of Emergency Medical Care. When a physician provides emergency medical care to a participant without prior HREC review and approval, to the extent permitted by law, such activities will not be recognised as research nor will the data obtained by any such activities should it be used in support of research.

10.Final reports. When you have completed (no further participant enrolment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Final Report to the HREC.

11.On-Site Evaluations, MCC Inspections, or Audits. If you are notified that your research will be reviewed or audited by the MCC, the sponsor, any other external agency or any internal group, you must inform the HREC immediately of the impending audit/evaluation.

Chapter 2

2.1 Literature Review

2.1.1 Introduction

Burns are a common form of injury leading to presentation at a health care facility. In 2004, nearly 11 million people worldwide suffered burns severe enough to require medical attention. Burns may be caused by heat, radiation, radioactivity, electricity, friction or contact with chemicals.[2] An annual estimated 265 000 deaths worldwide are caused by burns, mostly occurring in low- and middle-income countries. Non-fatal burns are a leading cause of morbidity and prolonged hospitalization. It also causes disfigurement and disability, often with resulting stigma and rejection. Burns are one of the leading causes of disability-adjusted life-years (DALYs) lost in low- and middle-income countries.[2] It is estimated that US$ 26 million is spent annually for care of burns from kerosene (paraffin) cook stove incidents in South Africa. It has further socio-economic impact due to lost wages, prolonged care for deformities and emotional trauma, as well as commitment of family resources.[2]

According to most recent data, males and females have broadly similar rates for burns. Burn risk correlates with socio-economic status regardless of the level of development of countries. Specific risk factors for burns as listed by the World Health Organization, which are well known to be prevalent in South Africa are:

- poverty, overcrowding and lack of proper safety measures
- placement of young girls in household roles such as cooking and caring for small children
- underlying medical conditions, including epilepsy, peripheral neuropathy, physical and cognitive disabilities, alcohol abuse and smoking
- easy access to chemicals used for assault (such as in acid violence attacks)
- use of kerosene (paraffin) as a fuel source for non-electric domestic appliances.[2]

Patients with serious or extensive burns often have prolonged hospital admission as well as repeated surgical interventions. Surgery related to burns is often associated with severe and incompletely treated post-operative pain. Post-operative pain in developing countries has been reported to be higher than in developed countries.[1] Patients suffering burn injuries are at risk of developing opioid tolerance due to prolonged admission with long term opioid treatment.[1,3] Tolerance is characterized by a reduced responsiveness to opioid agonists such as morphine and is manifested by needing to increase opioid doses to achieve the desired effect.[4] As suggested in an article by Murray and Retief (2016), cost-effective ways to improve analgesia need to be found. They recommend the targeting of populations with a higher incidence of post-operative pain and fully utilizing basic analgesic methods. Infrequent administration of analgesic agents was shown to be a possible contributor to uncontrolled pain. [1]

2.1.2 Mechanism of aggravated pain in burn injuries

The early pain after a burn injury is due to direct stimulation and injury of the epidermal and dermal nociceptors. This leads to the transmission of nerve impulses by A-delta and C-fibers to the dorsal horn of the spinal cord. The magnitude of these impulses are modulated by the peripheral stimuli as well as descending influences from the brain.[5]

Within minutes from the time of injury an inflammatory response is initiated. This leads to the release of numerous chemical irritants that sensitize and stimulate the nociceptors at the site of the burn injury for several days. This site remains painful and sensitive to mechanical and thermal stimuli – known as primary hyperalgesia. Tissues adjacent to the site of injury may undergo a change in sensitivity to mechanical stimuli known as secondary hyperalgesia. With the gradual subsiding of the inflammatory response, the quality of pain changes. The intensity of pain varies, being typically at its maximum in places of skin loss and tissue donor areas. The destruction of nerve endings in severe burns may lead to local insensitivity to pain. Disorderly regeneration of nerve tissue in these areas predispose to neuropathic pain.[6]

Four patterns of pain have been described in patients with burn injuries.

- Background pain is the constant pain at rest and in motion.
- Breakthrough pain is intense and sudden worsening of pain that is episodic.
- Procedural pain is related to specific procedures e.g. dressing changes.
- Post-operative pain is pain experienced following a surgical procedure e.g. debridement of skin, amputation or skin grafting.[6]

2.1.3 Causes for inadequate analgesia in postoperative patients

Continued or repeated pain stimuli in the setting of inadequate background or procedural analgesia gives rise to central nervous system adaptations. Pain signals and perception thereof become facilitated and amplified, causing hyperalgesia. Unfortunately these changes may become irreversible with time and then lead to chronic pain. Mechanisms involved in this wind-up are sensitization of peripheral receptors, an increase in excitability at the dorsal horn of the spinal cord involving N-methyl-D-aspartate (NMDA) receptor systems as well as descending pathway activation.[7] The use of pre-operative and intra-operative opiates, younger age, larger burn size and increased pre-operative pain is associated with more post-operative pain. Tolerance, which involves the physiologic adjustment to the analgesic effects of many analgesic agents, may be partially responsible for this phenomenon.[8]
A lack of nursing knowledge regarding pain assessment and pain management strategies leads to the under treatment of pain in patients.[9–11] Nursing reliance on their own subjective judgment is a barrier to effective management of patients' pain. Nurses who have had additional focused education regarding pain management were found to have better knowledge about pain management.[9]

The lack of integrating the current knowledge and practice of effective pain management by health care staff has negative effects on patient well-being.[10] It has been shown that the use of systematic nursing pain assessment tools as well as pain flow sheets leads to improved pain documentation and management.[12]

2.1.4 Consequences of uncontrolled post-operative pain

Burn pain is a very difficult form of acute pain to treat. Standard burn care is also likely to worsen background pain.[13] Acute postoperative hyperalgesia will likely increase the amount of pain experienced by the patient. This then has the potential to increase the effects of subsequent and ongoing nociceptive inputs from the wound on the patient in the areas of stress, immunity and tissue-tropism. These effects increase the risk of complications, impair mobilization, prolong hospital admission and may cause other unwanted consequences following surgery.[7] Examples of these include amongst others: decreased alveolar ventilation, pneumonia, hypertension, deep venous thrombosis (DVT), tachycardia, myocardial infarction and insomnia. Increased pain perception leads to increased analgesia use with the side effects thereof – well documented in the case of opioid use with respiratory, gastrointestinal and urologic side effects.[7]

Pain can interfere with wound care and there is also an association with general emotional distress as well as long-term post-traumatic stress disorder.[13]
Chronic pain is a well-recognized complication following burn injuries. Nerve tissue that was damaged and regenerate can give rise to complex neuropathic pain syndromes. In these the sensation of the painful stimulus far outlives its expected duration. Patients may experience hyperalgesia where there is an increased response to a painful stimulus and also allodynia where a normal innocent stimulus is perceived as painful. This problem can start early on after the initial injury and persist for many years thereafter. This chronic pain is often resistant to conventional analgesics. Chronic symptom severity is often related to burn size as well as number of skin graft procedures performed.[14]

2.1.5 Methods of pain measurement

Pain scales in use are the Visual analogue scale (VAS), Verbal numeric rating scale (VNRS), Verbal rating scale (VRS), Faces pain scale and PAINAD Scale. [15] The VAS is well validated for acute pain and post-operative pain.[16–20] There is a good correlation between the 4 point categorical pain scale and the VAS.[18,20,21] We categorized the pain scale into similar categories than previous studies, in order to

do comparisons: (1) No Pain (0 - 5mm), (2) Mild Pain (5 - 40mm), (3) Moderate Pain (41 - 75mm) and (4) Severe Pain (76 - 100mm).[1,22] VAS is the most sensitive to different pain intensities.[23] No difference was found between the completion thereof by men or women[21] and it can be used to rate current, most or average pain over a period (retrospective).[18,23]

In a literature review by Coll (2003) based on established criteria, the VAS was found to be methodologically sound, conceptually simple, easy to administer and unobtrusive to the respondent. On these grounds, the VAS seemed to be most suitable for measuring intensity of pain after day surgery.[24]
In a multivariate analysis was found that none of the variables such as age, gender, and education level had significant effects on correlation between visual analogue scale and faces rating scale.[25] The pain assessment tool for this study was the visual analogue scale.

According to an article by Kelly (2001), the minimum clinically significant difference (MCSD) in VAS pain scores does not differ with the severity of the pain being experienced. The overall MCSD in VAS score for the whole group was 12 mm. MCSD in VAS score for the “mild pain” group was 11mm, for the “moderate pain” group 14 mm for the severe pain group, 10 mm.[26]

2.1.6 Approaches to post-operative pain in burns patients

The goal of post-operative pain management is to have optimal pain relief while minimizing the side effects of the analgesia. Pre-emptive analgesia may decrease post-operative pain as well as decrease post-operative analgesia requirements.[27]
Using a validated pain assessment tool to evaluate post-operative pain and managing the pain according to it, is strongly recommended by the American Pain Society.[28] Anaesthesia for burn injuries as well as intensive care can form a significant part of the anaesthetic workload in the hospital with a burn center.

Anaesthetists need an appreciation of analgesia management related to the pathophysiology of the burn, as their role in supporting analgesia for burn patients is crucial. Generalist anaesthetists are also key role players because burn patients

usually present at their local hospitals first. Early appropriate management of burn pain have a significant impact on the later experience of pain.[14]

Patients commonly suffer low-grade but persistent discomfort after initial treatment and between procedures. The nature of this has been repeatedly shown to be under-appreciated even by experienced staff. It is difficult to treat adequately while aiming to minimize the patient's exposure to side-effects. Adequate treatment is however essential to patient well-being.[14]

In a review article by Norman and Judkins (2004), multimodal analgesia is advocated, using low dose oral opioids in combination with NSAIDs. Regular evaluation of extent of pain relief is required as is careful titration of analgesic doses,[14] which is difficult in resource limited settings. The challenges surrounding the use of NSAIDs are mentioned later on in this literature review. Pre-emptive, regular dosing with analgesia combined with additional supplemental analgesia for the treatment of breakthrough pain is very effective in clinical practice.[14]

Burn patients may not only suffer pain from the burn wound area and skin donor areas, but also from other related injuries. This is especially true in major or multiple injuries including fractures. Pain of co-existent abdominal injuries should be managed appropriately. Pain in a limb with circumferential burns may allude to compartment syndrome. Surgical decompression would then be required. Pain may also be a sign of cellulitis or pus formation in the recovery phase of burn injuries.

Major burns may be associated with many complications including perforation of an abdominal viscus, colonic pseudo-obstruction, abdominal compartment syndrome and heterotopic bone deposition. A change in the type of pain or the magnitude of pain may be the first indication of a complication.[14]

Pain management in burn patients remain challenging for the multidisciplinary team. An understanding of the complexity of the pathophysiological, psychological, and biochemical changes presented by a burn patient is of cardinal importance in achieving success in analgesic management.[6]

Burn care staff may be reluctant to aggressively treat pain out of fear for creating dependence on opioids. Evidence does suggest though that opioid addiction does not occur more commonly in burn patients than in other populations who required opioids for treatment of acute pain – about 1 in 3000.[13]

Paracetamol's analgesic effects are due to action both centrally and peripherally. Used as the sole analgesic it has a weak analgesic effect but it has a very good synergistic effect when used in combination with opioids. It has few contraindications and an excellent risk profile. If not contraindicated, paracetamol should be used regularly in all burn patients at its maximal dose of 90 mg/kg/day with 4 or 6 hourly dosing.[5] The different mechanisms of action of paracetamol involve the inhibition of activity of cyclo-oxygenase 2 (rather than 1), inhibition of central prostaglandin synthesis and the activation of descending serotonergic pathways.[29]

The central analgesic effects of mu-opioid receptor agonists such as morphine are effected by actions on neurons within brain regions such as the mid-brain periaqueductal grey (PAG). Mu-opioid agonists inhibit GABAnergic influences on output projection neurons within the PAG.[30]
Mu-opioid receptor agonists, such as morphine, are widely used effective analgesic agents. It is however commonly accompanied with unwanted side effects such as respiratory depression, sedation and constipation. They have a strong potential for addiction and often need to be used in escalating doses because of the rapid development of tolerance to the analgesic actions of the drugs.[30]

Tramadol is a synthetic atypical opioid analgesic and acts by binding mainly to the mu-opioid receptor at the central nervous system.[31] It also inhibits the reuptake of noradrenaline and serotonin and is therefore regarded as having a multimodal mechanism of action.[32] It is relatively devoid of serious side-effects[33] and has been shown to potentiate the analgesic effect of ketamine.[31] It is well known that tramadol acts synergistically with paracetamol to provide an analgesic effect.[32]

Ketamine is a non-competitive antagonist on the N-methyl-D-aspartate (NMDA) receptor which is a ligand gated calcium channel using glutamate as its major endogenous agonist. Activation of this calcium channel is a major contributor to the

'wind-up' phenomenon which leads to central sensitization. Ketamine is therefore said to be effective in pathological pain states caused by this process.[34] It is often used for conscious sedation during dressing changes in burn patients.[35]

Ketamine at sub-anaesthetic doses of 0.1 -0.3 mg/kg is effective for pain relief. Ketamine at such low doses is safe, effective and when combined with opioids it improves pain management. Ahern et al (2015) did a large series reporting on the use of low dose ketamine for pain relief in an emergency department (ED) setting. They found it to be feasible and safe for the treatment of a wide variety of painful conditions. The adverse event rate was 6% overall, which is lower than the rate of that of opioids in hospitalized patients. The adverse events were easily identified and managed by ED staff. Furthermore none of the adverse events had caused harm or changed disposition. There were no reported incidents of apnea, laryngospasm, hypertensive emergency, or cardiac arrest. They concluded that low dose ketamine, either used alone or in combination with other pain medications, in a diverse ED patient population as a primary or rescue analgesic appears to be safe and feasible for the treatment of many types of pain.[36]

In addition to prevention of awareness and recall in anaesthetized patients, ketamine also possesses anti-inflammatory and anti-tumour actions. It also potentiates opioid analgesia and prevents opioid induced acute tolerance and possibly also opioid induced spinal ischaemia after cross clamping of the aorta.[3]

