EFFECTIVENESS OF POST-OPERATIVE PAIN MANAGEMENT AMONG PATIENTS IN A SURGICAL WARD AT WINDHOEK CENTRAL HOSPITAL IN NAMIBIA

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ABSTRACT

Effective management of post-operative pain improves patient outcomes and quality of life. Although internationally validated pain scales have been implemented for evaluation of post-surgical pain, the majority of patients who undergo surgery in both high-income and low- and middle-income countries continue to experience ineffective management of acute pain. This study aimed to assess effectiveness of post-operative pain management among patients in a surgical ward at Windhoek Central hospital in Namibia by comparing the proportion of patients with moderate to severe pain at 24 h and 48 hours post-operatively. A prospective cohort design was utilized to assess post-operative pain at 24 hours and 48 hours using two different pain assessment tools. Data related to prescribing patterns were collected from patient's clinical records using a standardized data collection tool. Data were analyzed using SPSS v22 software. The study was conducted among 75 participants. Of 75 participants, 48 (64.0%) were males. The mean age was 37.41± 11.13 years. Among the patients involved in the study, 74.7% experienced moderate to severe pain at 24 hours post-operatively which reduced to 41.3% by 48 hours. The difference was statistically significant. Overall, over 5% of the study participants experienced moderate to severe pain at 48 hours post-operatively compared to a UK target of less than 5%, showing inadequate management of pain. The cumulative median pain scores for visual analogue scale and numeric pain scale were 5.50 at 24 h and 2.00 at 48 h post-operatively. The difference in median pain scores was statistically significant (p<0.05). The commonly prescribed analgesics were paracetamol injection (68%), strong opioids (54%) and weak opioids (23%) while adjuvants, and NSAIDs accounted for 8% each, respectively. Out of 75 clinical records reviewed, only 47 (62.7 %) followed WHO guidelines on pain management. There is a need to more frequently assess patient's level of pain after surgery to ensure effective pain management. In conclusion, post-operative pain is inadequately controlled at WCH.

KEY WORDS: *Post-operative pain; effectiveness; prescribing patterns; pain scales; appropriateness*

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LIST OF ABBREVIATIONS AND/ OR ACRONYMS

APS	Acute Pain Service
ERAS	Enhanced Recovery after Surgery
GA	General Anesthesia
HIC	High income countries
HREC	Human research ethics committee
IASP	International Association for the study of pain
IBM	International business machines
IM	Intramuscular
IOA	Intra-operative analgesia
IVI	Intravenous infusion
LMIC	Low and middle income countries
MOHSS	Ministry of health and Social Services
NPS	Numeric pain scale
NSAIDs	Non-steroid anti-inflammatory drugs
OEP	Opioid Exit Plan
PI	Principal Investigator
PO	Per os
SD	Standard deviation
SPSS	Statistical Package for Social Sciences
UK	United Kingdom
USA	United States of America
VAS	Visual analogue scale
VPIS	Verbal pain intensity scale
VPS	Verbal pain scale

WCH Windhoek Central Hospital

WHO World health organization

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DECLARATIONS

I, **Maano Nelao Oletu Mika**, hereby declare that this study is my own work, and is a true reflection of my research, and that this work, or any part thereof has not been submitted for a degree at any other institution.

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Name of Student **Signature** **Date**

CHAPTER ONE:

INTRODUCTION

1.1 Background of the study

The Taxonomy Committee of International Association for the study of Pain (IASP), defines pain as *"An unpleasant sensory or emotional experience associated with or resembling that associated with, actual or potential tissue damage."*(1). Post-operative pain is hence defined as any form of pain experienced as a result of surgical trauma in which the inflammatory response has been stimulated (2).

Kasahun and colleagues have reported that the majority of patients who undergo surgical procedures experience under-treatment of post-operative pain, which therefore amounts to medical negligence (3). The Commission on Provision of Surgical Services of Britain reported that despite discrepancies in pain management, globally about 75% of patients suffer from moderate to severe pain in the postoperative period (4). In Africa, up to 95.2% of the patients continue to experience post-operative pain and its management is still a major concern (5–8).

Literature evidence has shown that the majority of patients who undergo surgery in both high-income (HIC) and low- and middle-income countries (LMICs) experience ineffective management of acute pain (3–5,9–13). Ineffective management of postoperative pain remains a primary concern for patients undergoing surgical procedures and healthcare practitioners who are directly involved in the management of post-operative pain (10). Lack of adequate pain control post-operatively can compromise a patient's quality of life and therefore, it is an important public health problem (11). The resulting negative psychological and physiological patient outcomes of poorly managed pain can lead to chronic pain and thus have a considerable financial impact on the health care system (12).

Regular assessment of pain intensity constitutes an integral component of pain management. It is associated with improved patient outcomes and better quality of life (13). Internationally validated tools such as verbal pain intensity scale (VPIS), visual analogue scale (VAS) and numeric pain scale (NPS) have been implemented for evaluation of post-surgical pain in adult patients and have been used effectively in many studies (11,14,15). The visual analogue scale is a 10cm line which constitutes of two end points; zero for no pain and 10 for the worst possible pain. Once patients have recorded their pain intensity, the pain intensity level is scored by measuring the distance between the no pain end and the patient's mark (14,16,17). The VAS has been reported to be commonly used in research and clinical practice due to its validity and reliability (16). Research further revealed that there is a significant correlation between pain intensity measured using a VAS, verbal and numeric scale (2,11,16,18). Many studies prefer using a VAS due to its ratio scale properties, however it is reported to be difficult to understand and complete and therefore time consuming (2,11,16–18). On the other hand, a NPS comprises of eleven numbers, where zero indicates no pain while 10 represents the worst possible pain . Participants are required to identify a number that best decribes their intensity of pain on a scale of 0-10 (16,17). The NPS has been proved to have high consistency and also easy to complete. The draw backs of using a NPS are that it is less sensistive compared to VAS (2,16,17). Whereas verbal pain scale, (VPS) measures the intensity of pain using a range of adjectives namely; no pain, mild pain, moderate pain and severe pain. Each adjective is allocated a corresponding score from 0 to 10 whith zero representing no pain while 10 represents the worst level of pain experienced by the patient (16,17). Altough the VPS has been reported to be easy to administer and score, it incorporated the use of words which

may exaggerate the patient's level of pain (16,17). For post-operative pain management to be effective, adequate pain control measures must be initiated during surgery and continued throughout the early and late postoperative period (19). Given that pain is a subjective experience, analgesia route of administration should be customized and tailored based on patient's severity of pain (19).

Several studies in LMICs have revealed that analgesics in general, and non-steroid anti-inflammatory drugs (NSAIDs) in particular, are amongst the most highly prescribed medicines (2,3,6,11). These products have a high risk of being prescribed irrationally leading to potential patient harm as a result of their common side effects such as gastro-intestinal bleeding and acute kidney injury (20). If all factors that affect drug absorption and availability are not taken into account, a particular analgesic dose that produces successful pain relief in one patient may generate adverse effects and insufficient pain control in another person (21). Moreover, the World Health Organisation (WHO) (22) has endorsed the following guideline in the management of pain which was later adopted in the management of post-operative pain, as shown in the table below:

Table 1: Recommendations for post-operative pain management

Pain level	Recommended therapeutic management
Mild pain	• Paracetamol 650mg q4h • Aspirin 650mg q4h • Ibuprofen 400mg q4h or other • NSAIDs plus adjuvants such tricyclic anti-depressants, and antiepileptic drugs
Moderate pain	• Paracetamol 325mg + codeine 30mg q4h • Paracetamol 325mg + codeine 60mg q4h • Paracetamol 325/500mg + oxycodone 5mg q4h plus adjuvants • Stronger opioids at a total daily dose of 400mg/day of codeine or 80mg/day of oxycodone
Severe pain	• Morphine 5-10mg q4h titrate to pain • Hydromorphone 1-4 mg q4h titrated to pain • Long-acting morphine (MS-Contin) or other long-acting opioid 30-60mg q8-12 h • Fentanyl 25ųg/ hour plus morphine sulphate 5 mg q 2 hours for breakthrough

Note. Adapted from WHO (22)

1.2 Statement of the problem

The incidence of poor post-operative pain management remains high with up to 80% of patients who undergo surgical procedures in Sub-Saharan Africa being inadequately and inappropriately treated (23,24)**.** Studies have revealed that poorly managed post-operative pain has consequences such as increased morbidity, prolonged duration of opioid use, reduced quality of life, impaired sleep, impaired physical function as well as high economic costs due to hospital-readmission in addition to delayed recovery and development of chronic pain (24). Currently, there is dearth of knowledge about post-operative pain management in Namibia. It is therefore essential to assess the current management and determine the prescribing patterns for post-operative pain in

Namibia, which could lead to policy changes for the improvements in quality of patient's care.

1.3 Objectives of the study

1.3.1 General objective

To estimate effectiveness, as well as prescribing patterns of post-operative pain management among patients in a surgical ward at Windhoek Central Hospital (WCH), Namibia.

1.3.2 Specific objectives

(i). To assess the effectiveness of post-operative pain management among patients admitted to the surgical ward at 24 hours and 48 hours post-operatively

(ii). To describe the prescribing patterns in the management of post-operative pain among patients admitted to the surgical ward of WCH

(iii). To assess the extent to which post-operative pain prescribing follows the WHO guidance on pain management

1.4 Hypotheses of the study

Null hypothesis: There is no difference in the proportion of patients with moderate-severe pain at 24 hours and 48 hours post-operatively following post- operative pain management.

Alternate hypothesis: There is a difference in the proportion of patients with moderate-severe pain at 24 hours and 48 hours post-operatively following post-operative pain management.

1.5 Significance of the study

Reviewing effectiveness and determining the prescribing patterns for post-operative pain management in our local setting can guide health providers on how to optimize the patient's quality of care post-operatively. The findings on the effectiveness of post-operative pain management showed suboptimal management of post-operative pain at WCH, with up to 41.3% of patients experiencing moderate tosevere pain at 48 hours after surgery. This data will therefore lead to the development of Acute Pain Service (APS) groups and Enhanced Recovery after Surgery (ERAS) programs which will aim to establish pain score monitoring protocols and help to inform and improve current pain management strategies within the surgical ward with the ultimate goal of improving patient outcomes and public health in general. This study will also lead to opportunities for pharmacists to be more involved in direct patient care.

1.6 Delimitation of the study

The study was confined to assessing the effectiveness of post-operative pain management among adult patients, determining the prescribing patterns and assessing the extent to which post-operative pain prescribing follow WHO guidance on pain management. This study did not focus on pediatric patients and did not also explore adverse effects of analgesia. Patients' satisfaction with post-operative analgesia was not investigated.

1.7 Limitations of the study

The study was carried out as a single center study therefore the study findings may not be generalizable to other settings. The transferring of patients from one hospital or ward to another interrupted the pain assessment process, therefore some study

participants had to be excluded because pain assessment could not be performed at 48 hours. Even though consent form and participant information sheet/ leaflet were both translated into 7 locally spoken languages, there was still communication barrier, in absence of translators some participants could not be included in the study.

During the conduct of the study, there were a variety of surgeries included, each with varying levels and kinds of pain. Because of the sample sizes, it was therefore not possible to evaluate pain control for each individual surgery type.

CHAPTER TWO:

LITERATURE REVIEW

2.1 Literature search

A search was conducted to gather information relevant for this study using databases and search engines such as Mendeley, PubMed, Google Scholar and Medscape. The following keywords were used to identify relevant articles; prescribing patterns, effectiveness, assessment tools, post-operative pain and analgesia. The articles searched were confined to English language publication because of the necessity to read in detail and be able to summarize findings of each study. There was no time limitation, hence relevant articles up to November 2021 were included.

2.1.1 Effectiveness of postoperative pain management

A study by Awan *et al*. reported that 68.7% patients had moderate to severe pain in the first 24 hours of surgery which reduced to 51.7% in 48 hours (15). Results of a survey carried out among 200 patients in Pakistan also revealed a reduction in mean pain scores with passage of time, which indicates improvement in the incidence of post-operative pain relief (25). The proportions of patients with moderate-severe pain reduced from 55% at 24 hours post-operatively to 34% 48 hours post-operatively (25). Salaudeen and colleagues in Nigeria also reported an overall prevalence of moderate-to severe pain of 54.3% at 6 hours post-operatively with a mean pain score > 2 (2.20 ± 0.97) which reduced to 1.20 ± 0.97 after administration of oral analgesics (8). However, in their study, they did not assess post-surgical pain at 24 hours and 48 hours.

A review of evidence from a prospective study carried out in Spain, published data on effectiveness of post-operative pain management showed the overall incidence of moderate to severe pain to be 29% and the overall incidence of severe pain to be 9% in the first 24 hours after surgery (26). The review also highlighted a significant reduction in the incidence of pain over time both at rest and on movement (26). The review findings were similar to the incidence of moderate to severe pain (30%) reported by Huang *et al* in Kenya in 2013 (27).

Similarly, pain assessment was done at 24 hours and 48 hours after operation in a Tanzanian study, showed that patients continued to experience pain in the first 48 hours after surgery (28). The percentage of patients who experienced moderate-severe at rest was 40.3% 24 hours post-operatively which reduced to 26.6% at 48 hours (28). Findings from a cross sectional study which was conducted in the United Kingdom (UK) over fifteen thousand patients on effectiveness of acute post-operative pain management reported that 48% of patients recorded moderate to severe pain in the first 24 hours after surgery (2). None of the survey hospitals reached a target of 5% severe pain level which indicated that there is a need for modifications to the current analgesic techniques (2).

Another stream of research in Pakistan has studied the effectiveness of paracetamol in control of breakthrough pain (11). In their randomized controlled trial among 220 patients at 24 hours and 48 hours post-operatively, 56.8% of control group patients had moderate or severe pain at 24 hours measured by the cumulative pain score from NPS and VAS whereas the intervention group had 18.5%. In the next 48 hours, 35% of patients had moderate to severe pain in the control group while in the test group,

5.9% of patients had moderate-severe pain (11), highlighting the role of paracetamol for improving post-operative pain management.

2.1.2 Prescribing patterns in the management of post-operative pain

A study carried out by Rawal in Sweden revealed that ineffective post-operative pain management is a serious concern (30). Opioids remain the drug of choice in the management of post-operative pain, despite a number of concerning side-effects such as, constipation, over-sedation, somnolence and respiratory depression (31). Meanwhile, Rawal also found regional anesthetic techniques including epidural analgesia to be the most effective way of managing pain post-operatively(29).

A number of studies in other settings have looked at prescribing patterns for post-operative pain control. Menezes *et al*. conducted a study at a teaching hospital in India which found that opioids (47%) and NSAIDs (36%) were the most commonly prescribed post-operative analgesia for pain control (32). Of the opioids used, tramadol (56%) was the most frequently used followed by morphine (38%) (32). A study undertaken by Haque *et al.* in Pakistan found similar results with tramadol (76%), diclofenac (74%), ketorolac (52%) and paracetamol (55%) being the most commonly used analgesics post-operatively (33).

Two studies were conducted in Tanzania, the first one was carried out among 124 patients, and it revealed that intramuscular pethidine (83%) was the most prescribed post-operative analgesia followed by diclofenac (43%), tramadol (36%) and paracetamol (28). The second study invoving 136 patients, was carried out in a regional referral hospital Dar es Saalam with the goal of assessing post-operative pain management practices and satisfaction among operated cases (34). The authors

revealed similar outcomes: the commonest prescribed drugs were injectable pethidine (50.5%), injectable tramadol (48.9%) and oral tramadol (47.6%) (35). Ogboli-Nwasor *et al*., in a study carried out in Nigeria stressed that the prescribing patterns for post-operative pain management differ from center to center and mainly depends on the availability of the medications. Nonetheless, intermittent intramuscular injections of opioids were found to be the most prescribed analgesics (91.3%) followed by intermittent intramuscular injections with NSAIDs (6.5%) and oral paracetamol (4.3%) (6). Similar findings were reported by a study that was carried out in South Africa on management of post-operative pain which showed that regardless of their unfavorable side effects, opioids remain the treatment of choice in the management of moderate to severe pain. The widespread use of opioids in management of post-operative pain revealed by the studies could be related to the fact that opioids' have a shorter onset of action, suitable parenteral routes of administration as well as lack of ceiling effects (36). Tegegne and colleagues, in a study carried out in Ethiopia among 200 patients found NSAIDs (50%) to be the most commonly prescribed followed by paracetamol (37%) and opioid analgesics (13%) (37).

2.1.3 Adherence of prescribing in post-operative pain management to WHO guidelines

In 1986, the World health organization (WHO) developed a pain ladder to guide the management of pain among cancer patients. This ladder, was later recommended for the general management of all types of pain (22). The ladder comprises of three pain categories which are represented on a scale of 1-10. Category 1, or mild pain is from 1-3 out of 10. Category 2, or moderate pain is 4-6 out of 10. Category 3, or severe pain constitutes 7-10 out of 10 (22).

Gulik and colleagues in Netherlands as well as Nasrulloh *et al*. in Indonesia reported similar findings on adherence of post-operative prescribing to pain management protocols, with 88% of the post-operative analgesics adhering to all steps of post-operative management protocol (34,38). A few studies have also looked at adherence of post-operative prescribing to either WHO pain ladder or local post-operative pain management guidelines but findings were insignificant (5,39). Negussie *et al*., in their study emphasized how pain assessment and adherence to post-operative pain management protocols constitutes a critical step in the effective management of post-operative pain (41). They further stressed that pain assessment must be performed regularly (at least once per shift or ideally every two hours) using a standard format and that pain should be re-assessed after each intervention to determine effectiveness of post-operative analgesic and need for therapy modification (41). All patients presenting with moderate and severe pain during pain assessment should be recommended analgesics as stipulated by the WHO pain ladder and re-assessed after each intervention (33). Adequate pain control was defined as a 33% to 50% decrease in pain intensity (42). However, standards recommended by the audit commission of Britain in 2002 were found to be more suitable for the hypothesis of this study and thus adopted to define adequate pain control as a target of less than 5% of patients experiencing moderate-severe pain at the end of the assessment period (2).

2.1.4 The impacts of potential confounders on the severity of pain

According to the literature, age, sex and pre-operative pain were found to be major factors associated with moderate to severe pain in postoperative pain management (35,43–45). A study conducted in Germany further listed type of anesthesia and type

of surgical procedure as potential confounders of severity of post-operative pain (43). These results were contradictory to discoveries of a qualitative systematic review and meta-analysis that was carried out by Yang and colleagues on pre-oeprative predictors of poor acute post-operative pain control, which summarized that age was commonly found to have a negative correlation with post-operative pain intensity (45). Findings regarding correlation between gender, type of analgesic and post-operative pain outcomes were inconsistent (35,44,45). A prospective cohort study conducted by Liu *et al*. to identify the predictors of the severity of acute post-surgical pain following gastro intestinal surgery among 345 adult patients as well as Rogers *et al.* in Netherlands also performed multiple linear regression analysis and found that age and type of surgery play a significant role in the severity of post-surgical pain (5,44). Hauglum in the United States of America, (USA) also reported the same findings (46). Other studies also scrutinized use of intra-operative analgesic as a possible confounder for severity of post-operative pain but findings were not significant (2,24).