A review by Carstensen and Moller (2010) of randomized, double-blinded clinical trials where ketamine was added to morphine in intravenous Patient Controlled Analgesia (PCA) for postoperative pain, found that the ketamine–morphine combination could significantly reduce pain scores, cumulative morphine consumption, and postoperative desaturation in patients undergoing thoracic surgery compared to the use of intravenous morphine only PCA. This effect was less clear in orthopaedic and abdominal surgery.[37] Opioid tolerance and hyperalgesia are of particular importance in patients suffering from intractable severe pain due to trauma, malignancy or neuropathy. Opioid tolerance and dependence may result from long term or high-dose exposure to opioids, or both.[3]

Ketamine is rapidly metabolized in the liver and lung to norketamine. Norketamine has been reported to have anti-nociceptive actions in addition to enhancing morphine's anti-nociceptive action to thermal nociception, peripheral neuropathy, and tonic inflammatory pain. Norketamine also blocked tolerance.[38] Immuno-inhibitory effects of ketamine were found to be partly due to inhibition of Transcription Factor Activator Protein-1 and Nuclear Factor-kB (NF-kB), these play a role in regulation of the production of pro-inflammatory mediators.[3]

In an article by Jouguelet-lacoste et al. (2015) it was reported that four meta-analyses out of five concluded that ketamine was safe to be administered as it did not increase the incidence of adverse side effects, this was irrespective of the route of administration. The meta-analysis that did find an elevated occurrence of side effects showed them to be all minor psychotomimetic effects. These were short term and reversible, ceasing when stopping the ketamine infusion or using benzodiazepines. The reviews reported ketamine had no impact on sedation scores.[39] Ketamine was found to decrease the incidence of nausea and vomiting.[39,40] In the 39 clinical trials of low dose ketamine (IV infusion rate of less than 1.2 mg/kg/h and bolus dose less than 1 mg/kg) included in the review by Jouguelet-lacoste et al., there were no occurrence of liver toxicity. Their review showed ketamine reduced opioid consumption, enhanced post-operative analgesia and that low-dose ketamine is safe to administer. Ketamine's benefit is believed to be predominantly from a reduction of opioid burden more than a reduction of pain scores. The drug's optimal dose and regimen of administration, however, remain unknown.[39]

Ketamine gives an improved quality of pain control as well as decrease in the consumption of opioids. Nightmares and hallucinations are more commonly encountered but sedation not. Ketamine had significant analgesic benefit in procedures involving the thorax and upper abdomen but not for tonsillectomy, dental, head and neck surgery. The perioperative use of adjuvant Ketamine for analgesia was shown to be relatively safe with no serious side effects. Ketamine is known for its neuropsychiatric side effects which are often a drawback for the routine use of this drug. These side effects were more prevalent with treatment efficacy. Most individual articles found these effects to be not statistically significant and many papers reported that the psychological side effects were well tolerated. Laskowski,

Stirling, Mckay & Lim (2011) proposed that there is little to be gained from further randomized control trials evaluating ketamine's role in surgery known to produce mild pain, instead further studies should focus studying patients at risk for severe postoperative pain and respiratory depression and on investigating the rescue of patients who continue to suffer severe postoperative pain despite routine treatment. Subgroup analyses has shown the greatest opioid sparing effect of ketamine occurs when high maximum postoperative pain scores are encountered.[40]

Nonsteroidal anti-inflammatory drugs (NSAIDs) have analgesic, anti-inflammatory, and antipyretic properties.[5] The action of NSAIDS include reversibly inhibiting cyclo-oxygenase as well as inhibiting prostaglandin production, and sometimes by inhibiting the lipoxygenase pathway.[30] NSAIDS work very well when combined with opioids. They decrease central hyperalgesia, act synergistically with opioids and are also opioid sparing.[5,41]

The side effects of NSAIDs that limit their use in burns are as follows:

1) Mucosal irritation and ulceration of stomach.[5,41]
2) Platelet dysfunction that may cause bleeding problems.[5,41]
3) Impaired renal function that may lead to renal failure.[5,41]
4) Alteration of the concentration of protein-bound medication (eg. warfarin).[41]

For these reasons, NSAIDs are not routinely used in the Tygerberg Hospital burns unit.

2.1.7 Compliance with prescribing analgesia and issuing analgesia

Poor adherence by nursing personnel to issue analgesia according to the prescription chart is a known phenomenon. This is more frequently encountered when opioids are used. Reasons for this are their anxiety regarding respiratory depression and the possibility of patient addiction developing. The pressure of time on nurses also hinders compliance to prescription orders. The ease of administering non-opioid analgesia is a further reason why opioids are poorly administered despite having been prescribed.[42]

To improve the treatment of pain, pain needs to be routinely assessed and once identified, appropriate analgesia needs to be administered.[43] Regular monitoring of pain as the 5th vital sign in addition to blood pressure, pulse, respiratory rate and temperature forms part of the South African Acute Pain Guidelines.[15]
Educational interventions are of great importance to improve the standard of care and regular audits are recommended in order to maintain greatest benefit.[44,45] Posters can be used to communicate a change in policy and for educational purposes.[46]

2.1.8 Interventions made at Tygerberg burns unit

Several changes have been made by the Department of Anaesthesiology and Critical Care following the study of Murray and Retief in the identified high risk patient group of burns.[1] Previously there was no formal pain monitoring but it has subsequently become part of the monitoring of patients' vital signs by the nursing staff. Analgesia was not always administered frequently but subsequent training of nursing staff has focused on creating awareness of pain as well as improving compliance to prescribed analgesia. While there was no standardised prescription of analgesia by anaesthetists, there is now a standardised analgesia protocol.

The comprehensive analgesia management plan is essentially made up of the following:

- Posters are displayed in the burns unit as well as in the burns theatre with the protocol for analgesia prescription on it (Appendix F).
- Pain protocol (pre-operative):
    - Patients receive a premedication of morphine 5 - 10mg intramuscular or subcutaneously.
    - The anaesthetist may prescribe a premedication of paracetamol 1g per os.

- Pain protocol (intra-operative):
    - Dosing of morphine is done by the anaesthetist and is individualized according to the patient's opioid history in the ward prior to the surgery, estimated body mass index (BMI) as well as other comorbid conditions.
    - Titration of intravenous morphine intra-operative is done against the vital signs and also the extent of spontaneous breathing when not muscle-relaxed.
    - Patients receive an intravenous bolus dose of ketamine 0.25 – 0.5 mg/kg intra-operatively, with the option of repeating this if deemed necessary by the anaesthetist.
    - The anaesthetist may consider an intravenous infusion of ketamine 1-2mg/kg/hour for the duration of the surgery.
    - Patients who did not receive paracetamol as a premedication may receive intravenous paracetamol (15mg/kg to a maximum of 1 gram) intra-operatively, or in the recovery room directly after the surgery.
- Pain protocol (post-operative):
    - Patients receive oral paracetamol at a dose of 20mg/kg (maximum 1g) every 6 hours, as well as oral tramadol 50mg 6 hourly.
    - Where available, patients can receive intravenous paracetamol (15mg/kg, maximum 1g) 6 hourly rather than orally.
    - Routine intramuscular / subcutaneous morphine 10mg every 4 hours post-operatively, according to the pain score reported by the patient, the dose is once again adjusted up or down according to the opioid history as well as response to opioids pre-operatively, BMI and the comorbid conditions.
    - Naloxone is readily available in the Burns unit for use in the case of opioid overdosing.
    - Post-operatively patients are prescribed ketamine 0.25mg/kg intramuscular every 4 to 6 hours depending on the pain score the patient reports.

- Ongoing nursing education with the aim of:
    - Increasing awareness of the fact that patients experience pain.
    - Improving compliance to the prescribed analgesic regimen.
    - Motivation to continue with pain scores as part of routine observations and correctly acting upon it.
- Formal pain monitoring:
    - Dedicated postoperative observation chart where pain scores are documented.
    - Guidelines on how to act upon unacceptably high pain scores.

The analgesia protocol is not there to replace clinical judgement of the attending clinicians and an emphasis is placed on evaluating the analgesic needs of the patient with the analgesia protocol serving as a framework. Deviations from the protocol are allowed as it was not intended to be a “one size fits all” solution.

Chapter 3

3.1 Methodology and Materials

This was a follow-up observational study of the burns population identified as high risk for poorly controlled postoperative pain according to Visual Analogue Scale (VAS) measurement in a study done by Murray and Retief in 2012 (published in 2016) when there was no standard analgesic protocol.[1]

A repeat sample of the burns population in the burns unit of Tygerberg Academic Hospital was evaluated with regards to their experience of postoperative pain in the first 24 hours after wound debridement or skin grafting. The time interval between the implementation of the new protocol and the start of the audit was five months.
The study population included all patients that were scheduled for surgery above the age of 12 years in the Burns Unit.

Exclusion criteria were as follows:

- Age younger than 13 years.
- Visual or intellectual impairment to such an extent that the patient is unable to understand his/her role in participation in the study, or where he/she is unable to give informed consent via an interpreter.
- Psychosis or delirium.
- Patients with a contra-indication for the medication used in the comprehensive analgesia management plan.
- Clinically unstable patients in whom the completion of the questionnaire may not be possible.
- Patients who were kept sedated or intubated and ventilated at the end of the surgical procedure and are therefore not able to give an accurate account of the post-operative period of pain relief.
- Patients arriving in the recovery unit before 7h00 am or after 18h00 pm.

The pain assessment tool that was used in this study as well as the initial study in 2012 was the VAS. It has been well validated for postoperative pain in men and

women. A difference in VAS scores of 12 mm is regarded as the minimum clinically significant difference according to the literature. [26]

Data was collected on a 100 mm paper VAS by the investigators in three of the local languages (English, Afrikaans and isiXhosa). Patients were interviewed as close as possible to 24 hours after surgery, after informed consent was obtained. VAS scores for worst pain in the first 24 hours postoperative as well as the current level of pain at the time of the interview were obtained. The number of analgesic doses received for different oral and parenteral analgesic drugs were obtained from the prescription charts in patient folders.

3.2 Statistics and power analysis

The sample size calculation was subjective to the sample size from the previous study by Murray and Retief, which had 57 participants and would form the first study group. We would not have the power to detect a 12 mm difference as is the minimal clinically significant number, but we would be able to detect a difference of 18 mm, which we expected to obtain. The standard deviation of 31 mm from the previous study was used to calculate the sample size to detect a predicted difference of 18 mm between the initial and new mean VAS pain scores. If a power of 0.80 and an alpha value of 0.05 are used during parametric methods (Two sided T-test), the sample size needed to detect an 18 mm difference between two means in a population with a standard deviation of 31 mm would be 51. These values were obtained by using the STATA 14 statistical software.

Due to the skewness and ordinal character of pain scale data, it is recommended that medians with non-parametric statistics should be used. The study population should therefore be increased with 10%, making 57 patients in each group adequate to detect an 18 mm difference in medians.

Data was captured on an Excel spread sheet. Patient confidentiality was maintained with the name of the patients and study results not being in the same document. Data was analyzed with the help of the Biostatistics Unit at the Tygerberg Campus of Stellenbosch University using STATA 14 statistical software.

The outcome was measured as a difference in post-operative VAS scores between the reference and follow-up groups. Data was described and compared using median values (with confidence intervals), interquartile ranges and ranges. A Chi square test was done to detect the probability of a difference to be by chance. A p-value of below 0.05 was deemed statistically significant. The median difference between the medians was calculated with 95% CI.

Data from the reference and follow-up groups were dichotomized into two groups. The first group included no or mild pain (0-40mm VAS score) and the second group moderate to severe pain (41-100 mm VAS score). Odds Ratios with 95% confidence intervals and Numbers Needed to Treat were subsequently calculated. A Chi square test was done to detect the probability of a difference to be by chance.

Chapter 4

4.1 Results

4.1.1 Descriptive statistics

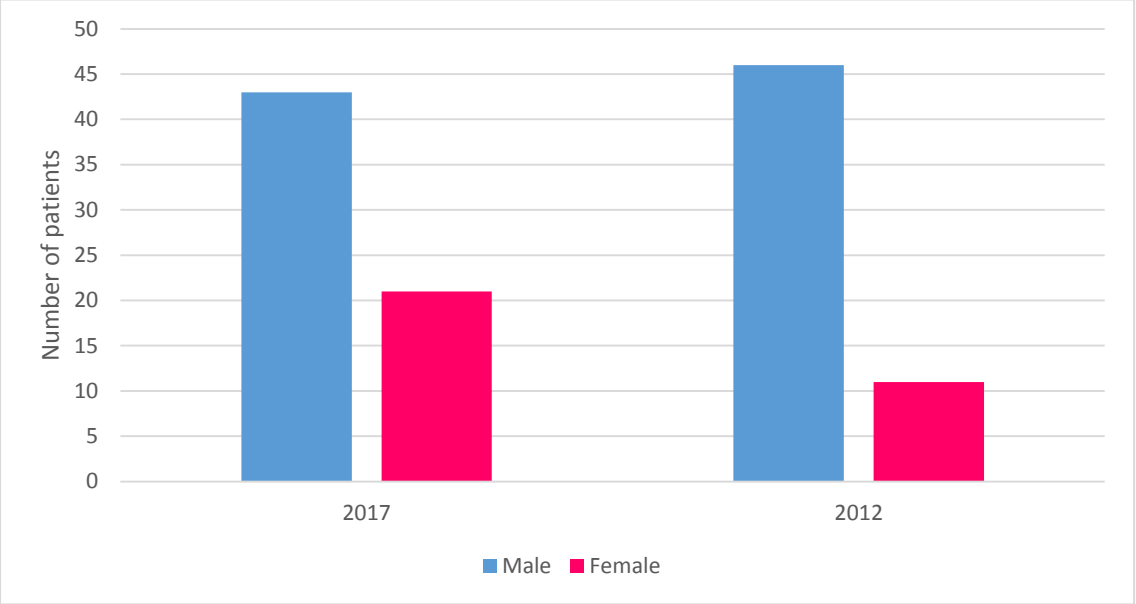
A total of 64 patients were enrolled in the audit. Data was collected over a period of 12 weeks from the 3rd of May 2017 to the 20th July 2017. Patients were interviewed as close as possible to 24 hours postoperatively in the Burns Unit of Tygerberg Academic Hospital. Only patients who complied with the criteria listed above were approached to participate. There was a 100% compliance rate with no one refusing to be interviewed.

Table 1: Age summary of different groups

	2017	2012
Mean age (years)	34	34
SD	12	12
Range	14 to 67	14 to 70

The mean age of participants in 2017 as well as 2012 was 34 years. The standard deviations for both groups were 12. The range for age in 2017 was 14 to 67 compared to 14 to 70 in 2012. The p-value for comparing the mean age of the two groups is 0.96.

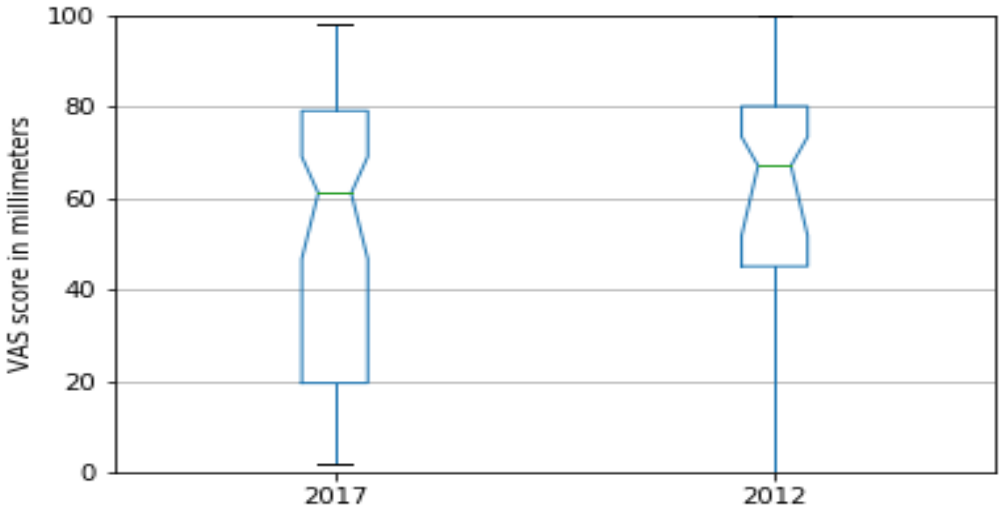
Graph 1: Gender distribution for 2012 and 2017



There were 43 males and 21 females in the study group of 2017, compared to 46 males and 11 females in 2012. The p-value for gender comparison between the groups is 0.09.

4.2 Worst pain scores

Graph 2: Notched box and whiskers plot for worst pain



In 2017 the range for worst pain scores as indicated on a VAS was 2mm to 98mm. The 25th percentile was 19.5mm and the 75th percentile was 79mm. The median value was 61mm. The 95 percent confidence interval for the median value was 46.6mm to 69.0mm. In 2012 the range for worst pain scores as indicated on a VAS was 0mm to 100mm. The 25th percentile was 45mm and the 75th percentile was 80mm. The median value was 67mm. The 95 percent confidence interval for the median value was 51.7mm to 73.3mm.

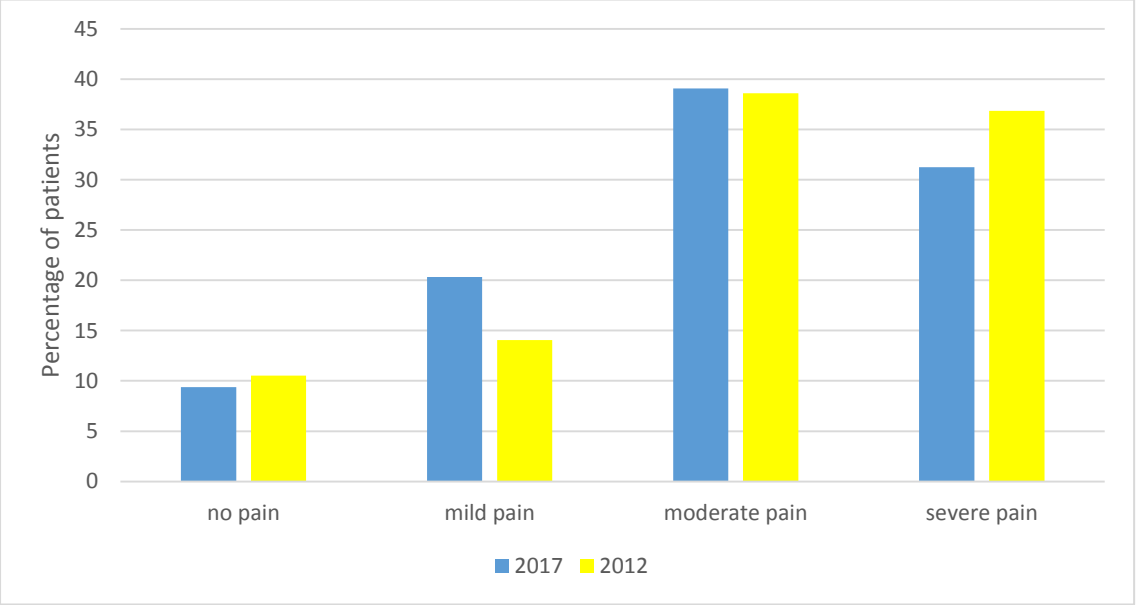
Table 2: Categorisation of worst pain scores

	2017			2012		
	N	**%**	**95% CI**	**n**	**%**	**95% CI**
no pain	6	9.4	4.2 - 19.7	6	10.5	4.7 - 22.0
mild	13	20.3	12.0 - 32.3	8	14.0	7.0 - 26.1
moderate	25	39.1	27.7 - 51.8	22	38.6	26.6 - 52.1
severe	20	31.2	20.9 - 43.9	21	36.8	25.1 - 50.4
total	64	100		57	100	

Pain was categorised into the following groups according to the VAS scores: (1) No Pain (0 - 5mm), (2) Mild Pain (5 - 40mm), (3) Moderate Pain (41 - 75mm) and (4) Severe Pain (76 - 100mm). When evaluating the worst pain experienced in the first 24 hours postoperatively in the 2017 group that had 64 patients, the results were as follows. There were 6 patients with no pain, representing 9.4% of the group, with a confidence interval of 4.2 to 19.7. There were 13 patients with mild pain, representing 20.3% of the group, with a confidence interval of 12.0 to 32.3. There were 25 patients with moderate pain, representing 39.1% of the group, with a confidence interval of 27.7 to 51.8. There were 20 patients with severe pain, representing 31.2% of the group, with a confidence interval of 20.9 to 43.9. When evaluating the worst pain experienced in the first 24 hours postoperatively in the 2012 group that had 57 patients, the results were as follows. There were 6 patients with no pain, representing 10.5% of the group, with a confidence interval of 4.7 to 22. There were 8 patients with mild pain, representing 14% of the group, with a confidence interval of 7 to 26.1. There were 22 patients with moderate pain,

representing 38.6% of the group, with a confidence interval of 26.6 to 52.1. There were 21 patients with severe pain, representing 36.8% of the group, with a confidence interval of 25.1 to 50.4. The p-value for comparing worst pain scores between the two groups is 0.4.

Graph 3: Worst pain measurements



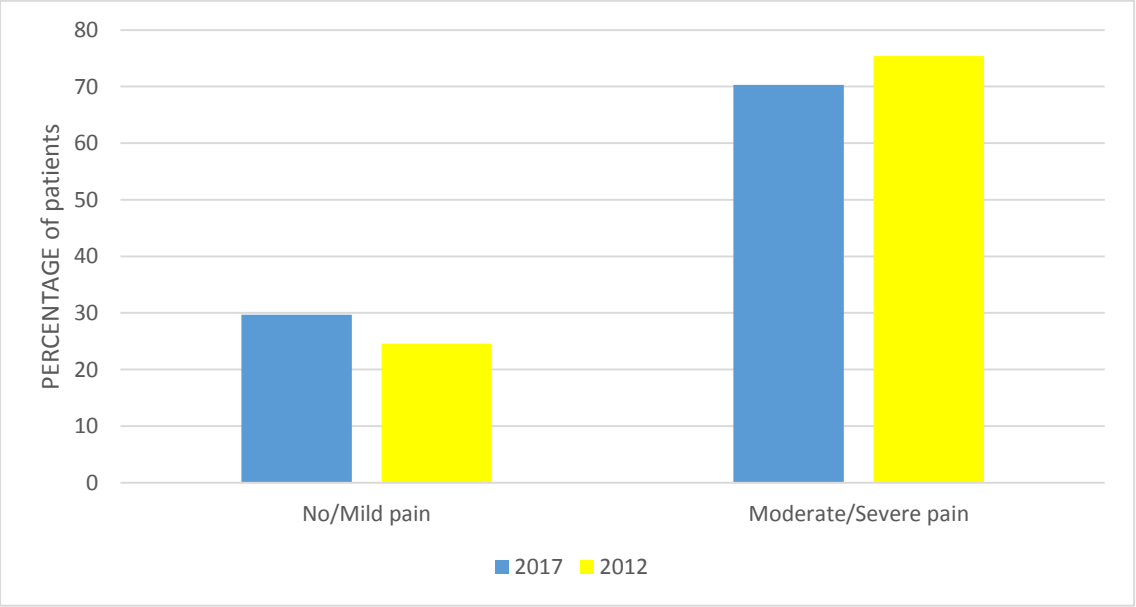
When evaluating the worst pain experienced in the first 24 hours postoperatively, 9.4% of patients in 2017 had no pain compared to 10.5% in 2012. Mild pain was reported by 20.3% in 2017 compared to 14% in 2012. Moderate pain was reported by 39.1% of patients in 2017 compared to 38.6% in 2012. Severe pain was reported by 31.2% of patients in 2017 compared to 36.8% in 2012. The p-value for comparing worst pain scores between the two groups is 0.4.

Table 3: Dichotomisation of worst pain scores

	2017		2012	
	n	%	n	%
No- / mild pain	19	29.7	14	24.6
Moderate- / severe pain	45	70.3	43	75.4
Total	64	100	57	100

In 2017 there were 19 patients (29.7%) that reported no- or mild worst pain in the first 24 hours and 45 (70.3%) that had moderate to severe pain. In 2012 there were 14 patients (24.6%) with no to mild pain and 43 (75.4%) with moderate to severe pain. The p-value for comparing worst pain between groups after dichotomisation equals 0.53

Graph 4: Dichotomisation of worst pain scores



In 2017 there were 29.7% of patients that reported no or mild worst pain in the first 24 hours and 70.3% that had moderate to severe pain. In 2012 there were 24.6 % of patients with no to mild pain and 75.4% with moderate to severe pain. The p-value for comparing worst pain between groups after dichotomisation = 0.53

Table 4: Odds Ratio for moderate / severe pain in 2017 compared to 2012

	Odds Ratio	95% CI
Moderate / severe worst pain in 2017 vs 2012	0.77	0.34 – 1.73

The Odds Ratio for having moderate or severe worst pain in 2017 as opposed to 2012 was 0.77 with a 95% confidence interval of 0.34 to 1.73.

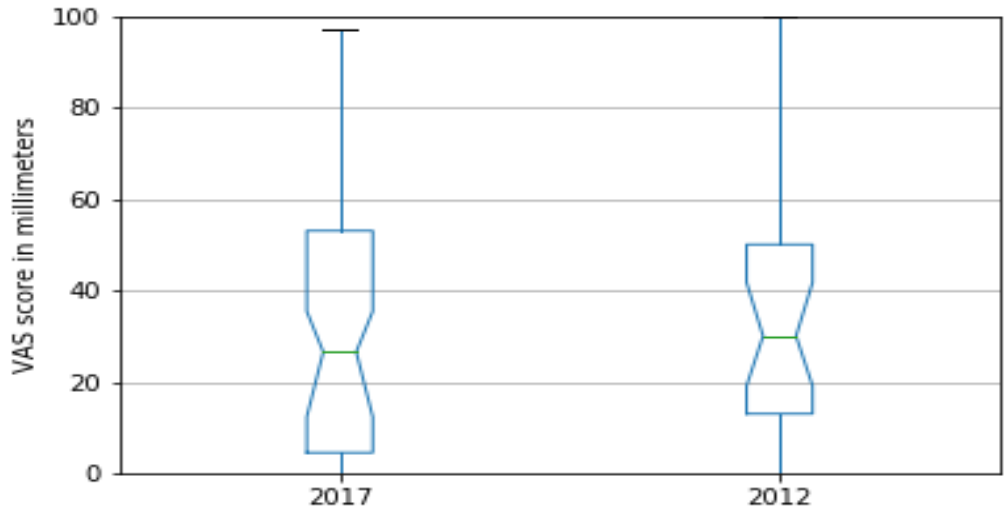
Table 5: Number needed to treat in 2017 for worst pain

	Number Needed to Treat
Moderate / severe worst pain	20

The number of patients needed to treat with the protocol of 2017 to prevent one patient from having moderate/severe worst pain compared to 2012 is 20.

4.3 Pain scores at 24 hours

Graph 5: Notched box and whiskers plot for current pain



In 2017 the range for current pain scores as indicated on a VAS was 0mm to 97mm. The 25th percentile was 4.5mm and the 75th percentile was 53mm. The median value was 26.5mm. The 95 percent confidence interval for the median value was 12.3mm to 35.4mm. In 2012 the range for current pain scores as indicated on a VAS was 0mm to 100mm. The 25th percentile was 13mm and the 75th percentile was 50mm. The median value was 30mm. The 95 percent confidence interval for the median value was 19.1mm to 41.7mm.