Other demographic factors such as type of anesthesia were only assessed in a few studies and findings were also not consistent (44,45). In contrast, a survey of post-operative pain management at a teaching hospital in Rwanda found no significant association between the worsening of pain and differences in age , gender or type of surgery (47).

CHAPTER THREE:

RESEARCH METHODS

3.1 Research design

A prospective cohort design was used to estimate the effectiveness of post-operative pain management among patients in a surgical ward at Windhoek Central Hospital (WCH), Namibia. The research design was appropriate for the study as participants were followed up over a 48 hours period. Data related to prescribing patterns and pain intensity were collected from clinical records of patients who were admitted to the general surgical ward at WCH between September 2020 and November 2020.

3.2 Study population

The target population for the study included all male and female adult patients who underwent general surgical procedures and were alive 48 hours after surgery.

3.3 Sample

Sample size was determined using Statulator, an online sample size calculator for comparing paired proportions (48). The proportions of patients with moderate to severe pain at 24 hours and 48 hours post-operatively of 69% and 52%, respectively, (19) as well as a correlation between paired pain scores of 50% were assumed and used to calculate a sample size of 75 patients to achieve a power of 80% and a level of significance of 5% (two sided), for detecting a difference of -0.17 between marginal proportions.

3.4 Sampling Method

A non-probability sampling method, namely convenience sampling, was used to select clinical records of eligible surgical patients.

3.4.1 Inclusion criteria

Male and female adult patients aged at least 18 years old who underwent general surgical procedures such as abdominal surgery, thyroidectomy, breast surgery, hemorrhoid surgery, amputations and skin grafting and were alive 48 hours after surgery were included.

3.4.2 Exclusion criteria

Patients under 18 years of age and those who were unconscious during the first 48 hours post-operatively were excluded. Clinical records with missing data were excluded from the analysis. Patients younger than 18 years were excluded as they were not eligible to give informed consent.

3.5 Research Instrument

Pain scores were assessed using two internationally validated pain scales: numeric analogue scale and visual analogue scale (Appendix D). A combined cumulative pain score (out of 10) was generated by combining VAS (a scale of 0-10cm) and NPS (a scale of 1-10) (11). Researchers have found VAS to be more sensitive and more accurate in assessing the intensity of pain (2,11). However, a combination of VAS and NPS which is said to be moderately correlated has been recommended (2,11,18). The pain scores were classified as no pain (0/10), mild (1-3/10), moderate (4-6/10) and severe (7-10/10). Adherence to WHO was defined as medications that were prescribed

in line with patient's intensity of pain as stipulated by the WHO pain ladder. Demographic data and patient characteristics such as gender, age, type of surgery performed, previous surgical history, anesthesia type, intra-operative analgesia, analgesic prescribed post-operatively, dose prescribed, and the method of delivery for this analgesia were collected using a pain management checklist (Appendix D).

3.6 Procedure

For this study, data collection process was commenced upon ethical approval from the Ministry of Health and Social Services during the period from September 2020 to November 2020. The principal investigator (PI) recruited participants from the theatre booking list and the nurses collected pain scores at two time points: 24 hours and 48 hours post-operatively. Once a day, the PI rounded in the surgical ward to identify new potential participants. If a participant met the inclusion criteria, the PI then approached the participants, explained the details of the study before consent was obtained. After the participant provided consent, the PI informed the nurses to administer the 2 pain scales to consenting eligible participants at 24 hours after surgery and 48 hours after surgery. At 24 hours post-surgery, the PI reviewed the patients' medical charts and dispensations to collect data on prescribing patterns of post-operative pain management. In order to determine the extent to which the post-operative prescribing follows WHO guidance on post-operative pain management medications were categorized into different pain medication groups as per WHO's classification and determine which ranks of the ladder were prescribed while data on effectiveness of post-operative pain management were collected by assessing patients' level of pain at 24 hours and 48 hours. Adequate pain control was defined as less than 5% of patients

experiencing moderate or severe pain at the end of pain assessment period (48 hours) after surgery (2)**.**

Reliability and validity of the study

Validity of the study

To ensure face validity, the data collection tool was pre-tested by the principal investigator and research assistants in May 2019. A pilot study was carried out in May 2019, the data collection tool was pre-tested by the principal investigator and research assistants to identify potential problems. The data collection tool was also reviewed by the research supervisors and one surgeon working in the surgical ward/theatre. This also ensured clarity and minimized the chances of omissions and errors.

Reliability of the study

Reliability was ensured through training of nurses involved in the collection. The nurses were trained on pain assessment using the three pain scales.

3.7 Data analysis

Data were entered into a database in Microsoft Excel, cleaned and exported to Statistical Package for Social Sciences (SPSS) version 22 (IBM, Corporation, Chicago, IL, USA) to perform statistical analyses. Participant demographics were analysed using descriptive statistics. Categorical variables were presented as proportions while continuous variables were expressed as mean, median, range and standard deviation. McNemar's test was used to assess the effectiveness of post-operative pain management by comparing the proportion of patients with moderate-severe postoperative- pain at 24 hours and 48 hours. Effectiveness of post-operative

pain management was also assessed by comparing differences in median or mean pain scores at 24 hours and 48 hours post-operatively using paired t-tests or Wilcoxon's matched pair tests if the data were normally or non-normally distributed. A normality test was performed on paired differences between 24 hours and 48 hours to determine whether data were normally or non-normally distributed. The impact of intra-operative analgesia and other potential confounders such as the type of surgery, adherence to WHO pain ladder as well as type of analgesic on the severity of pain (≤ moderate or ≥ severe pain) at 24 hours were determined using bivariate analysis. . Pearson's chi-square of association analysis was carried out to determine the association between variables such as use of use of intra-operative analgesia, type of anesthesia, adherence to WHO and severity of pain while chi square of independence was used to determine the relationship between type of surgery, types of analgesics and severity of pain. Multivariate analysis was performed using binary regression. A p value of < 0.05 was considered statistically significant.

CHAPTER FOUR:

RESEARCH ETHICS

This study was designed to address key research ethical principles including autonomy, respect for persons, beneficence, and non-maleficence, and justice.

Autonomy/Respect for Persons

This study involved direct contact with patients during assessment of pain scores, thus patient consent was required. A consent form clearly explaining voluntary participation and free will to withdraw from the study at any time was provided to all study participants (***see Appendix C***). Effort was also made to translate the contents of the form into participants' vernacular languages to ease communication. Participants were made aware of the purpose of the study, duration of participation, risks and benefits as well as expectations via provision of participant information sheet (***Appendix C)*** which was also translated into seven locally spoken languages such as Afrikaans, Otjiherero, Oshiwambo, RuKwangali and siLozi. They were further allowed to ask questions prior to signing consent form. Formal ethical clearance was obtained from the Human Research Ethics Committee (HREC) at the University of Namibia on the 24th July 2020 *reference number; H-G/574/2020* (***Appendix A***) and the ethics committee at the Ministry of Health and Social Services (MoHSS) on the 10th September 2020 *reference number; 17/3/3MNM* (***Appendix B***). Permission to conduct the study was granted by the management of Windhoek Central Hospital on the 17th September 2020 (***Appendix C***).

Beneficence and Non-maleficence

The study was envisaged to inform the management of post-operative pain with a goal of improving patient outcomes. In addition, the study benefited patients directly as the intensity of their pain was known and the attending doctor/nurse helped to relieve it. The study did not involve any risk of harm to patients. Confidentiality of participants was ensured by storing data in encrypted files on a password-protected personal computer and back up flash that was password-protected and stored in a lockable cabinet within the researcher's work premises which was secured throughout the day. No patient identifiers were documented in order to protect the anonymity and confidentiality. Each participant was allocated a unique subject code.

Justice

Due to the limited study population, a non-probability convenience sampling method was used to select study participants. This ensured a pre-determined chance of including all available study subjects and ensuring justice during data collection. The findings of the study will be presented at scientific meetings/conferences/symposia as a group to avoid pin-pointing of individuals. The findings will also be published in a peer-reviewed journal subject to obtaining all necessary approvals from MoHSS.

CHAPTER FIVE:

RESULTS

5.1 Demographics of study patients

A total of 75 adult patients were included in the study. Most of patients who underwent surgical procedures were male (64.0%). The mean age of patients was 37.41±11.13 years. About 98.7% of the patients received general anesthesia during operation. Only 37.8% of the patients received intra-operative analgesics, (IOA). Most of the patients (70.7%) underwent gastrointestinal surgery. The demographics of the post-operative patients are shown in Table 2.

Table 2: Demographic data of patients

Patient characteristics	
Age	
Mean ± SD (yrs.)	*37.41± 11.13*
Range (yrs)	*41*
Gender	
Male n (%)	*48 (64.0)*
Female n (%)	*27 (36.0)*
Use of IOA	
No n (%)	*47 (62.7)*
Yes n (%)	*28 (37.3)*
Type of anesthesia	
General anesthesia n (%)	*74 (98.7)*
Local anesthesia n (%)	*1 (1.3)*
Type of surgery	
Gastrointestinal n (%)	*53 (70.7)*
Neurosurgery n (%)	*10 (13.3)*
Orthopaedics n (%)	*6 (8.0)*
Cardiothoracic n (%)	*2(2.7)*
Breast n (%)	*4 (5.3)*

5.2 The effectiveness of post-operative pain management

An exact McNemar's test was performed to determine whether there was a difference in the proportion of patients with moderate or severe pain at 24 hours versus 48 hours post-operatively using VAS. The proportion of patients with moderate or severe pain at 24 hours and 48 hours postoperatively was 81.3% and 48.0%, respectively. The difference in the proportion of patients with moderate or severe pain was statistically significant, $p < 0.001$. This change was a consequence of 25 patients (33.3%) who had moderate or severe pain at 24 hours which reduced to no pain or mild pain 48 hours post-operatively. Similarly, a McNemar's test with continuity correction was run to determine if there was a difference in the proportion of patients with moderate or severe pain at 24 h and 48 hours post-operatively using the NPS. The proportion of patients with moderate-severe pain reduced from 81.3% at 24 hours to 38.7% at 48 hours post-operatively. The McNemar's test was compared to the chi squared distribution. The difference was statistically significant, χ^2 (1) =30.03, $p<0.001$. This change could be attributed to 32 patients (42.7%) who had moderate or severe pain at 24 hours which reduced to no pain or mild pain at 48 hours post-operatively. Furthermore, an exact McNemar's test was undertaken to establish whether there was a difference between the proportion of patients with moderate or severe pain at 24 and 48 hours post-operatively using cumulative pain scores generated from VAS and NPS. The proportion of patients with moderate or severe pain reduced from 74.7% at 24 hours to 41.3% at 48 hours post-operatively. The change occurred as a result of 25 patients (33.3%) who had moderate-severe pain at 24 hours which reduced to no pain or mild pain 48 hours post-operatively. The difference was statistically significant, $p <0.001$. Based on the findings above, the null hypothesis that there is no difference in the proportion of patients with moderate-severe pain at 24 hours and 48 hours

following post-operative pain management should therefore be rejected. A summary of the results of the proportion of participants with controlled pain at 24 versus 48 hours is presented in table 3.

Table 3: Effectiveness of post-operative pain management by comparison of proportions of patients with moderate-severe pain at 24 hours and 48 hours

Variable	% Frequency	*p*-value
VAS pain intensity at 24 h		
No pain-mild pain (0-3)	*14 (18.7)*	
Moderate-severe (4-10)	*61 (81.3)*	
VAS pain intensity at 48 h		*<0.001*
No pain-mild pain (0-3)	*39 (52.0)*	
Moderate-severe (4-10)	*36 (48.0)*	
NPS intensity at 24 h		
No pain-mild pain (0-3)	*14 (18.7)*	
Moderate-severe (4-10)	*61 (81.3)*	
NPS intensity at 48 h		*<0.001*
No pain-mild pain (0-3)	*46 (61.3)*	
Moderate-severe (4-10)	*29 (38.7)*	
Cumulative pain score 24 h (VAS + NPS)		
No pain-mild pain	*19 (25.3)*	
Moderate severe	*56 (74.7)*	
Cumulative pain score 48 h (VAS + NPS)		*<0.001*
No pain-mild pain	*44 (58.7)*	
Moderate-severe	*31 (41.3)*	

A Wilcoxon signed rank test was performed to ascertain whether there was a median difference in pain scores between patients at 24 hours versus 48 hours post-operatively using VAS, NPS as well as the cumulative scores generated by VAS and NPS. Data are medians unless otherwise stated. Using VAS, there was a statistically significant decrease in matched median pain scores of patients, z = -6.786, $p < 0.001$. Also, the numeric pain scale revealed that there was a median decrease in pain scores of patients at 24 and 48 hours post-operatively. The difference was statistically significant, z = -7.110 $p < 0.001$. In addition to that, the cumulative pain scores generated using VAS and NPS divulged that there was a statistically significant median decrease in pain scores at 24 and 48 hours post-operatively, z = -6.412, $p < 0.001$. The median pain scores were 5.50 at 24 h and 2.00 at 48 hours post-operatively.

The pain scores obtained from visual analogue scale and numeric pain scale were used to generate cumulative pain scores as shown in table 4 below. A Spearman's rank-order correlation was performed to assess the relationship between pain scores generated using VAS and NPS at 24 h and 48 hours post-operatively. Pre-liminary analyses showed the relationship to be linear with both variables non-normally distributed as assessed by Shapiro-Wilk's test ($p < 0.05$) and there were no out-liers. There was a statistically significant strong positive correlation between pain scores obtained using VAS and NPS at 24 hours (r (73) = 0.83, $p<0.001$) and 48 hours (r (73) = 0.87, $p<0.001$) postoperatively.

Table 4: Effectiveness of post-operative pain management by comparison of median difference in pain scores at 24 h and 48 hours post-operatively

Variable	Median ± Standard Deviation	*p*-value
VAS at 24 h	*6.50 ± 2.46*	
VAS at 48 h	*3.50 ± 2.22*	*<0.001*
NPS at 24 h	*5.00 ± 2.32*	
NPS at 48 h	*3.00 ± 2. 23*	*<0.001*
Median cumulative of 24 h (VAS + NPS)	*5.50 ± 1.82*	
Median cumulative of 48 h (VAS + NPS)	*2.00 ± 1.68*	*<0.001*

5.3 Prescribing patterns of post-operative analgesics

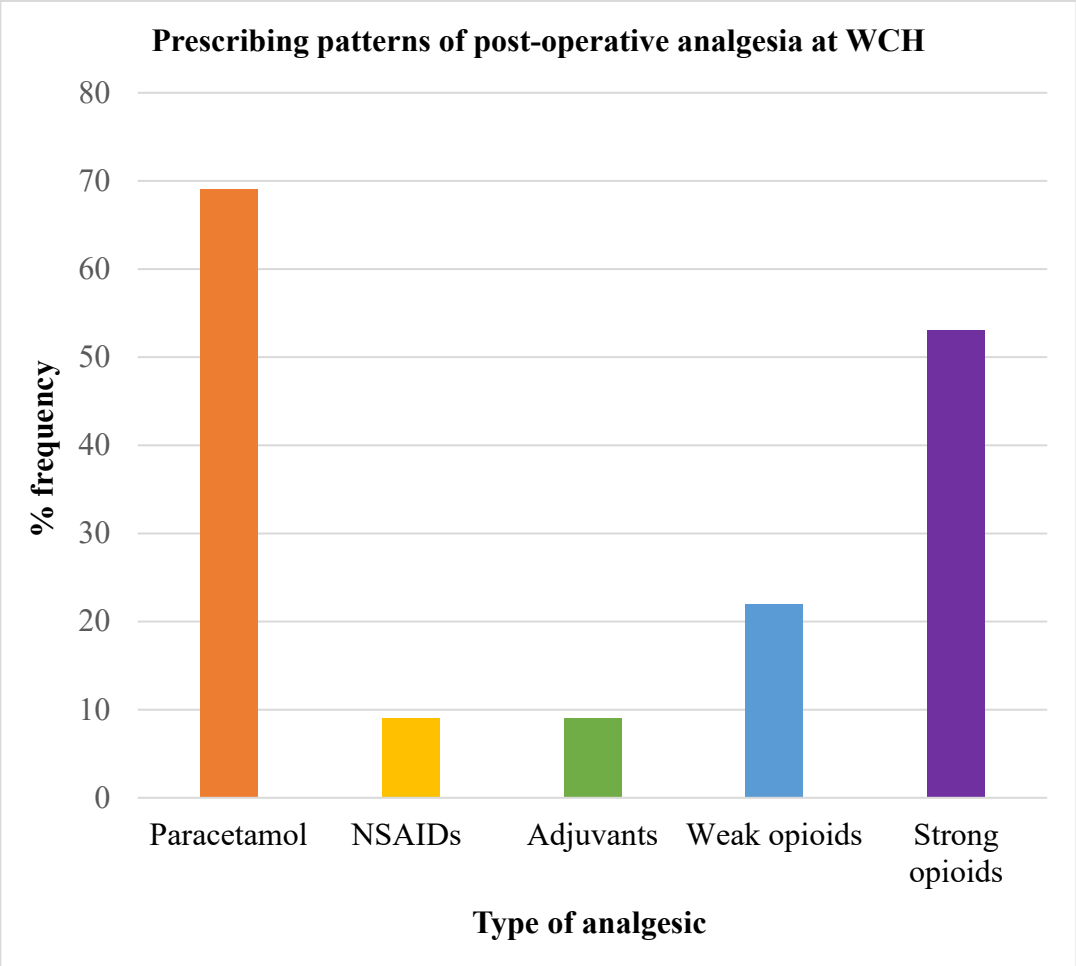

Figure 1: Prescribing patterns of post-operative analgesia (n=75)

In total, five different classes of analgesics were prescribed as shown in figure 1 above. About 68% of patients who underwent surgical procedures were prescribed paracetamol injection (WHO anatomical therapeutic chemical (ATC) code: N02BE01). Strong opioids (ATC codes: N02AA01, N02AB02) accounted of the second highest percentage (54%) of the drugs prescribed post-operatively. Only 23% of the prescriptions had weak opioids (ATC codes: N02AX02 and N02AJ06). NSAIDS (ATC codes: M01AE01, M01AB05 and M01AB01) and adjuvants (ATC code: H02AB02) each accounted for 8% of all analgesics prescribed. Patients were prescribed an average of two analgesics. All the analgesics prescribed were from the essential medicines list. Over 90% of the analgesics used in the management of post-operative pain management were prescribed by generic name.