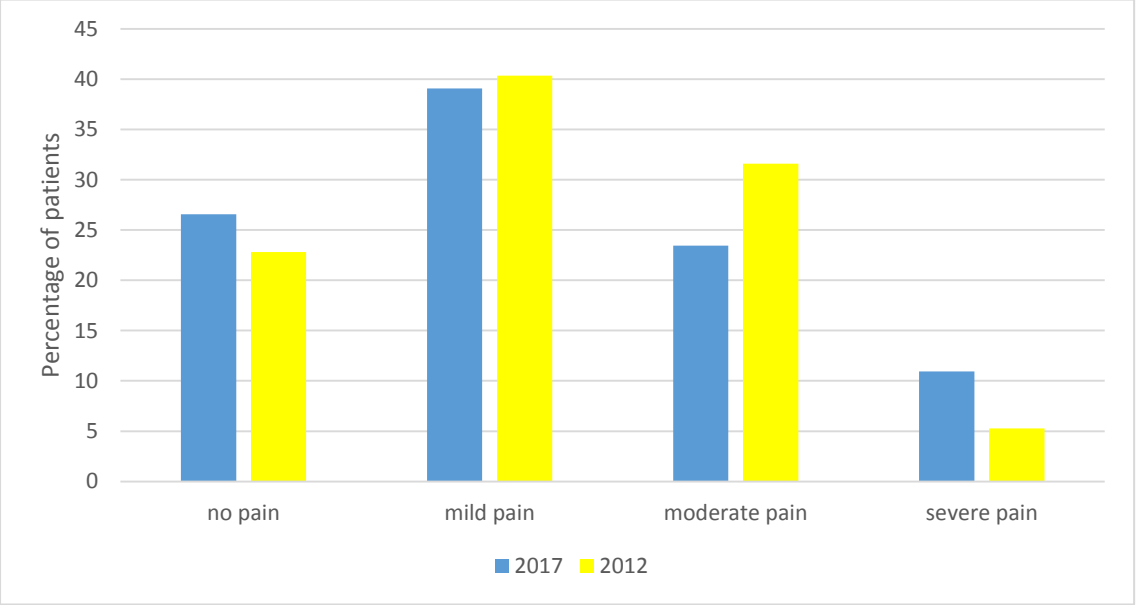
Table 6: Categorisation of current pain scores

	2017			2012		
	n	**%**	**95% CI**	**n**	**%**	**95% CI**
no pain	17	26.6	17.0 - 39.0	13	22.8	13.5 - 35.9
mild	25	39.1	27.7 - 51.8	23	40.4	28.2 - 53.9
moderate	15	23.4	14.5 - 35.7	18	31.6	20.6 - 45.1
severe	7	10.9	5.2 - 21.6	3	5.3	1.6 - 15.6
total	64	100		57	100	

Pain was categorised into the following groups according to the VAS scores: (1) No Pain (0 - 5mm), (2) Mild Pain (5 - 40mm), (3) Moderate Pain (41 - 75mm) and (4) Severe Pain (76 - 100mm). When evaluating the pain experienced at the time of the interview 24 hours postoperatively in the 2017 group that had 64 patients, the results were as follows. There were 17 patients with no pain, representing 26.6% of the group, with a confidence interval of 17.0 to 39.0. There were 25 patients with mild pain, representing 39.1% of the group, with a confidence interval of 27.7 to 51.8. There were 15 patients with moderate pain, representing 23.4% of the group, with a confidence interval of 14.5 to 35.7. There were 7 patients with severe pain, representing 10.9% of the group, with a confidence interval of 5.2 to 21.6. When evaluating the pain experienced at the time of the interview 24 hours postoperatively in the 2012 group that had 57 patients, the results were as follows. There were 13 patients with no pain, representing 22.8% of the group, with a confidence interval of 13.5 to 35.9. There were 23 patients with mild pain, representing 40.4% of the group, with a confidence interval of 28.2 to 53.9. There were 18 patients with moderate

pain, representing 31.6% of the group, with a confidence interval of 20.6 to 45.1. There were 3 patients with severe pain, representing 5.3% of the group, with a confidence interval of 1.6 to 15.6. The p-value for comparing current pain scores between the two groups is 0.89.

Graph 6: Current pain measurements



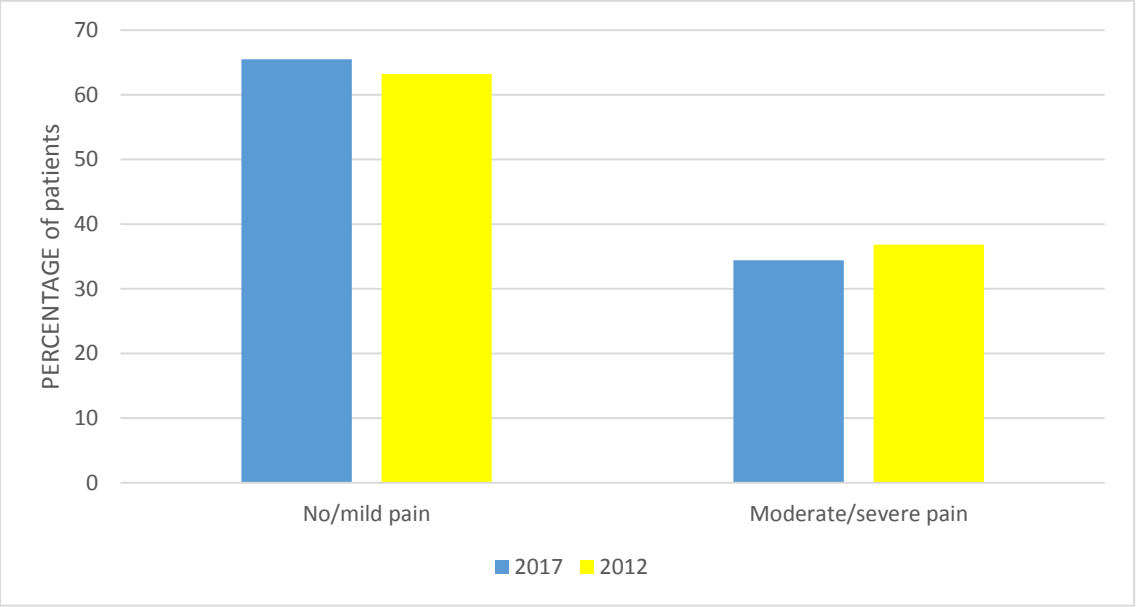
When evaluating the current pain experienced in the first 24 hours postoperatively, 26.6% of patients in 2017 had no pain compared to 22.8% in 2012. Mild pain was reported by 39.1% in 2017 compared to 40.4% in 2012. Moderate pain was reported by 23.4% of patients in 2017 compared to 31.6% in 2012. Severe pain was reported by 10.9% of patients in 2017 compared to 5.3% in 2012. The p-value for comparing current pain scores between the two groups is 0.89.

Table 7: Dichotomisation of current pain scores

	2017		2012	
	n	%	n	%
No/mild pain	42	65.6	36	63.2
Moderate/severe pain	22	34.4	21	36.8
Total	64	100	57	100

In 2017 there were 42 patients (65.6%) that reported no or mild current pain in the first 24 hours and 22 (34.4%) that had moderate to severe pain. In 2012 there were 36 patients (63.2%) with no to mild pain and 21 (36.8%) with moderate to severe pain. The p-value for comparing current pain at 24 hours postoperatively between two groups after dichotomisation is 0.77.

Graph 7: Dichotomisation of current pain scores



In 2017 there were 65.6% of patients that reported no or mild current pain in the first 24 hours and 34.4% that had moderate to severe pain. In 2012 there were 36 patients with no to mild pain and 21 with moderate to severe pain. The p-value for

comparing current pain at 24 hours postoperatively between two groups after dichotomisation is 0.77.

Table 8: Odds Ratio for moderate / severe pain in 2017 compared to 2012

	Odds Ratio	95% CI
Moderate / severe current pain in 2017 vs 2012	0.9	0.43 – 1.9

The Odds Ratio for moderate or severe current pain in 2017 as opposed to 2012 was 0.9 with a 95% confidence interval of 0.43 to 1.9.

Table 9: Number needed to treat in 2017 for current pain

	Number Needed to Treat
Moderate / severe current pain	34

The number of patients needed to treat with the protocol of 2017 to prevent one patient from having moderate/severe current pain at 24hours postoperatively compared to 2012 is 34.

4.4 Compliance to pain scores and analgesia administration:

Table 10: Amount of documented pain scores (2017 only)

Mean	1.38
Standard Deviation	1.6
Range	0 - 5

The mean amount of pain scores done in the 2017 group was 1.38 with a standard deviation of 1.6 and range of 0 to 5.

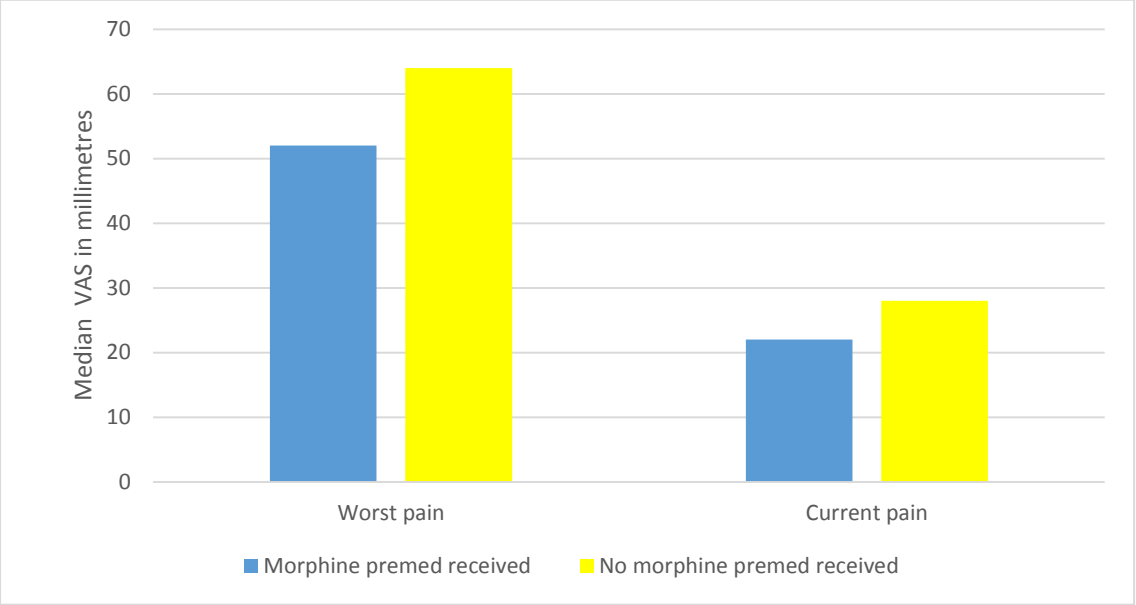
4.5 Morphine admistration

Table 11: Morphine premedication received (2017)

	n	%
Yes	30	47
No	34	53
Total	64	100

In the 2017 group, 30 patients received a premedication of morphine and 34 did not, this represented 47% and 53% of the study population respectively.

Graph 8: Effect of morphine premedication on VAS scores



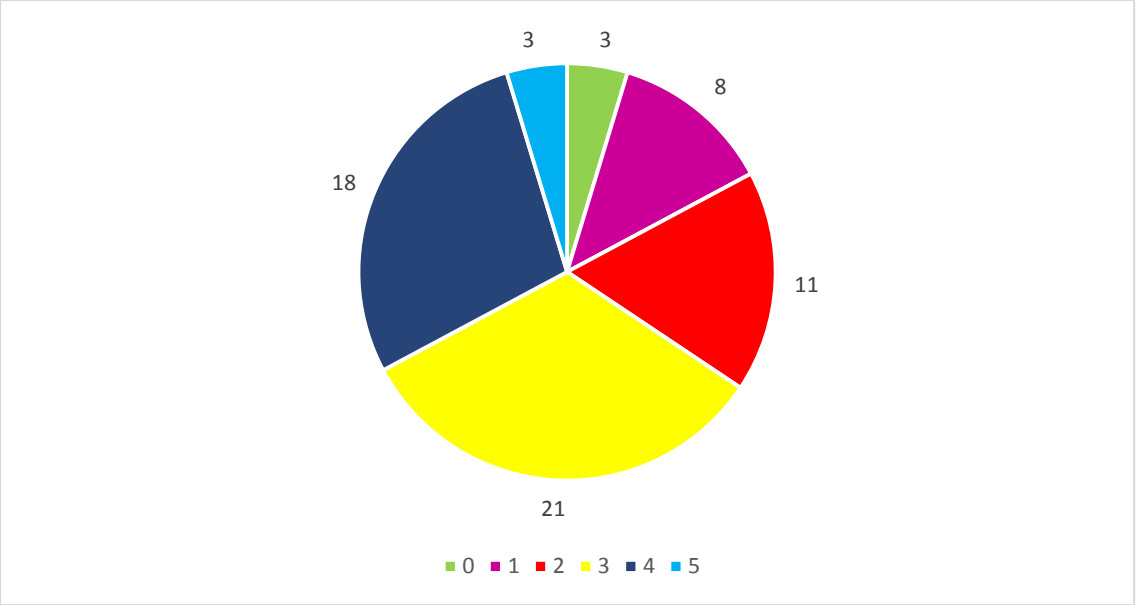
The median VAS score for worst pain was 52mm for those who received a morphine premedication, compared to 64mm for those who did not, p-value is 0.21. The median VAS score for current pain was 22mm for those who received a morphine premedication, compared to 28mm for those who did not, p-value is 0.26.

Table 12: Morphine doses received in first 24 hours post-operatively (2017)

Mean	2.8
95% CI	2.5 – 3.1
Standard Deviation	1.25
Range	0 – 5
Frequency (24h / mean)	8.5 hourly
Patients who received no morphine (n)	3

In 2017, patients received a mean of 2.8 morphine doses in the first 24 hours post-operatively with a 95% confidence interval of 2.5 to 3.1. The standard deviation was 1.25 and the range 0 to 5. This equates to a dose of morphine administered every 8.5 hours. There were 3 patients who did not receive any morphine post-operatively.