5.4 Adherence of prescribing in post-operative pain management to WHO guidance

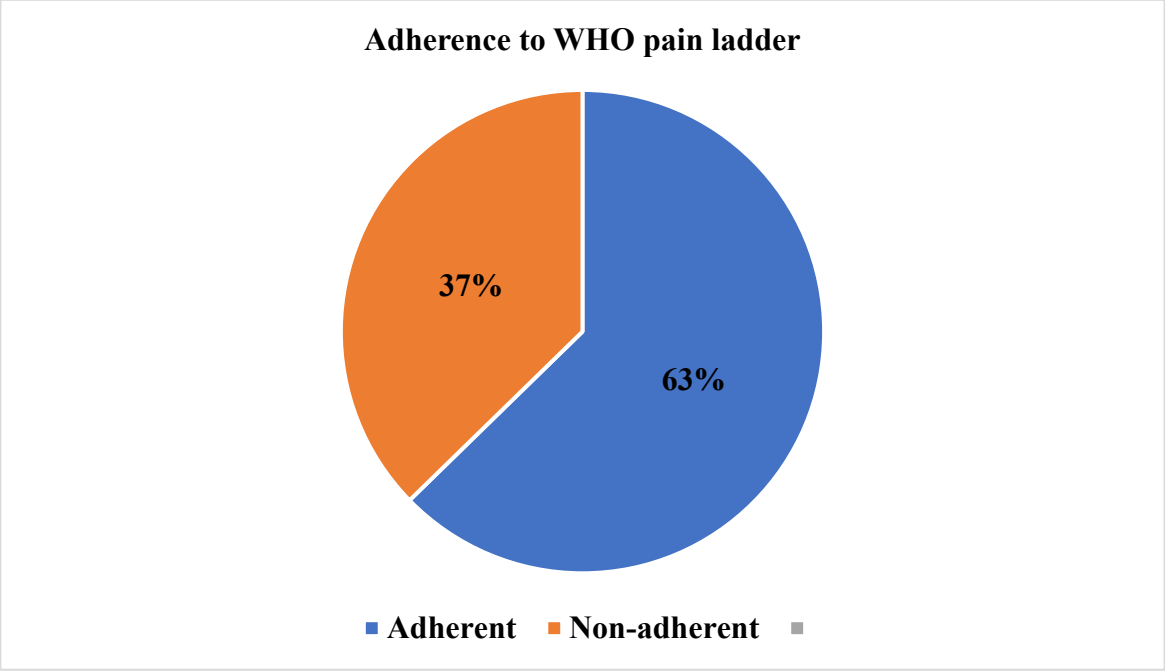

Figure 2: Adherence of post-operative pain management to WHO pain ladder (n=75)

The percentage of prescriptions for post-operative pain that adhered to WHO pain ladder accounted for 62.7% of all prescriptions (figure 2)

5.5 The impact of potential confounders on the severity of pain

The impact of potential confounders on the severity of pain at 24 hours post-operatively is shown in table 5. A chi square test of independence was conducted between type of surgery and severity of pain at 24 hours. All expected cells frequencies were greater than five. There was a statistically significant association between the types of surgery and severity of pain**,** χ^2 (1) =8.36, p=0.004. The association was moderately strong, Cramer's V=0.334. Similarly, a chi square of independence was carried out between type of analgesic and severity of pain at 24 h. All expected cells frequencies were greater than five. There was no significant association between type of analgesics and severity of pain recorded, χ^2 (1) = 0.74, p=0.390. The association was also small, Crame's V= 0. 099. A chi square test of association was conducted between use of intra-operative analgesia, type of anesthesia, adherence to WHO pain ladder and severity of pain at 24 hours. Moreover, there was no statistically significant association between use of intra-operative analgesia and severity of pain, χ^2 (1) =0.003, p=0.959. All expected cells frequencies were greater than five. The association between use of intraoperative analgesic and severity of pain was small, φ =0.006, p=0.959. Again, there was no statistically significant association between type of anesthesia and severity of pain, χ^2 (1) = 0.344, p = 0.558. All expected cells frequencies were greater than 5. The association between type of anesthesia and severity of pain was small, φ=0.068, p=0.558. However, a statistically significant

association was recorded between adherence to WHO pain ladder and severity of pain, χ^2 (1) =18.83, p<0. 001. All expected cells frequencies were greater than five. There was a strong association between adherence to WHO and severity of pain, φ=0.501, p<0.001.

Table 5: the impact of potential confounders on the severity of pain at 24 hours post-operatively

Confounders	**Cramer's V value**	***p*-value**
1. Type of surgery	*0.334*	*0.004**
2. Use of IOA	*0.006*	*0.959*
3. Type of anesthesia	*0.068*	*0.558*
4. Adherence to WHO	*0.501*	*<0.001**
5. Type of analgesic	*0.099*	*0.390*

** = significant p value by Pearson Chi square*

A binomial logistic regression was performed to determine the effects of type of surgery, type of analgesic, type of anesthesia, use of intra-operative analgesia and adherence to guidance on post-operative pain management on the severity of pain. The logistic regression model was statistically significant, χ^2 (5) = 27.744, p<0.001. The model explained 45.6% (Nagelkerke R^2) of the variance in severity of pain and correctly classified 82.7% of cases. Sensitivity was 85.7%, specificity was 73.7%, positive predictive value was 90.6% and negative predictive value was 63.6%. Among the 5 predictor variables, only adherence to WHO pain ladder and type of surgery were statistically significantly suggested to be true independent predictors of severity of

pain post-operatively as shown in table 6. Prescriptions that did not adhere to WHO guidance on post-operative pain management had 13.4 times higher odds to result in patients experiencing moderate or severe pain.

Table 6: Multivariate logistic regression for predictors of severity of pain at 24 h post-operatively

Variable	B	SE	Wald	Df	*p-value*	cOdds ratio (95% CI)
Type of surgery	*2.368*	*1.122*	*4.450*	*1*	*0.035**	*10.6(1.183, 96.312)*
Use of IOA	*- 0.521*	*0.715*	*0.531*	*1*	*0.466*	*0.5 (0.146, 2.411)*
Type of anesthesia	*19.949*	*40192.93*	*0*	*1*	*1.000*	*461083305.4(0)*
Adherence to WHO	*2.595*	*0.706*	*13.503*	*1*	*<0.001**	*13.4 (3.357, 53.488)*
Type of analgesic	*0.193*	*0.700*	*0.076*	*1*	*0.782*	*1.2 (0.308, 4.781)*
Constant	*-25.178*	*40192.99*	*0*	*1*	*1.000*	*0*

***Significant p-value by crude binary logistic regression*

CHAPTER SIX:

DISCUSSION

The overall aim of this study was to estimate effectiveness and determine prescribing patterns of post-operative pain management among patients in a surgical ward at Windhoek Central Hospital (WCH), Namibia. The effectiveness of post-operative pain management was assessed by comparing the proportion of patients with moderate or severe pain at 24 hours versus at 48 hours following post-operative pain management. The study found post-operative pain management at WCH, to be inadequately controlled as nearly half of the study participants (41.3%) continued to experience moderate or severe pain at 48 hours post-operatively. A set target of less than 5% of patients experiencing moderate or severe pain at the end of pain assessment period (48 hours) after surgery was not attained (2). Paracetamol injection (N02BE01) was found the most prescribed analgesic post-operatively (68%). Adherence to WHO guidance on post-operative management and type of surgery are independent predictors of severity of pain.

6.1 Demographic data of patients

The current study found that majority of the patients who underwent post-operative pain management were male. The mean age was 37.41±11.13. The majority of patients who were operated were under general anesthesia and did not receive any intra operative analgesia. This study has identified 5 different types of surgery with gastrointestinal surgery being the most common surgical procedure. Similar findings have been reported in Tanzania and Ethiopia (23,28,35). However, a study carried out in Nigeria by Salaudeen and colleagues found the use of local anesthesia and

peripheral surgery to be the most common (8). Comparing patient demographic factors across different studies has been reported to help identify potential modifiable predictors of severity of post-operative pain (49). The difference in the study findings could be attributed to different hospital types which could mean different populations with different ailments and case complexity.

6.2 The effectiveness of post-operative pain management among patients admitted to the surgical ward

Post-operative pain management was found to be inadequate at WCH when compared to the UK set standard of less than 5% of patients experiencing moderate-severe pain at the end of pain assessment period (48 hours) after surgery (2). There is no local effective post-operative pain management threshold that could be used in comparison with the findings of the current study, thus the study was designated to look at change in pain control. The study findings revealed that, among the patients involved in the study, 74.7% experienced moderate or severe pain at 24 hours post-operatively which was statistically significantly reduced to 41.3% by 48 hours. Similar findings have been reported in Pakistan by Awan *et al.* Results were similar because the study designs used were alike and also patients were followed up over similar time period. (15). On a contrary, results of further research carried out in Pakistan showed a relatively slightly lower proportion of patients with moderate or severe pain at 24 hours and 48 hours post-operatively than reported in the current study (55% to 34%; 56.8% to 35%) (11,25). Other studies conducted in the Spain, Kenya and Tanzania showed remarkably lower proportions of patients with moderate or severe pain at both 24 and 48 hours post-operatively (29%, 40.3% to 26.6% and 48%) (26,28).

The proportion of patients with moderate or severe pain at 24 hours and 48 hours post-operatively was expected to be below the set standard of less than 5% of patients experiencing moderate or severe pain at the end of the pain assessment period among countries in Sub-Saharan Africa due to limited availability and accessibility of post-operative analgesic (27,29,41,50). A possible explanation for the difference in the proportions of patients with moderate or severe pain across all studies could be attributed to different health care systems, allocation of funds, and acute pain service organization models (8). This advocates for the development of appropriate clinical guidelines for the management of post-operative pain (7), as individuals having surgery should be entitled to adequate pain management regardless of the country where they have surgery. Based on available evidence, training of health workers directly involved in the management of post-operative pain in addition to the implementation and use of guidelines can improve the effectiveness of post-operative pain management (7,8).

A wide variation in research methodology across different studies might also have contributed to different findings. The current study was carried out as single centered whereas some studies were carried out as national surveys and multicenter analysis. Moreover, the current study only assessed the severity of pain at rest while in previous studies the assessment of severity of pain was either performed at rest, on movement or both over a follow up duration range of 6 hours to 72 hours post-operatively (8,11,23,51). On the other hand, the current study observed a decrease in median pain scores with passage of time (from 5.50 ± 1.82 at 24 hours to 2.00 ± 1.68 at 48 hours post-operatively). No similar findings were reported on effectiveness of post-operative pain management by comparison of differences in median pain scores. However, the

results of the current study were relatable to findings from a study by Salaudeen and colleagues in Nigeria (8), which reported a reduction in mean pain scores among all post-operative patients with passage of time (from 2.20 ± 1.20 6 hours post-operatively to 0.21 ± 0.16 72 hours post-operatively). Even though the median difference in pain scores decreased as expected, a number of patients continued to experience moderate or severe pain at 48 hours in this study, which highlights a need for implementation of regular pain assessment and review of the current pain management protocol at WCH in order to improve the quality of post-operative pain management and patient outcome.

In the current study, paired differences in pain scores were non-normally distributed and thus difference in median pain scores were used while the Nigerian study had normally distributed data and thus mean pain scores were used. Also, in the current study patients were admitted a day before their respective surgical procedures and provided with counselling prior to surgery whereas in Nigeria patients simply walked down to the surgical ward or surgical outpatient clinic on the booked day of surgery without prior counselling on the day of surgery (8). It has been reported that patients who prioir to surgery, receive adequate counselling on the treatment options available for post-operative pain relief were able to discuss the suitable treatment options and give better reports during post-operative pain assessment (52). It is therefore recommended that pre-operative counseling be re-enforced to enhance the effectiveness of post-operative pain management.

6.3 Prescribing patterns of analgesics used in the management of post-operative pain among patients admitted to the surgical ward

In the current study, the most common post-operative analgesics used over 48 hours post-operatively were paracetamol injection (68%) followed by strong opioids (54%), weak opioids (23%) then NSAIDs (8%) and adjuvants (8%). The post-operative analgesics were either used alone or in combination with each other. Similar findings were reported in India, Pakistan, Ethiopia and Tanzania (13,25,32,35,37). However, the percentage of opioids and NSAIDs used in a study undertaken by Haque *et al.* in Pakistan was higher than in the current study whereas the percentage of paracetamol was slightly lower [tramadol (76%), diclofenac (74%), ketorolac (52%)] and paracetamol (55%)] (25). Menezes *et al*. in India also reported a higher percentage of opioids (47%) and NSAIDs (36%) then in the current study (32). Of the opioids used, tramadol (56%) was the most frequently used followed by morphine (38%) (32) while the current study discovered among the opioids a high percentage use of pethidine (69.3%).

Across all the studies, Tanzania recorded the highest percentage use of pethidine (83%) (28). On the other hand, Ogboli-Nwasor *et al*. in a study carried out in Nigeria stressed that the prescribing patterns for post-operative pain management differ from center to center and mainly depends on the availability of the medications (53). Although their findings were comparable to the current study, Nigeria recorded the highest percentage use of strong opioids (91.3%) followed by South Africa (68%) yet the least percentage use of NSAIDs (6.5%) and oral paracetamol (4.3%) (36,53). Literature showed that regardless of their undesirable side effects, opioids still remain

the treatment of choice in the management of moderate and severe pain (29,32,36). The widespread use of opioids in management of post-operative pain revealed by the studies highlighted could be related to the fact that opioids' have a shorter onset of action, suitable parenteral routes of administration as well as lack of ceiling effects (36). The variation in percentage use of post-operative analgesics could be linked to prescriber's preference as well as availability and affordability of post-operative analgesics. In the current study, the majority of the patients received paracetamol injection due to shortage of pethidine. Intravenous paracetamol has been reported to be effective in the management of post-operative pain with minimal side effects, hence reducing the need for post-operative opioid use (11,54). By better knowing the prescribing patterns in the management of post-operative pain, reports on medicine utilization review can be easily generated. Similarly, this study creates opportunities for pharmacists to be more involved in direct patient care. For instance, a hospital pain management team operating a pharmacist-led opioid exit plan (OEP) can be established and utilized as key to guiding the appropriate prescribing practice of opioids and aid with transitions of care on discharge(23,31).

Prescribing patterns in the current study were further described in terms of applicable WHO prescribing indicators namely; percentage of drugs prescribed by generic name, average number of drugs prescribed per encounter as well as the percentage of medicines prescribed from the essential drug list. Only the percentage of post-operative analgesic prescribed from essential drug list was found to be consistent with the standard values of prescribing indicators recommended by WHO (100% vs. 100%) (55). The current study reported an average of 2 drugs (post-operative analgesics) per patient which is very close to the WHO standard value of less than 2 (55). The slight

difference could be due to presence of confounder variables which worsen the severity of post-operative pain and thus requiring health professionals to prescribe more than one analgesic. The percentage of drugs prescribed by generic name in the current study was also lower than the WHO standard (90% vs. 100%) (55). Previous studies have reported that prescribing drugs by generic names reduces dispensing errors and average time spend on a prescription by pharmacists (55,56), again identifying a role for clinical pharmacist involvement.

A systematic review by Ofori-Asenso *et al* in Africa as well as a systemic review carried out by Tefera and colleagues in Ethiopia also reported inconsistency among WHO prescribing indicators with an average number of 2 drugs prescribed per prescription recorded in Ethiopia which is exactly the same as in the current study whereas other studies across Africa reported a higher number of medications per patient (3.1) (56,57). However, the percentage of drugs prescribed by generic name in Ethiopia was also below the WHO standard, it was higher than in rest of Africa and slightly higher than in the current study (94% vs. 68% vs. 90%) (56,57). Contextualizing post-operative analgesics prescribing patterns in terms of WHO prescribing predictors highlights a need for improvements in post-operative analgesic prescribing practices.

6.4 Adherence of post-operative pain prescribing to WHO guidance on pain management

The current study found the majority of the analgesics prescribed post-operatively (62.7%) to be in accordance with the WHO pain ladder. Gulik and colleagues in Netherlands as well as Nasrulloh *et al*. in Indonesia also reported similar findings, with

88% of the post-operative analgesics adhering to all steps of post-operative management protocol (34,38), a percentage relatively higher than in the current study. The difference in the study findings is highly linked to the lack of awareness and familiarity of WHO pain ladder existence among prescribers. This highlights a need for routine post-surgical pain assessment to ensure that all medications prescribed are in accordance with the patient's level of pain at all times and also ensure that maximum quality of treatment benefits and care are obtained. Effective use of medications will also reduce financial constraints on the hospital. A few studies have also studied the adherence of post-operative prescribing to either WHO pain ladder or local post-operative pain management guidelines but findings were insignificant (14,39). Negussie *et al.* in their study emphasized how pain assessment constitutes a critical step in adherence to post-operative pain management protocols and effective management of post-operative pain (41).

6.5 The impact of potential confounders on the severity of pain

This study found adherence to WHO guidance on post-operative pain management and type of surgery to be independent predictors of severity of pain (OR 13.4, 95% CI 3.357, 53.488 and OR 10.6, 95% CI 1.183, 96.312). Other factors identified as potential confounders in other studies for the severity of post-operative pain were: type of anesthesia and types of analgesics in addition to the use of intra-operative analgesic. However, the current study did not find a statistically significant relationship between severity of pain and any of the factors mentioned above. Part of the current study findings are inconsistent with a study on surveys of post-operative pain management that was carried out in a teaching hospital in Rwanda that there is no significant association between the worsening of pain, and differences in age, gender or type of

surgery (47). Moreover, a prospective database analysis that was carried out in Germany looked at type of anesthesia and type of surgery as potential confounders of severity of pain in postoperative pain management and also reported no significant association (43). However, findings of a prospective cohort study conducted by Liu *et al.* in China as well as Rogers *et al*. in Netherlands discovered age and type of surgery to be independent predictors of the severity of post-surgical pain which concur with findings of the current study (5,44). Hauglum also found similar findings among patients in the United States (46). Discrepancies between the current study findings and previous studies could be due to different study designs as well as different time points of post-operative pain assessment or sample size. For instance, in the current study a prospective cohort design was used to assess post-operative pain at 24 hours and 48 hours whereas in Netherlands a cohort study design was used in the first hour post-operatively. There is evidence that severity of post-operative can be easily predicted via a scoring rule immediately upon awakening from general anesthesia using patient demographics (5).

On the other hand, discoveries of a qualitative systemic review and meta- analysis that was carried out by Yang and colleagues on pre-operative predictors of poor acute post-operative pain control summarized that age was commonly found to have a negative correlation with post-operative pain intensity (45). A better understanding of predictors of severity of post-operative pain enables healthcare professionals to choose the most appropriate medication and give the best advice to particular patients.

Findings regarding correlation between gender , types of analgesic and post-operative pain outcomes were inconsistent (23,35,45). Other demographic factors such as type of anesthesia were only assessed in a few studies and findings were also not consistent

(45,58). Several studies also scrutinized use of intra-operative analgesics as a possible confounder for severity of post-operative pain but findings were not significant (2,3).