Graph 9: Number of morphine doses received per patient

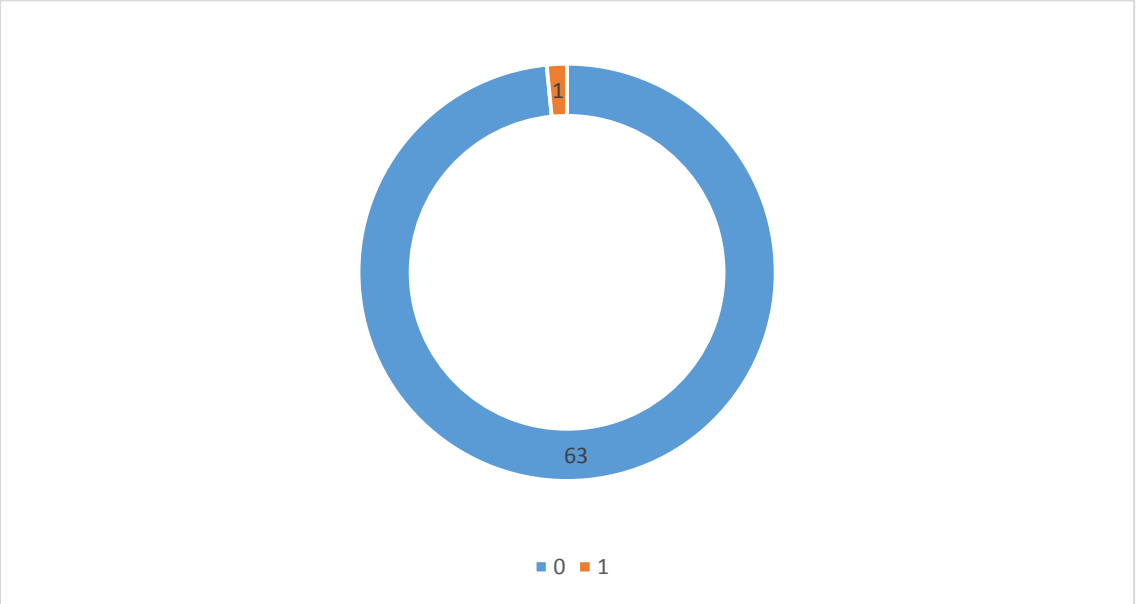


In the study of 2017, in the first 24 hours post-operatively there were 3 patients that received no morphine. 8 Patients received a single dose while 11 received 2 doses. There were 21 patients that received 3 doses and 18 that received 4 doses. There

were 3 patients that received 5 doses of morphine in the first 24 hours post-operatively.

4.6 Ketamine administration

Graph 10: Ketamine doses received



There was only patient out of 64 that received a dose of ketamine for post-operative pain in the first 24 hours.

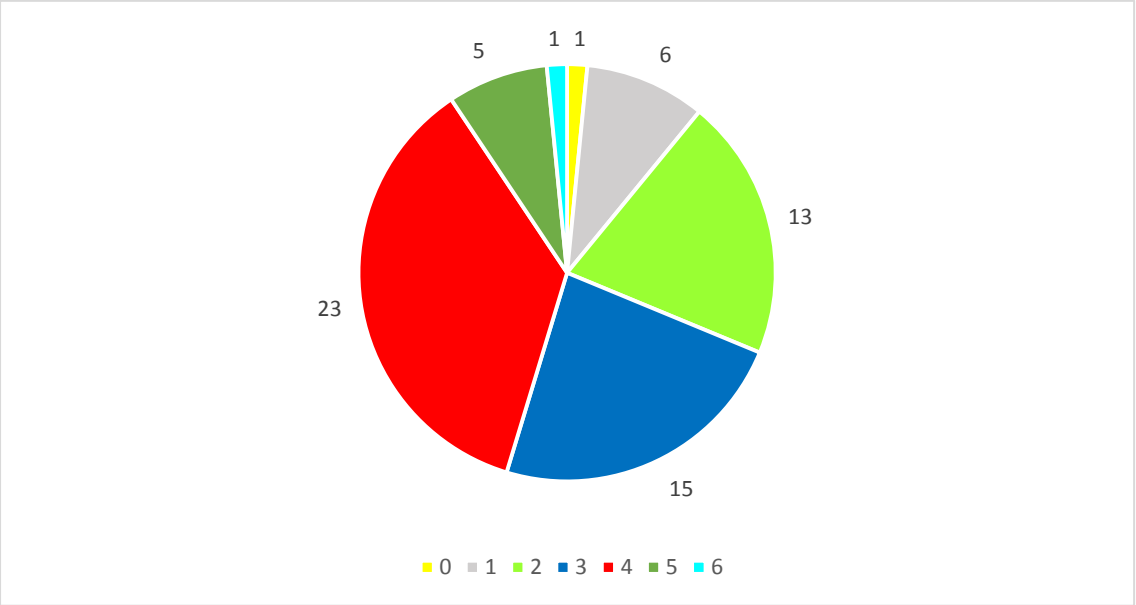
4.7 Paracetamol

Table 13: Paracetamol doses received in first 24 hours post-operatively

Mean (Confidence interval)	3.1
95% CI	2.8 - 3.4
Standard Deviation	1.2
Range	0 - 6
Frequency (24h / mean)	7.7 hourly
Patients who received no paracetamol (n)	1

The mean amount of paracetamol doses received in the first 24 hours post-operatively was 3.1 with a 95% confidence interval of 2.8 to 3.4. The standard deviation was 1.2 and the range 0 to 6. This equates to a dose of paracetamol administered every 7.7 hours. There was only one patient who received no paracetamol post-operatively.

Graph 11: Number of paracetamol doses received per patient



In the first 24 hours post-operatively, there was 1 patient that received no paracetamol and 6 that received a single dose. A total of 13 patients received 2 doses and 15 received 3 doses. There were 23 patients that received 4 doses and 5 patients that received 5 doses. There was 1 patient that received 6 doses in the first 24 hours post-operatively.

4.8 Tramadol administration

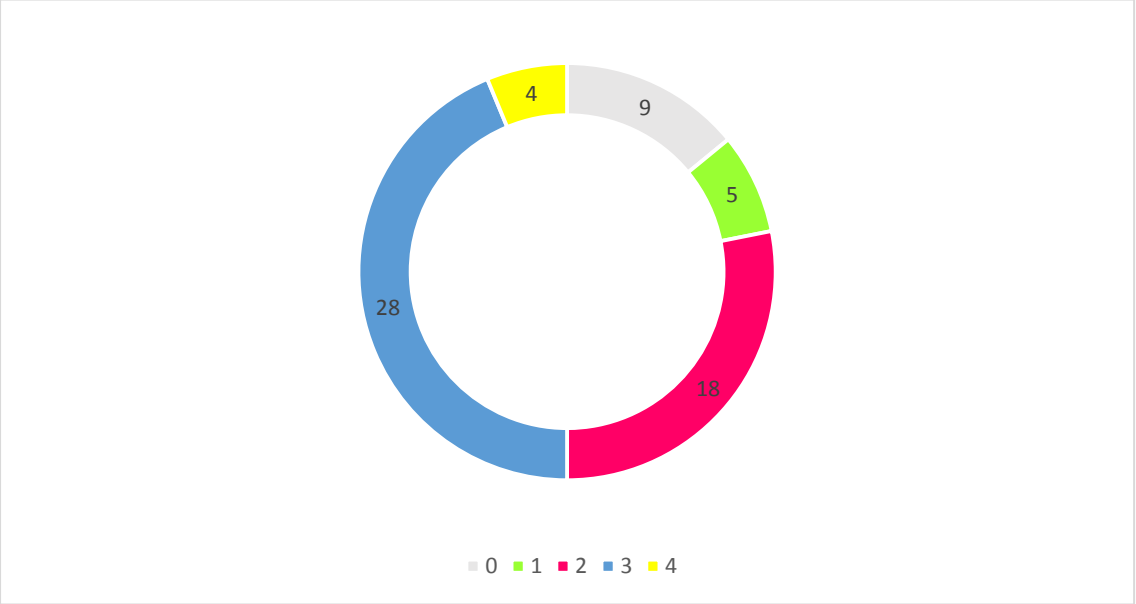
Table 14: Tramadol doses received in first 24 hours post-operatively

Mean (Confidence interval)	2.2
95% CI	1.9 - 2.5
Standard Deviation	1.1

Range	0 - 4
Frequency (24h / mean)	10.9 hourly
Patients who received no tramadol (n)	9

The mean amount of tramadol doses received in the first 24 hours post-operatively was 2.2 with a 95% confidence interval of 1.9 to 2.5. The standard deviation was 1.1 and the range 0 to 4. This equates to a dose of tramadol administered every 10.9 hours. There were 9 patients who received no tramadol post-operatively.

Graph 12: Number of tramadol doses received per patient



In the first 24 hours post-operatively, there were 9 patients that received no paracetamol and 5 that received a single dose. A total of 18 patients received 2 doses and 28 received 3 doses. There were 4 patients that received 4 doses in the first 24 hours post-operatively.

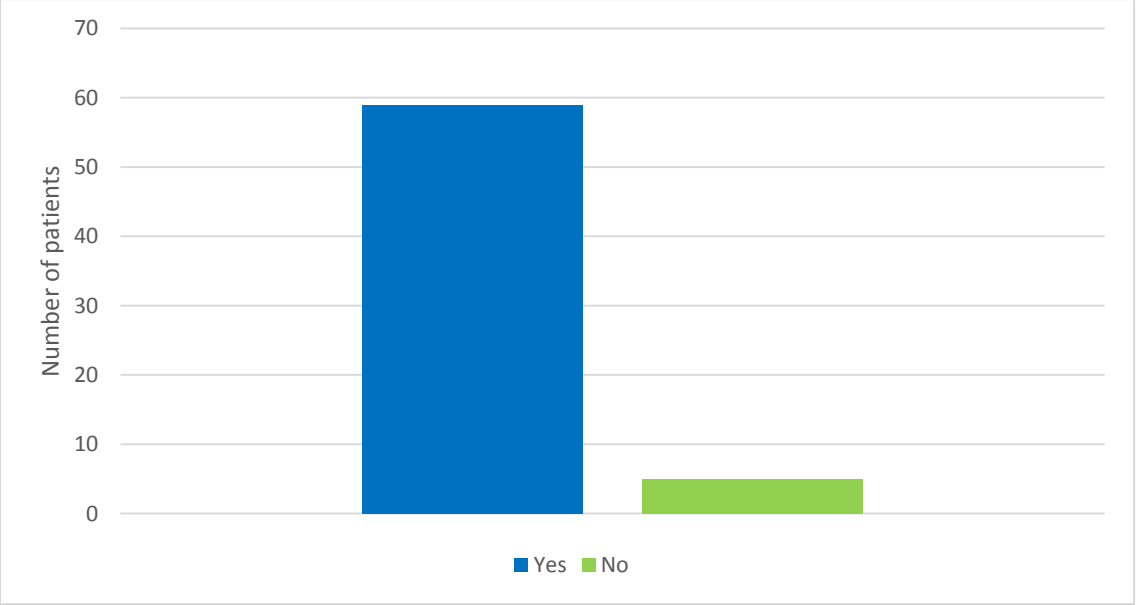
4.9 Patient satisfaction

Table 15: Patients who indicated dissatisfaction with their pain treatment

Patient nr	Gender	Morphine premedication	Morphine doses	Paracetamol doses	Tramadol doses	Ketamine doses	Worst pain	Current pain	Amount of pain scores
3	M	Y	2	3	3	0	78	75	0
10	F	Y	3	4	3	0	41	43	0
19	F	Y	3	3	3	0	94	92	4
49	F	N	4	4	3	0	89	88	2
53	M	N	2	1	1	0	77	58	2

Two male and three female patients were not satisfied with their analgesia. Two of these patients did not receive a premedication of morphine. All the patients received morphine, paracetamol and tramadol in the first 24 hours after surgery. None of these patients received ketamine during that period. Worst pain scores varied between 41 and 94, while current pain scores varied between 43 and 92. Only three of these patients had documented pain scores.

Graph 13: Patient satisfaction with the analgesia received (2017)



59 patients indicated their satisfaction with the analgesia they received and five were unhappy with it.

For the duration of the study, there had not been any reported adverse events.

Chapter 5

5.1 Demographics

In this study of 2017, the mean age of participants was 34 years with a range of 14 to 67 years old. This compares favourably with the data set from 2012 where the mean age of the 57 participants was also 34 years and the range was 14 to 70 years old. A two sample t-test was done to test if the two population means are equal. The p-value was 0.96 which indicates that there was no statistical difference shown between the two means.

There was a clear male dominance in 2017 with 43 males and 21 females (67.2% versus 32.8%). The 2012 group also had a male dominance with 46 males and 11 females (80.7% versus 19.3%). The p-value as calculated by the Pearson Chi Square test was 0.09, indicating that there is no statistical significant difference between the two groups in terms of gender distribution.

5.2 Pain scores

The median worst pain score in 2017 was 61mm (95% CI of 46 - 69) compared to 67mm in 2012 (95% CI of 50 - 75). This is only a difference of 6 mm and is less than the 12 mm clinically significant number or the 18 mm we had predicted beforehand. The p-value as determined by the two-sample Wilcoxon rank-sum (Mann-Whitney U) test for the worst pain scores between the 2012 and 2017 data was 0.4 which is greater than 0.05. The median difference between medians was -5 mm (95%CI -6 to -3). It was therefore statistical significant (not including zero) according to this calculation, but not clinically significant (less than the minimum of 12 mm or the 18 mm expected).

The median current pain score in 2017 was 26.5 mm (95%CI of 11 - 36) versus 30mm in 2012 (95% CI of 18-44), a difference of only 3.5mm. The p-value according to the two-sample Wilcoxon rank-sum (Mann-Whitney) test for current pain scores between the 2012 and 2017 data was 0.89, again much greater than 0.05. The median difference between medians was -1 mm (95% CI of -3 to 1). It was therefore not statistically significant (included zero).