CHAPTER SEVEN

7.0 CONCLUSION AND RECOMMENDATIONS

7.1 Conclusion

Overall, post-operative pain is inadequately controlled at WCH as more than 5% of patients continue to experience moderate or severe pain 48 hours post-operatively. This creates a need for improvement and refinement in the current post-operative pain management protocol. There were a variety of post-operative analgesics prescribed but paracetamol injection and strong-opioids are the mainstay of the management of post-operative pain. The use of strong opioids is a major weakness in this practice as high-income countries have shifted away from its use due to concerns around the opioid epidemic. The majority of the analgesics prescribed post-operatively were in accordance with the WHO pain ladder. During the conduct of this study, it was discovered that routine pain assessment is necessary for effective post-operative pain management. Further clinical evidence is needed to support the development of guidelines for post-operative pain management to expedite the rational use of post-operative analgesics.

7.2 Recommendations

The choice of analgesics prescribed post-operatively is severely affected by availability of medications at the hospital pharmacy, which can affect the patient's level of pain. Pharmacists should ensure that parenteral formulations are reserved for patients in moderate or severe pain and use oral formulations for mild pain.

There is a need to routinely assess patient's level of post-surgical pain using the validated tools and manage it in accordance with WHO pain ladder.

One strategy for improvement may include nurse documentation. For instance, nurses should document on the medication administration chart what transpired when a prescribed post-surgical analgesic dose has not been administered e.g. patient refused, patient sleeping, patient not in pain, or medication not available.

Post-operative pain management can be improved by increasing the awareness of pain medicine among all health care workers involved in the management of post-operative pain via professional education and training to enhance their skills and knowledge in this area as well as designing systems to ensure pain is measured and appropriately treated.

Further studies need to be carried out to support the development of guidelines for post-operative pain management and determine a local effective post-operative pain management threshold.

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APPENDICES

Appendix A: Ethical clearance letter

UNAM
UNIVERSITY OF NAMIBIA

ETHICAL CLEARANCE CERTIFICATE

Ethical Clearance Reference Number: H-G /574/2020 **Date: 24 July, 2020**

This Ethical Clearance Certificate is issued by the University of Namibia Research Ethics Committee (UREC) in accordance with the University of Namibia's Research Ethics Policy and Guidelines. Ethical approval is given in respect of undertakings contained in the Research Project outlined below. This Certificate is issued on the recommendations of the ethical evaluation done by the Faculty/Centre/Campus Research & Publications Committee sitting with the Postgraduate Studies Committee.

Title of Project: Effectiveness of Post-operative pain management among patients in a surgical ward at WCH, Namibia

Researcher: MIKA MAANO

Student Number: 200844725

Supervisor(s): Prof Jonkman *(Main)* Mr Mubita *(Co)*

Campus: Hage Geingob Campus
Take note of the following:

(a) Any significant changes in the conditions or undertakings outlined in the approved Proposal must be communicated to the UREC. An application to make amendments may be necessary.
(b) Any breaches of ethical undertakings or practices that have an impact on ethical conduct of the research must be reported to the UREC.
(c) The Principal Researcher must report issues of ethical compliance to the UREC (through the Chairperson of the Faculty/Centre/Campus Research & Publications Committee) at the end of the Project or as may be requested by UREC.
(d) The UREC retains the right to:

(i) Withdraw or amend this Ethical Clearance if any unethical practices (as outlined in the Research Ethics Policy) have been detected or suspected,
(ii) Request for an ethical compliance report at any point during the course of the research;
(iii) Cognizance and the observation of Namibia's Research Science and Technology Act, 2004 which makes it compulsory for Non-Namibian based researchers to obtain the compulsory Research Permit from the National Commission on Research Science and Technology (NCRST), FIRST, BEFORE the research can commence.

UREC wishes you the best in your research.

Prof. Dr. J.E. de Villiers: HREC Chairperson

Ms. P. Claassen: HREC Secretary

Appendix B: Research approval letter

REPUBLIC OF NAMIBIA

Ministry of Health and Social Services

Private Bag 13198
Windhoek
Namibia

Ministerial Building
Harvey Street
Windhoek

Tel: 061 – 203 2507
Fax: 061 – 222558
E-mail: itashipu87@gmail.com

OFFICE OF THE EXECUTIVE DIRECTOR

Ref: 17/3/3MNM
Enquiries: Mr. A. Shipanga

Date: 10 September 2020

Ms. Maano N.O. Mika
PO Box 27733
Wanaheda
Windhoek

Dear Ms. Mika

Re: Effectiveness of Postoperative pain management among patients in a surgical ward at Windhoek Central Hospital in Namibia.

1. Reference is made to your application to conduct the above-mentioned study.

2. The proposal has been evaluated and found to have merit.

3. **Kindly be informed that permission to conduct the study has been granted under the following conditions:**

3.1 The data to be collected must only be used for academic purpose;

3.2 No other data should be collected other than the data stated in the proposal;

3.3 Stipulated ethical considerations in the protocol related to the protection of Human Subjects should be observed and adhered to, any violation thereof will lead to termination of the study at any stage;

3.4 A quarterly report to be submitted to the Ministry's Research Unit;

3.5 Preliminary findings to be submitted upon completion of the study;

3.6 Final report to be submitted upon completion of the study;

3.7 Separate permission should be sought from the Ministry for the publication of the findings.

4. All the cost implications that will result from this study will be the responsibility of the applicant and not of the MoHSS.

Yours sincerely,

BEN NANGOMBE
EXECUTIVE DIRECTOR

Appendix C: Research permission letter

Private Bag 13215 Windhoek Namibia	Harvey Street Windhoek Central Hospital	Tel. No: (061) 203 3024 Fax No: (061) 222886
Enquiries: Mrs. A. Mootu	Ref.	Date: 17 September 2020

OFFICE OF THE MEDICAL SUPERINTENDENT

Ms. Maano N.O. Mika
P.o Box 27733
0813420336

Dear Ms. Mika

SUBJECT: PERMISSION TO CONDUCT A RESEARCH STUDY ON EFFECTIVE OF POST - OPERATIVE PAIN MANAGEMENT AMONG PATIENTS IN SURGICAL WARD AT WINDHOEK CENTRAL HOSPITAL

1. Reference is made to your application to conduct the above-mentioned study

2. This letter serves to inform you that permission has been granted for you to conduct a study at Windhoek Central Hospital, on the above mentioned subject as you have requested and does not include any remuneration.

3. Patient/Client's information should be kept confidential at all times.

4. Preliminary findings to be submitted to Customer care office, Windhoek Central Hospital upon completion of the study.

Thank you.

Yours sincerely

17-09-2020

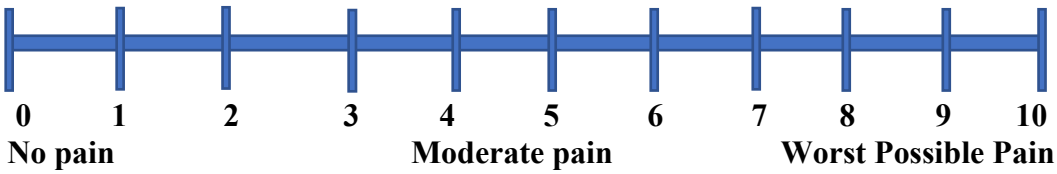
Dr .F. ZAM
ACTING CHIEF MEDICAL SUPERINTENDENT

Appendix D: Research Instruments

i. Pain Assessment tools

No pain **Worst pain**

a) Visual analogue scale



b) Numeric Pain Scale

<table>
<tr><td rowspan="2">Age</td><td colspan="2">Sex</td><td colspan="2" rowspan="2">Type of surgery</td><td rowspan="2">Previous surgical history</td></tr>
<tr><td>Male</td><td>Female</td></tr>
<tr><td colspan="3">Type of analgesics administered post-operatively:</td><td colspan="3">Was there any type of intra-operative analgesia used?</td></tr>
<tr><td colspan="3">1.
2.
3.
4
5.</td><td colspan="3">If yes,
Name

Dose

Route of administration</td></tr>
<tr><td colspan="3">Dose administered:</td><td colspan="3">Total number of analgesic doses administered</td></tr>
<tr><td colspan="3">1.
2.
3.
4.
5.</td><td colspan="3">1.
2.
3.
4.
5.</td></tr>
<tr><td colspan="6">Route of administration :
1.
2.
3.
4.
5.</td></tr>
<tr><td colspan="6">Type of anesthesia administered;</td></tr>
</table>

ii. PAIN MANAGEMENT CHECKLIST

iii. Informed consent

Declaration by participant

By signing below, I ……..……. agree to take part in a research study entitled EFFECTIVENESS OF POST-OPERATIVE PAIN MANAGEMENT AMONG PATIENTS IN a SURGICAL WARD AT WINDHOEK CENTRAL HOSPITAL NAMIBIA.

I declare that:

a) 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.

b) I have had a chance to ask questions and all my questions have been adequately answered.

c) I understand that taking part in this study is voluntary and I have not been pressurized to take part.

d) I may choose to leave the study at any time and will not be penalized or prejudiced in any way.

e) 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 (*place*) .....…..…….. On (*date*) ……...…….. 2020.

....

Signature of participant Signature of witness

Declaration by investigator

I *MAANO* NELAO OLETU MIKA 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 (*place*) .....…..…….. On (*date*) ……...…….. 2019.

....

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 (Oshiwambo, Otjiherero, Afrikaans, Orukwangari, Silozi etc.)

Appendix E: Participant information sheet (translated into 7 locally spoken languages)

TITLE OF THE RESEARCH PROJECT: Effectiveness of Post-operative pain management among Patients in a surgical ward at Windhoek Central Hospital Namibia

PRINCIPAL INVESTIGATOR: Ms. Maano Nelao Oletu Mika

ADDRESS: Windhoek Central Hospital, Ooievaar Street, Windhoek North

CONTACT NUMBER: 061 203 3160

I would like to invite you to take part in a research study. It is very important that you take some time to read the information provided below so that you fully understand the purpose of this study and what is expected of you before you decide to take part. Please ask questions and further clarification on any piece of information that you do not fully understand. Your participation in this study is voluntary and you should also feel free to withdraw from this study at any time. Take note that during this study all the ethical guidelines and principles of the International Declaration of Helsinki and Namibian National Research Ethics will be adhered to. The study has also been approved by the University of Namibia as well as by the Ministry of Health and Social Services Ethical Committee. Last but not least, approval was also obtained from the Windhoek Central hospital superintended office.