A Pearson Chi square test was done to detect the probability of any difference in the Worst Pain category between 2012 and 2017 data to be due to chance after dichotomisation into the no/mild and moderate/severe groups. The p-value of 0.53 is much higher than the predetermined acceptable value of 0.05. This proves that there was no statistical significant difference found between the 2012 and 2017 groups in this regard.

When considering worst pain scores, the odds ratio for having moderate/severe pain in 2017 versus 2012 was 0.77 with a 95% confidence interval of 0.34 to 1.73 that includes one, thus meaning there is no real difference in outcome.

When looking at the Numbers Needed Treat in 2017 to prevent one patient from having moderate/severe pain compared to 2012 by worst pain score, it is 20. This is much more than the range of 2 to 3 that is usually considered to reflect very effective treatment.[47]

A Pearson Chi square test was done to detect the probability of any difference in the current pain category between 2012 and 2017 data to be due to chance after dichotomisation into the no/mild and moderate/severe groups. The p-value of 0.77 is much higher than the predetermined acceptable value of 0.05.This proves that there was no statistical significant difference found between the 2012 and 2017 groups in this regard.

When comparing current pain scores, the odds ratio for having moderate/severe pain in 2017 as opposed to 2012 was 0.9 with the 95% confidence interval of 0.43 -1.9 (includes 1.0) also proving that there was no real difference detected.

When looking at the numbers needed to treat in 2017 to prevent one patient from having moderate/severe pain compared to 2012 by current pain score it is 34, again much higher than the range of two to three that is considered to be very effective according to McQuay and Moore.[47]

5.3 Morphine, Ketamine, Paracetamol and Tramadol administration

The prescription of morphine and or paracetamol as a premedication was left up to the clinical judgement of the attending anaesthetist. Factors involved in the decision of the type of premedication, if any, that would be prescribed was the type and extent of surgery, the time spent in the ward on analgesics pre-operatively, the co-morbid conditions of the patient as well as the size of the patient. A total of 30 patients received intramuscular morphine as a premedication (47%). The administration of a morphine premedication did not result in a statistical significant decrease in VAS scores for both worst pain and current pain.

Patients who received a premedication of morphine had a median worst pain score of 52mm compared to 64mm in those without the premedication. A Two-sample Wilcoxon rank-sum (Mann-Whitney) test was done to determine whether there is any difference between the worst pain scores between the group two groups. The calculated p-value was 0.21. There could have been selection bias as patients who were expected to have more pain, probably received morphine.

The median current pain score for those who did receive a morphine premedication was 22mm, compared to 28mm for those who did not. A Two-sample Wilcoxon rank-sum (Mann-Whitney) test was done to determine whether there is any difference between the current pain scores between the group that did receive morphine premedication and the group that did not. The calculated p-value was 0.26 for the current pain outcome.

Administration of oral analgesia appears to be good, with patients receiving at least one dose of paracetamol in 98% of cases and at least one dose of tramadol in 86% of cases. However, when we examine the mean doses of analgesia drugs received, it becomes clear that medicine was not given at fixed dose intervals.

If paracetamol had been given intra-operatively or at the end of surgery in the recovery room, then we would expect that patients would receive a further four doses of paracetamol in the first 24 hours post-op (a dose at 6, 12, 18 and 24 hours post-op). Instead of receiving four doses, the mean amount of doses received was 3.1. There were some patients that received a single dose of intravenous (IV) paracetamol in the recovery room, those numbers are included in the quoted figures for paracetamol doses received post-operatively as the specific amount of patients who received IV paracetamol was not documented as part of the data collection.

For tramadol we would expect to see three to four doses in the first 24 hours if it had been administered six to eight hourly, the mean however was only 2.2. Morphine was administered at a mean of 2.8 doses, again much less than the expected four to six doses in the first 24h post-op, had it been given four to six hourly.

Even though the morphine was prescribed in an “as needed” (prn) fashion, the results of the audit show that patients in 2017 experienced similar pain to those in 2012. One has to consider the contribution that infrequent dosing of morphine as well as the oral agents had on this. It is only logical to reason that infrequent administration of analgesia played a role in the poor outcomes with regards to pain scores.

Ketamine as an analgesic agent was essentially ignored. Only one out of the 64 patients in the study group received a single dose of ketamine in the first 24 hours post-operatively. The other 63 patients received no ketamine at all despite the pain scores showing that many patients would have qualified for the use thereof had the protocol been followed correctly.

It was agreed upon by the members of the Department of Anaesthesiology and Critical Care to complete the nursing instruction form (Appendix G) so that nursing staff was allowed to administer a prescribed dose of ketamine if the patient indicated a score of four or more out of ten, based on a numeric rating scale (NRS), at least one hour after a dose of morphine was given to treat pain. Although the NRS is different and more simplified than the VAS that was used in the post-op study

questionnaire, it would equate to 40mm on the VAS. Of note is the fact that 45 out of the 64 patients indicated a worst pain score of 40mm or more in the first 24h post-op and 22 reported a VAS of 40mm or more for current pain at 24h post-op. It is not possible to make accurate calculations on how frequently ketamine should have been administered based just on the scores indicated by patients on our questionnaire 24 hours after surgery.

5.4 Strengths and limitation of the study

There are multiple other factors required that cannot be elucidated from the data we have available. Acknowledging these limitations, it is still reasonable to accept that there were a significant amount of patients who did qualify to receive ketamine for analgesia, but never did so.

Only 34 out of the 64 patients had any documentation of pain scores post-operatively (53%), with a mean of only 1.4 pain scores per patient enrolled in the study. There were only 24 patients who had more than one documented pain score (38%). As already pointed out, the frequency of administration of oral drugs was not optimal. Parenteral morphine administration was also infrequent and ketamine as an analgesic agent was essentially ignored. It is therefore clear that compliance with the new protocol was very poor.

It was interesting to analyse the data of the five patients who indicated that they were not satisfied with the prescribed analgesia. The worst pain scores (in millimetres) of these patients were 78, 41, 94, 89 and 77 respectively. The details of their data are shown in table number 15 above.

Of note is the finding that 16 out of the 20 patients who had severe pain (worst pain score of 75mm or more) indicated that they were indeed satisfied with the analgesia they received. This finding proves that the experience of pain is truly subjective. 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.[48] Our findings are in line with the definition

that shows that the emotional part of pain experience may well differ between patients who indicated similar worst pain scores.

Consideration should be given to the expectation of patients regarding the amount of pain they will have after surgery. It might well be that patients expect to have a lot of pain after a surgical procedure and therefore they still report satisfaction with the analgesia received despite worst pain scores indicating that many of them had unacceptable high levels of pain.

By better educating patients that they need not be in suffering postoperatively and about the availability of proper and safe analgesia postoperatively, patients may be empowered to request rescue analgesia when routinely administered treatment fails to provide adequate analgesia. Patient expectations have to be explored to determine what their needs are while in hospital. This would however add to the heavy burden of the already limited amount of nursing staff. It would address the emotional aspect of patients' well-being and with pain also having an emotional component, it might well be a very valuable treatment target.

We need to ask whether the method of implementation of the new protocol was effective. Despite multiple contact sessions with nursing staff and the efforts made to involve staff of different shifts and the opportunities created to allow staff members to ask questions, there was still poor compliance. During the contact sessions that nursing staff had with members of the Department of Anaesthesiology and Critical Care, many questions were answered and uncertainties clarified.

Nursing staff had been excited about the new protocol. They felt that they would be empowered to treat pain more effectively and have a means of better assessing the level of pain that the patients were experiencing. They admitted to being apprehensive of giving morphine frequently in fear of patients developing tolerance and addiction to morphine. In this regard they welcomed the use of ketamine as a rescue analgesic and they were keen on using the agent as they already had experience with the use thereof in the Burns Unit, albeit at much higher doses for sedation during the dressing changes for burns patients.

It would seem that nursing staff chose to comply better with the parts of the protocol that was familiar to them i.e. oral analgesics as well as IM morphine. The unfamiliar parts of the protocol i.e. documenting pain scores and using ketamine as a rescue analgesic showed much less success. It is therefore reasonable to deduct that resistance to change is a real challenge. Staff tend to adhere to established habits and keep on doing that with which they are most familiar with.[49]

In an article by Gesme and Wiseman, they make the following statement: “Certain elements must be in place in an organization for change to take hold: an agreed-on direction for the practice, a functional and effective leadership structure, and a culture that promotes and rewards change.”[50] Yagasaki says that goal congruence is critical at the organizational level. It means that organizational goals are shared by all with support of the associated operations and activities.[51] This might well be part of the challenge at Tygerberg Academic Hospital.

We argue that the main driving force behind a change in analgesia protocol that is dependent on nursing interventions, has in fact got to be from nursing side. We would suggest that unit managers or shift leaders need to remind staff of the need to adhere to the protocol and also to check up on nursing staff to ensure that they do actually comply. This would be in line with the teaching of Gesme that says The vision for the change has to be communicated effectively to all the parties concerned but also needs be reinforced continually. [50]

There also needs to be equal partnership between all professionals at multidisciplinary level.[51] Greater co-operation and understanding between staff from different disciplines are needed. There needs to be an understanding of the pressure on nursing staff to look after many patients with specific unique needs in a burns unit.[50] These patients require dressing changes that take a lot of time and often they need to be fed if they sustained significant injuries to their hands, this is in addition to all the other basic nursing needs in the unit.

It therefore goes without saying that any protocol nurses need to follow has to be user friendly and simple to use.[51] A probable key to the success in implementing a new protocol would be for nursing staff to see the improvement it brings in patient

care and satisfaction. By showing individuals how change may help them to do their job more effectively could address their fears. [50]

Gesme and Wiseman says that the real enemy of change is complacency. Some other relevant factors that they describe which may have led to failure of the intervention at TAH are: full schedules, distracting events, fear of change and apathy. Fear of change may lead to resistance.[50] Fear of change and fear of the unknown also hinders compliance. Fear freezes the innovation process and lowers work productivity according to Serban.[52] Guideline implementation is hindered by lack of interest in them as well as passive attitudes. [51]

The established culture of an organization can also determine the amount of resistance to change. Changing the organizational culture is difficult. Culture is intrinsically inflexible and any attempts to change it might well be met with resistance. [52]

Chapter 6

6.1 Summary of finding

Compared to the study results of 2012, we were unable to show a statistically significant difference in outcome as judged by VAS scores, both for pain at 24 hours after surgery and the worst pain experienced in the 1st 24 hours post-operatively. Compliance to the new protocol was poor as evidenced by the very low amount of pain scores done post-operatively as well as the low frequency of analgesia administration.

6.2 Conclusion

The poor compliance to the protocol precludes the investigators from confidently concluding that the new protocol is ineffective and without proper clinical application. The investigators are still of the opinion that the new protocol potentially holds much value and could make a meaningful contribution to patient care. It also has the potential to make nursing staff feel empowered to better treat patients in a safe guideline based manner without fear of inadvertently causing harm to their patients.
Even though staff may indicate that they are excited about proposed new strategies to address issues that they agree are of concern to them, they still have a reluctance to fully embrace changes. Staff members comply much better with procedures that they are familiar with.

In order for the effectiveness of the new protocol to be evaluated fairly and to make valid conclusions about its clinical use, it would have to be better adhered to. Greater involvement from the side of nursing management / unit managers will have to be sought. It is neither reasonable nor practical for the anaesthetists who predominantly spend their time in the operating theatres to drive the change in units and wards where they are not actively involved in the day to day post-surgical management of patients once they leave theatre. It is the nursing staff leaders who can best drive the adherence to the protocol in the unit and ensure compliance by checking up on their staff and ensuring that they do comply.

6.3 Future Research Recommendations

The goal of the audit was to compare the new analgesia protocol to the previous practice, it was focused on the numbers and statistical outcomes. We did however identify many areas of concern that would make good future research topics. These are listed below.

- The impact that patients' preoperative expectations regarding the pain they will experience postoperatively have on the eventual pain experienced.
- Motivation for change of established behaviour and practices in a health care setting.
- Strategies for successful protocol implementation and staff education in health care settings.

Chapter 7

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Appendices

Appendix A: Data dictionary

Variable name	Variable description	Collected from	Type	Length	Coding/Format	Range/ Value	Logic checks
PID	Patient ID = unique identifier	Allocated to patient	Integer	2	May not be zero	01 - 99	No duplicates
DOB	Date of birth	Patient file	Date	8	DDMMYYYY Unknown= 01011800	< or = today	Must be before date of interview
Age	Age	Date of birth	Integer	3	Years	00 - 120	If DOB entered – default value= 999
Sex	Gender	Patient file	Integer	1	1=Male 2=Female 3=Unknown	1-3	May not be 0
WP	Worst pain in 1st 24h	VAS score sheet	Integer	3	Millimeters on VAS	0-100	May not be > 100
CP	Pain at time of interview	Vas score sheet	Integer	3	Millimeters on VAS	0-100	May not be > 100
MP	Morphine premed received	Patient file	Integer	1	1= yes 2= no	1-2	May not be 0
MD	Morphine doses received	Patient file	Integer	2	Amount	0-15	May not be >15

	post-op						
KD	Ketamine doses received post-op	Patient file	Integer	2	Amount	0-15	May not be >15
PD	Paracetamol doses (not tablets) received post-op (includes Recovery Room)	Patient file	Integer	2	Amount	0-10	May not be >10
TD	Tramadol doses received post-op	Patient file	Integer	2	Amount	0-10	May not be >10
AE	Adverse event	Patient file	Integer	1	1=yes 2=no	1-2	May not be >2
DAE	Describe adverse event	Patient file	Text	N/A	Description of adverse event	N/A	Must be text
PS	Amount of pain scores done in ward	Patient file	Integer	2	Amount	0-24	May not be text

Appendix B: Variables

Unique patient identifier number: A numerical value that will be allocated to each individual patient by the investigators in order of collecting the data eg. 1st patient interviewed will be nr 001, 2nd patient interviewed will be nr 002, etc.

Date of birth: Collected from the patient file and entered on the CRF in the format of DD/MM/CCYY. Will be entered on the Excel spreadsheet in the format of DD/MM/CCYY.

Age: Will be calculated from the CRF by using the Date of birth entered on it, will be displayed as years. Rounded down to the lower year eg. 42y 11m will be displayed as 42 years.

Sex: Collected from the patient file and recorded on the CRF. Will be entered on the Excel spreadsheet as 1 = Male , 2 = Female, 3 = Unknown.

Worst pain in 1st 24h: Collected from the CRF after the patient indicated this on the appropriate paper VAS. Will be measured by a standard ruler and recorded in millimeters for entry on Excel spreadsheet.

Current pain at time of interview: Collected from the CRF after patient indicated this on the appropriate paper VAS. Will be measured by a standard ruler and recorded in millimeters for entry on Excel spreadsheet.

Morphine premed received: Collected from the prescription chart in the patient's file and indicated as yes or no on the CRF. Will be entered on the Excel spreadsheet as 1 = yes and 2 = no.

Morphine doses received post-operatively: Collected from the prescription chart in the patient's file and recorded on the CRF as a numerical value.

Ketamine doses received post-operatively: Collected from the prescription chart in the patient's file and recorded on the CRF as a numerical value.

Paracetamol doses received post-operatively: Collected from the prescription chart in the patient's file and recorded on the CRF as a numerical value.

Tramadol doses received post-operatively: Collected from the prescription chart in the patient's file and recorded on the CRF as a numerical value.

Amount of pain scores documented on Nursing Observation Chart: Collected from the Nursing Observation Chart in the patient's file and recorded on the CRF as a numerical value.

Any adverse events: Collected from nursing and doctors' notes and recorded on CRF. Will be entered on the Excel spreadsheet as 1 = yes, 2 = no.

Describe adverse event: Collected from nursing and doctors' notes and recorded on CRF. Will be descriptive measurement entered on the Excel sheet.

Appendix C: Budget

Item	Cost in Rands
Statistician	600
Printing costs	400
Total Cost	1000

Statistician costs to be covered by Department Of Anaesthesiology and Critical Care.

Printing cost will be covered by principal investigator.

Appendix D: Patient information documentation

DEELNEMERINLIGTINGSBLAD EN -TOESTEMMINGSVORM

TITEL VAN DIE NAVORSINGSPROJEK:

Herevaluering van akute post-operatiewe pyn in 'n hulpbron beperkte Brandwond eenheid na die implementering van 'n omvattende pynverligting behandelingsplan.

VERWYSINGSNOMMER:

HOOFNAVORSER: Dr. Adriaan Johann Greyling

ADRES: Universiteit Stellenbosch, Fakulteit Geneeskunde en Gesondheidswetenskappe, Departement van Anestesiologie en Kritieke Sorg, Kliniese Gebou, Kamer 2041, 2de vloer, Francie van Zijllaan, Tygerberg, 7505, Kaapstad, Suid-Afrika

KONTAKNOMMER: 021 938 5142

U word genooi om deel te neem aan 'n navorsingsprojek. Lees asseblief hierdie inligtingsblad op u tyd deur aangesien die detail van die navorsingsprojek daarin verduidelik word. Indien daar enige deel van die navorsingsprojek is wat u nie ten volle verstaan nie, is u welkom om die navorsingspersoneel of dokter daaroor uit te vra. Dit is baie belangrik dat u ten volle moet verstaan wat die navorsingsprojek behels en hoe u daarby betrokke kan wees. U deelname is ook **volkome vrywillig** en dit staan u vry om deelname te weier. U sal op geen wyse hoegenaamd negatief beïnvloed word indien u sou weier om deel te neem nie. U mag ook te eniger tyd aan die navorsingsprojek onttrek, selfs al het u ingestem om deel te neem.

Hierdie navorsingsprojek is deur die Etiek Komitee oor Gesondheidsnavorsing van die Universiteit Stellenbosch **goedgekeur en sal uitgevoer word volgens die etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki en die Etiese Riglyne vir Navorsing van die Mediese Navorsingsraad (MNR).**

Wat behels hierdie navorsingsprojek?

- *Die navorsing word gedoen in die Brandwonde eenheid van Tygerberg Hospitaal.*
- *Die doel van die projek is om te bepaal hoeveel pyn pasiënte na operasies ervaar. Ons wil bepaal of die pynverligting vir ons pasiënte voldoende is.*
- *Ons versoek van u is om op die papier aan te dui hoeveel pyn u tans ervaar asook wat die ergste pyn is wat u sedert die operasie ervaar het.*
- *Ons benodig 57 pasiënte vir ons studie.*

Waarom is u genooi om deel te neem?

- *U het 'n operasie ondergaan as gevolg van die brandwond beserings wat u opgedoen het. Ons wil graag by u meer weet van die pyn wat u ervaar.*

Wat sal u verantwoordelikhede wees?

- *Om die pyn evaluasie vorm eerlik in te vul na die beste van u vermoë.*

Sal u voordeel trek deur deel te neem aan hierdie navorsingsprojek?

- *U self sal nie huidiglik bevoordeel word nie, maar pasiënte wat in die toekoms by hierdie hospitaal behandel word, mag wel voordeel trek uit u bydrae van vandag.*

Is daar enige risiko's verbonde aan u deelname aan hierdie navorsingsprojek?

- *Daar is geen gevare of risiko's vir u nie.*

Watter alternatiewe is daar indien u nie instem om deel te neem nie?

- *Ons respekteer u besluit en dit sal nie die behandeling wat u tans ontvang in enige wyse verander nie. Ons nader al die pasiënte in die Brandwonde Eenheid wat die vorige dag operasies gehad het vir hulle terugvoer.*

Wie sal toegang hê tot u mediese rekords?

- *U informasie sal vertroulik gehou word en u naam sal nêrens gebruik word waar dit u blootstel nie. Slegs Dr. A.J. Greyling en Dr. A. A. Murray wat die navorsing doen sal toegang tot u rekords hê.*

Wat sal gebeur in die onwaarskynlike geval van 'n besering wat mag voorkom as gevolg van u deelname aan hierdie navorsingsprojek?

- *Ons navorsing behels slegs die evaluasie van pynmedikasie en behandeling van pasiënte in die Brandwonde Eenheid wat vir 'n operasie was. Ons toets nie nuwe medisyne op u nie.*

Sal u betaal word vir deelname aan die navorsingsprojek en is daar enige koste verbonde aan deelname?

- *U sal nie betaal word vir deelname aan die navorsingsprojek nie. Deelname aan die navorsingsprojek sal u niks kos nie.*

Is daar enigiets anders wat u moet weet of doen?

- U kan Dr. A.J. Greyling kontak by tel 021-938 5142 indien u enige verdere vrae het of enige probleme ondervind.

- U kan die **Etiek Komitee oor Gesondheidsnavorsing** kontak by 021-938 9207 indien u enige bekommernis of klagte het wat nie bevredigend deur u studiedokter hanteer is nie.
- U sal 'n afskrif van hierdie inligtings- en toestemmingsvorm ontvang vir u eie rekords.

Verklaring deur deelnemer

Met die ondertekening van hierdie dokument onderneem ek,

……., om deel te neem aan 'n navorsingsprojek getiteld : *Het die implementering van 'n omvattende pynverligting behandelingsplan vir akute post-operatiewe pyn in Brandwond pasiënte die ervaring van pyn verminder in 'n hulpbron beperkte Brandwond eenheid?*

Ek verklaar dat:

- Ek hierdie inligtings- en toestemmingsvorm gelees het of aan my laat voorlees het en dat dit in 'n taal geskryf is waarin ek vaardig en gemaklik mee is.
- Ek geleentheid gehad het om vrae te stel en dat al my vrae bevredigend beantwoord is.
- Ek verstaan dat deelname aan hierdie navorsingsprojek **vrywillig** is en dat daar geen druk op my geplaas is om deel te neem nie.
- Ek te eniger tyd aan die navorsingsprojek mag onttrek en dat ek nie op enige wyse daardeur benadeel sal word nie.
- Ek gevra mag word om van die navorsingsprojek te onttrek voordat dit afgehandel is indien die studiedokter of navorser van oordeel is dat dit in my beste belang is, of indien ek nie die ooreengekome navorsingsplan volg nie.

Geteken te *Tygerberg Hospitaal op (datum)* …… 2017.

……	……
Handtekening van deelnemer	**Handtekening van getuie**

Verklaring deur navorser

Ek *(naam)* …… verklaar dat:

- Ek die inligting in hierdie dokument verduidelik het aan

  ……

- Ek hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.
- Ek tevrede is dat hy/sy al die aspekte van die navorsingsprojek soos hierbo bespreek, voldoende verstaan.
- Ek 'n tolk gebruik het/nie 'n tolk gebruik het nie. *(Indien 'n tolk gebruik is, moet die tolk die onderstaande verklaring teken.)*

Geteken te *Tygerberg Hospitaal* op *(datum)* …….…….…….. 2017.

…….. ……..
Handtekening van navorser **Handtekening van getuie**

Verklaring deur tolk

Ek *(naam)* …….…….. verklaar dat:

- Ek die navorser *(naam)* ……..…….. bygestaan het om die inligting in hierdie dokument in Afrikaans/Xhosa aan *(naam van deelnemer)* ……..…….. te verduidelik.
- Ons hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.
- Ek 'n feitelik korrekte weergawe oorgedra het van wat aan my vertel is.
- Ek tevrede is dat die deelnemer die inhoud van hierdie dokument ten volle verstaan en dat al sy/haar vrae bevredigend beantwoord is.

Geteken te *Tygerberg Hospitaal* op *(datum)* …….…….…….. 2017.

…….. ……..
Handtekening van tolk **Handtekening van getuie**

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

Reassessment of acute postoperative pain in a resource limited burns unit after the implementation of an analgesic management plan.

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR: Dr Adriaan Johann Greyling

ADDRESS: Stellenbosch University, Faculty of Medicine and Health Sciences, Department of Anaesthesiology and Critical Care, Clinical Building, Room 2041, 2nd floor, Francie van Zijl Drive, Tygerberg, 7505, Cape Town, South Africa.

CONTACT NUMBER: 021 938 5142

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- *This study is conducted in the Burns Unit of Tygerberg Hospital.*
- *The goal of this study is determine how much pain patients experience after an operation. We want to determine whether adequate pain relief is offered to our patients.*
- *We request you to please indicate on the paper how much pain you have currently and how bad your worst pain after the operation was.*
- *We require 57 patients for this study.*

Why have you been invited to participate?

- *You underwent an operation yesterday due to the burn injuries you sustained. We would like to know more about the pain you experience.*

What will your responsibilities be?

- *To complete the pain evaluation form honestly and to the best of your ability.*

Will you benefit from taking part in this research?

- *There are no immediate benefits for you personally, but other patients that will be treated at Tygerberg Hospital in future may benefit from your contribution.*

Are there in risks involved in your taking part in this research?

- *There are no risks involved for you.*

If you do not agree to take part, what alternatives do you have?

- *We respect your decision and it will by no means change any of the treatment you are receiving. We approach all the patients in the Burns Unit that had an operation the previous day.*

Who will have access to your medical records?

- *Your information will be kept confidential and your name will not be used anywhere you may be exposed. Only Dr A.J. Greyling and Dr A.A. Murray who are doing the study will have access to your information.*

What will happen in the unlikely event of some form injury occurring as a direct result of your taking part in this research study?

- *Our research is only to evaluate the current pain medicine and treatment that all patients in the Burns Unit receive after an operation. We are not testing any new medication.*

Will you be paid to take part in this study and are there any costs involved?

- *No, you will not be paid to take part in the study. There will be no costs involved for you, if you do take part.*

Is there any thing else that you should know or do?

- You can contact Dr A.J. Greyling at tel 021-938 5142 if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I ……..…… agree to take part in a research study entitled: *Did the implementation of a comprehensive analgesic management plan for acute post-operative pain in Burns patients improve the pain experience in a resource limited Burns Unit setting?*

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at Tygerberg Hospital on (*date*) ……..…….. 2017.

.....	.....
Signature of participant	**Signature of witness**

Declaration by investigator

I *(name)* ……..…… declare that:

- I explained the information in this document to ……
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*

Signed at Tygerberg Hospital on (*date*) ……..…….. 2017.

.....	.....
Signature of investigator	**Signature of witness**

Declaration by interpreter

I *(name)* ……..…… declare that:

- I assisted the investigator (*name*) …… to explain the information in this document to (*name of participant*) …….…… using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at Tygerberg Hospital on (*date*) ……..……2017

.....	.....
Signature of interpreter	**Signature of witness**

UNIVERSITEIT STELLENBOSCH

FAKULTEIT GESONDHEIDSWETENSKAPPE

INLIGTINGSTUK EN TOESTEMMINGSVORM VIR DEELNEMERS

TITEL VAN NAVORSINGSPROJEK:

Herevaluering van akute post-operatiewe pyn in 'n hulpbron beperkte Brandwond eenheid na die implementering van 'n omvattende pynverligting behandelingsplan.

NAVORSER(S): *Dr. A.J. Greyling en Dr. A.A. Murray*

ADRES: *Universiteit Stellenbosch en Tygerberg Hospitaal*

KONTAKNOMMER: 021 938 5142

Wat is navorsing?

Deur navorsing leer ons hoe dinge (en mense) werk. Ons gebruik navorsingsprojekte of -studies om meer oor siektes uit te vind. Navorsing leer ons ook hoe om siek kinders beter te help of te behandel.

Waaroor gaan hierdie navorsingsprojek?

Ons wil uitvind hoeveel pyn kinders na operasies het.

Hoekom vra julle my om aan hierdie navorsingsprojek deel te neem?

Jy het gister 'n operasie gehad, so jy kan vir ons vertel of jy enige pyn gehad het daarna.

Wie doen die navorsing?

Dr A.J. Greyling en Dr. A.A. Murray doen die navorsing vir die Narkose departement (Die dokters wat kinders laat slaap tydens opersaies.

Pro forma-toestemmingsvorm. Fakulteit Gesondheidswetenskappe, Universiteit Stellenbosch.
Weergawe 1. Junie 2009.

Wat sal in hierdie studie met my gebeur?

Jy hoef net op die papier vir ons te wys hoeveel pyn jy op die oomblik het en wat die ergste pyn was wat jy na die operasie gehad het.

Kan enigiets fout gaan?

Nee, ons toets nie enige medisyne op jou nie. Jy kry dieselfde medisyne as die ander kinders in die saal wat dieselfde operasie as jy gehad het.

Watter goeie dinge kan in die studie met my gebeur?

Jy kan help om in die toekoms vir ander kinders wat na Tygerberg Hospitaal toe kom vir operasies dinge beter te maak.

Sal enigiemand weet ek neem deel?

Slegs die dokters wat die navorsing doen sal van jou weet. Ons sit nie jou naam op enige plekke waar ander mense dit kan sien nie.

Met wie kan ek oor die studie praat?

Met Dr A.J. Greyling of Dr A.A. Murray by 021 938 5142

Wat gebeur as ek nie wil deelneem nie?

Jy mag verseker NEE sê. Ons dwing geen kinders om deel te neem nie en die behandeling wat jy kry sal nie verander indien jy nie deel wil wees van die navorsing studie nie. Selfs as jou ouers toestemming gee, mag jy weier en ons sal vir jou luister.

Verstaan jy hierdie navorsingstudie, en wil jy daaraan deelneem?

JA NEE

Het die navorser ál jou vrae beantwoord?

JA NEE

Verstaan jy dat jy kan ophou deelneem net wanneer jy wil?

JA NEE

_____ _____

Handtekening van kind Datum

Pro forma-toestemmingsvorm. Fakulteit Gesondheidswetenskappe, Universiteit Stellenbosch.
Weergawe 1. Junie 2009.

STELLENBOSCH UNIVERSITY

FACULTY OF HEALTH SCIENCES

PARTICIPANT INFORMATION LEAFLET AND ASSENT FORM

TITLE OF THE RESEARCH PROJECT:

Reassessment of acute postoperative pain in a resource limited burns unit after the implementation of an analgesic management plan.

RESEARCHERS NAME(S): *Dr A.J. Greyling and Dr A.A. Murray*

ADDRESS: *University of Stellenbosch and Tygerberg Hospital*

CONTACT NUMBER: 021 938 5142

What is RESEARCH?

Research is something we do to find new knowledge about the way things (and people) work. We use research projects or studies to help us find out more about disease or illness. Research also helps us to find better ways of helping, or treating children who are sick.

What is this research project all about?

We want to find out how much pain children have after operations.

Why have I been invited to take part in this research project?

You had an operation yesterday, so you can tell us about the pain you have.

Who is doing the research?

Dr A.J. Greyling and Dr A.A. Murray from the Department of Anaesthesiology (the doctors that make children sleep during operations).

What will happen to me in this study?

All you have to do is to indicate on the paper how much pain you have at this moment and also what the worst pain was that you had after the operation.

Can anything bad happen to me?

No, we are not testing any new medicine. You are receiving the same medicine as other children in this ward.

Can anything good happen to me?

You can help to make things better for other children that will come in the future for operations at Tygerberg Hospital.

Will anyone know I am in the study?

Only the doctors doing the research will know about you. We won't put your name anywhere that other people can see it.

Who can I talk to about the study? *Dr A.J. Greyling and Dr A.A. Murray at 021 938 5142.*

What if I do not want to do this?

You have the right to say NO. We do not force any children to take part in our research. The treatment you receive will also not change if you refuse to partake in the research.

Do you understand this research study and are you willing to take part in it?

YES NO

Has the researcher answered all your questions?

YES NO

Do you understand that you can pull out of the study at any time?

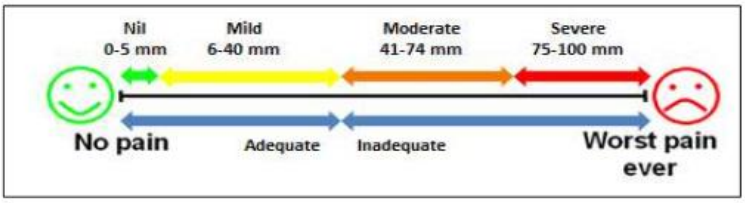
YES NO

_____ _____

Signature of Child Date

Assent template. Faculty of Health Sciences SU. Version 1. June 2009

Appendix E: Visual Analogue Scale pain score

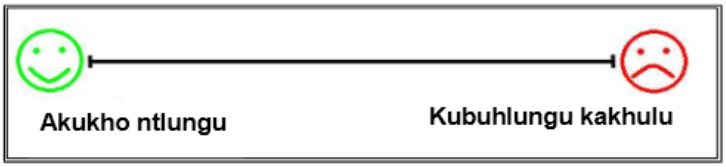


Division of visual analogue pain scale into categories:

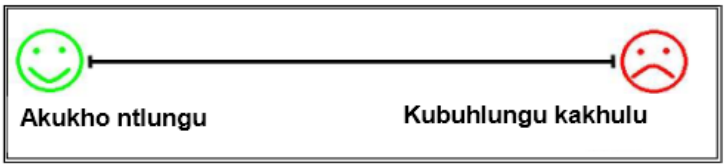
Nil (0-5mm), mild (6-40mm), moderate (41-74mm) and severe (75-100mm).

Postoperative acute pain survey - Xhosa

1) Nceda undikhombise kulomgca ungezantsi ukuba zingakanani intlungu zakho ngoku. Akukho zintlungu ngakwicala lasekhohlo, Zininzi intlungu kwicala lasekunene.



2) Nceda ubonise kulomgca ungezantsi indlela ozive ngazo intlungu emva koqhaqho: Akho ntlungu zivakalayo kwicala lasekhohlo, kubuhlungu kanobom kwicala lasekunene.

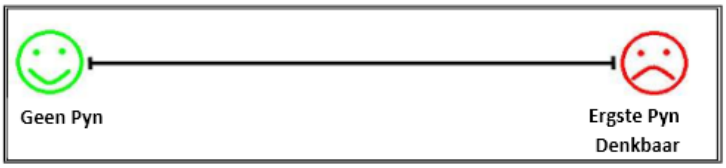


3) Wanelisekile lunyango lwentlungu olufumeneyo? Ewe/Hayi

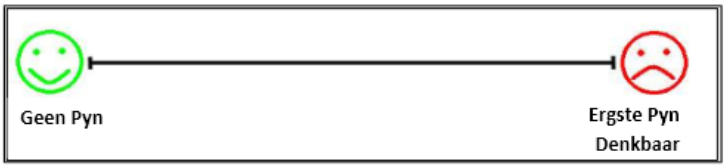
2

Postoperative acute pain survey - Afrikaans

1) Merk die punt op die volgende lyn wat jou pyn **op hierdie oomblik** die beste beskryf:
Geen pyn word heel links aangedui en die ergste pyn denkbaar heel regs.



2) Merk die punt op die volgende lyn wat jou **ergste pyn na die operasie** die beste beskryf:
Geen pyn word heel links aangedui en die ergste pyn denkbaar heel regs.

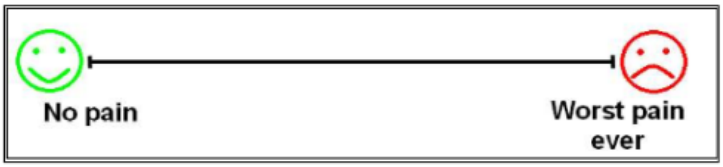


3) Is jy tevrede met die pyn medikasie wat jy ontvang het? Ja/Nee

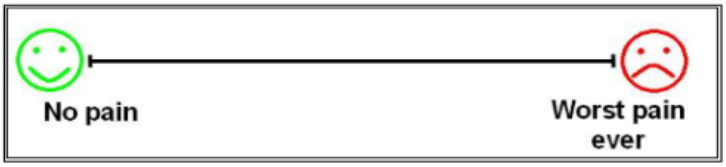
3

Postoperative acute pain survey - English

1) Please mark the point on the following line that best describe your **pain at this moment**:
No pain is indicated on the far left and the worst pain ever imaginable is indicated on the far right.



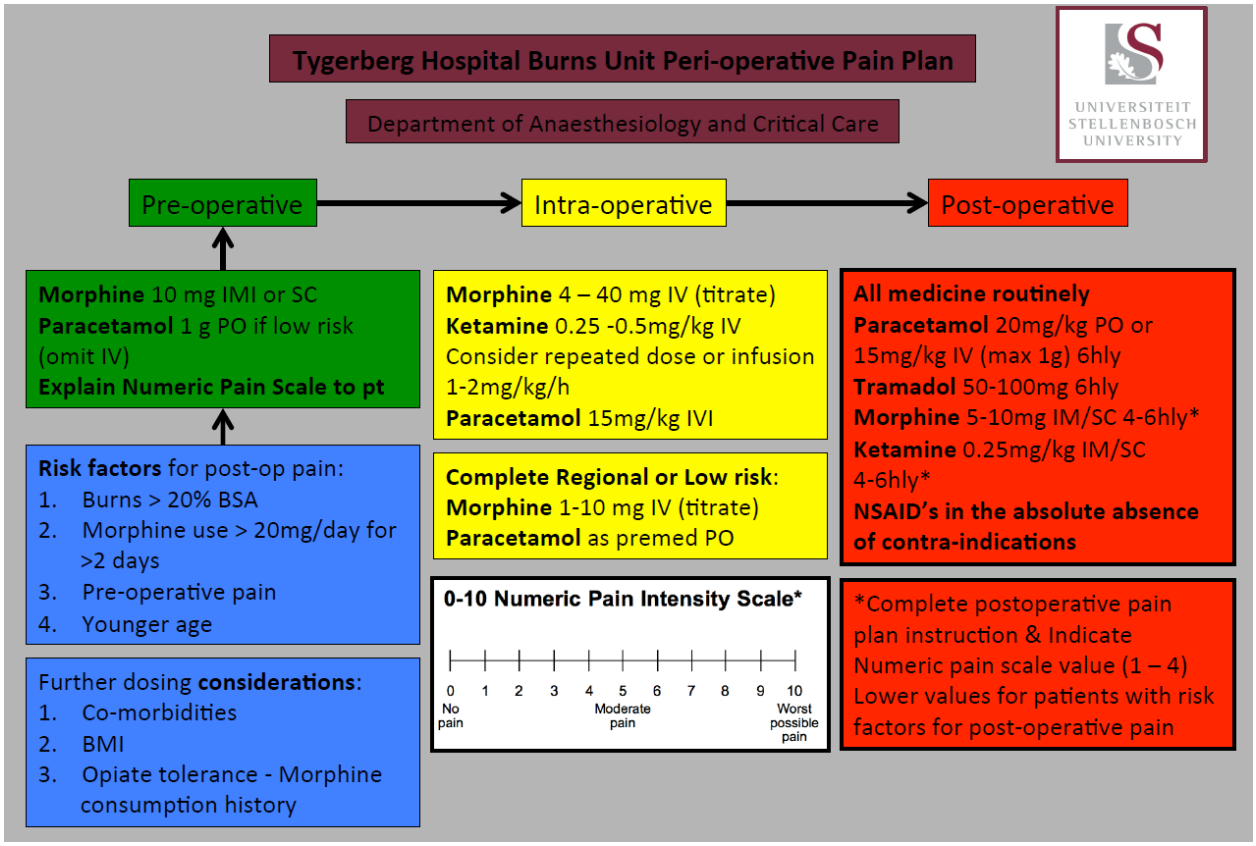
2) Please mark the point on the following line that best describe the **worst pain you experienced after surgery:**
No pain is indicated on the far left and the worst pain ever imaginable is indicated on the far right.



3) Are you satisfied with the pain medication you received? Yes/No

4

Appendix F: Post-operative pain poster



Appendix G: Nursing instruction form

TYGERBERG HOSPITAL POST-OPERATIVE PAIN MANAGEMENT PLAN

Post-operative burns patients have been identified as a population with a high incidence of pain. The goal of this pain management plan is to identify and manage patients with pain. Please contact the Anaesthetist on call if there are any queries / uncertainties.

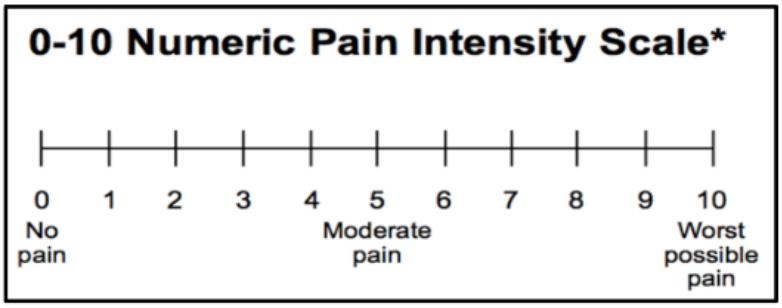
A Numeric Pain Scale (**NPS**) number (0 - 10) needs to be formally documented postoperatively as part of the routine observations. This must be done every time observations are being done, but at least:

- On arrival in ward then,
- 1 Hourly until 2 following pain scores of 3 or less then,
- 4 Hourly until 2 following pain scores of 3 or less then,
- 6 Hourly until 24 hours postoperative.

Ask the patient to rate their pain from 0 - 10 and document the number on the observation chart. The patient is allowed to look at the picture if necessary:

"Please tell me the number from 0 to 10 that best describes your current pain, where 0 means no pain and 10 means the worst pain you can imagine."

"Sê asseblief vir my die getal van 0 tot 10 wat jou huidige pyn die beste beskryf, waar 0 geen pyn beteken en 10 die ergste pyn waaraan jy kan dink. "



Analgesia:
Oral medications must be given routinely and strictly as prescribed, unless there is a contraindication.

Morphine (See prescription chart):
Administer when **NPS** of ____ or more and responds to verbal command or light touch

Ketamine (See prescription chart):
Administer when **NPS** of ____ or more and responds to verbal command or light touch

Doctor Name: _____ Signature: _____
Date: _____ HPCSA nr: _____