What is this research study all about?

The study will be carried out to find out how effective management of pain after an operation is among patients admitted to the surgical ward in Windhoek Central hospital over a period of three months. A nurse will rate and record the severity of your pain using three pain scales at 24 hours and 48 hours after your surgical operation.

Explain the use of any medication, if applicable.

This study does not have a purpose of giving participants any medication. However, all the ethical guidelines and principles of the International Declaration of Helsinki and Namibian National Research Ethics must be obeyed during the course of this study, thus patients presenting with moderate and severe pain during pain assessment will be recommended pain killers as specified by the WHO pain ranking.

Why have you been invited to participate?

You have been invited to participate because you are an adult patient (age > 18 years) who went through a general surgical procedure. A total number of 75 other participants will be taking part.

What will your responsibilities be?

Your only responsibility will be to tell the nurse how much pain you are experiencing which will be rated on three different pain scales. This will be done at 24 hours after surgery as well as 48 hours later.

Will you benefit from taking part in this research?

This study will benefit you directly as the severity of your pain will be known and your doctor/nurse may help to relieve it. In addition, the findings of this study may lead to improvement in the management of pain experienced by patients after a surgical operation.

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

Risks involved while participating in this study include discomfort while being questioned by the nurses.

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

If you refuse to take part in this study, this will not affect your standard of care.

Who will have access to your medical records? (Where applicable)

Only the principal investigator and those involved in collecting data will have access to the information provided during this study. Your privacy will be ensured by storing data on a password- protected personal computer and back up flash that is password-protected and stored in a lockable cabinet within the principal investigator's work premises which is secured throughout the day. None of your personal identifiers will be documented. You will instead be assigned a unique subject code. All the information gathered during this study will only be used for the purpose of this study.

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

The proposed study does not involve any risk of harm to you.

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

You will neither be paid for taking part in this study nor suffer any costs for participating.

Is there anything else that you should know or do?

You can contact Ms Maano Nelao Oletu Mika at 061 203 3160 if you have any further queries or encounter any problems.

You can contact the Centre for Research and Publications at +264 061 2063061; pclaassen@unam.na *if you have any concerns or complaints that have not been adequately addressed by the investigator.*

You will receive a copy of this information and consent form for your own records.

Appendix E: Orupa Rondjivisiro Yomunarupa Momakondononeno (Otjiherero version)

EPU RONGOḐONONENO Omatarero wonḓengu yomatauriro nge ka wondjisiwa potjipangero tja tjOmuise tjomondivitivi moNamibia.

OMUHONGORE WONGONḐONONENO: Ms. Maano Nelao Oletu Mika

EHA: Windhoek Central Hospital, Ooievaar Street, Windhoek North

ONOMORA: 061 203 3160

Me mu ṇanga amuhe kokutja mu kare norupa mongonḓononeno ndji. Ounahepero kweṇe okutja mu toore oruveze okuresa omatjangwa (ombuze) ngu ma ye teza kehi mba, kokutja mu tjiwe ounanḓengu wongonḓononeno ndji, nounahepero wayo nokutja ma ku undjirwa tjike kweṇe ngunda a mu hiya toora ondyero yokukara norupa motjitjitwa tji. Puree omapuriro ngamwa ngu mu hiya zuvire kokutja tu seturure nawa ombuze ndji. Omahongero nga o wa kamwahu nu omeriyandjerero woye omuini, mo nao otjeri oupaṭuruke kove okupita otja kombango yoye poo oiri ndji wa vanga. Me yauza kweṇe kutja momakayendero wotjiungura tji ongaro ombwa nomirari mbya zikamisiwa i yonganda ndji oInternational ***Declaration of Helsinki and Namibian National Research Ethics*** *ma ye kongorerwa. Otjiungura tji tja pewa ousemba i yozonganda nḓa oUniversity of Namibia, oMinistry of Health and Social Services Ethical Committee. Onganda ndji oWindhoek Central hospital superintended office.*

Ongonḓononeno ndji ohunga na tjike?

Ma i ka tara kokutja Ovavere mbe taurwa potjipangero i hi otja tjOmuise tjomondivitivi, kombunda yomiize vitatu vyomatauriro ve pewa ombango ndji i rivi, nu ovataurwe mba ve veruka poo ngee ndondo. Ozonurse (Ovapange) maze kara noukarata mu mave tjanga mo ondondo yomiihamo vyomipambo vyoye, a mave tara okombunda ozoiri omirongo vivari na ine (24 h) nokombunda ozoiri omirongo vine na hambondatu (48h)

Okukahurura ounahepero vomiti omipange, tjeri ohepero.

Omahongero nga maye munu kutja kahepero okuyandja omiti omipange kouṇepo auhe mbu ma u kara norupa. Posiya omirari nozoveta nḓa zikamisiwa i yonganda ndji oInternational Declaration of Helsinki noNamibian National Research Ethics maye sokukongorerwa ngandu komayandero yomahongero nga, ovavere mbu mave yarisa

omiihamo mave pewa ozoPain killer otja tji paraisiwa i yorutu rouye poo otja keraa roWHO.

Ongwaye tji wa ṉangwa okukara norupa?

Wa ṉangwa motjimbe tjokutja kori kehi yozombura (age > 18 years) nu wa rora okutaurwa. Ovandu votjivarero tjokombanda omirongo hambombari na ndano (75) ombu mave undjirwa okukara norupa motjitjitwa tji.

Omerizirira woye ma ye rire yeṉe?

Kove ma pe undjirwa kutja u zire omihiihamo mbi momunu okuza nokutaurwa. Omapuriro nga ma ye purwa kombunda yomatauriro woye kutja kombunda yozoiri omirongo vivari na mbari (24h00) vyari vi nu kombunda yozoiri omirongo vine na hambondatu (48) vi rivi.

Ma peya omunu ombwiro kombunda yokukara norupa mongonḓononeno ndji?

Ongonḓononeno ndji ya pwire ove tjinga ma rire oupupu konganga nozonesa okutjawa omiihamo vyoye nokuvipuparisa, wina otjiṉa tji ma tji vatere ozonongo zomitjise okutjiwa kutja ovandu mba taurwa kombunda yomatauriro ve ihamwa orure ndu ṯapi, mo nao mave yenene okuungurirako moruyaveze kokutja ve ṯune pu peri ohepero poo ve yere ondondo momaunguriro wawo nokutjave yete omarundurukiro ndoovazu ohepero.

Pe noukeuzeu okukara norupa mongonḓononeno ndji?

Oupotapota mbu ma u kara po okukara nongeyangeyero nondira kaṯiṯi tji mo kazira komapuriro tjiva ngu mo kapurwa i yovapange (Nurses).

Tji u hina okuitavera kokukara norupa, pe nomihingo viṉe vyarwe?

Tji u hiya karere norupa momahongero nga, kaye na ku ṯuna konḓengu yombangero ndji mo sokumuna.

Oouṉe ngu mayenene okutara okakarata koye kombangero? (Ndoovazu ohepero)

Omukonḓonene otjiuru, novapamwe naye motjiungura tjokuwonga ozombuze nḓa ombu ma ve yenene okutara mokakarata koye kouveruke nga, ngunda ongonḓoneno a

mai tjitwa. Ngamwa ombuze ndja toorwa mokakarata koye kouveruke nga mai rire oviundikwa, mai pukirwa moviṯiziro vyouye wa kandino (Okombiuta ndji mai yezururwa nozonomora nḏu maze tjiukwa i yomundu umwe karive ngo) kombanda ya nao ozokombiuta nḏa maze paterwa movipuikiro (Otjiraye) vyomukonḏononeno otjiuru, wina kapena ombuze imwe na imwe yoye ndji ma pitisiwa mozombapira, oviṉa avihe mbi ma vi kara mozokombiuta uriri. Ove mo kapewa ozonomora za peke (unique subject code. Ozombuze ngamwa nḏa wongwa nḏa maze ungurisiwa kongonḏoneno ndji uriri ka zena kwarwe ku maze kapitisiwa.

Mape tjitwa vi indi ndoovazu wa ihamenwa momakaondjero wotjiungura tji?
Omanigira wongonḏononeno ndji kaye nondando yokukuihamisa.

Ove mo sutwa tjike okukara norupa mongonḏonone ndji, mu novisuta vyaye?
Kapena otjisuta tji momunu okukara norupa nu kona tji mo pandjara wina.

Pe na tjike tji mo sokutjiwa poo tji mo sokuungura?
Mo yenene okutonena omuyozikwa (Ms) Maano Nelao Oletu Mika konomora ndji 061 203 3160 tji u nomapuriro poo tji wa kamuna ngamwa ouzeu.
Mo yenene okutona ongoze konganda ndji oCentre for Research and Publications at +264 061 2063061; pclaassen@unam.na *tji u nongendo poo ondjemeno ndji mo munu kutja omukonḏononene ka ṯunine ko nawa.*
Mo pewa otjiherengururwa tjombapira ndji mai raisa kutja ove wa itavera kokukara norupa monogonḏononeno ndji, ombapira ndji otjiraisiro tjokutja wa kara norupa motjiungura tji.

AANHANGSEL E: INFORMASIE BESONDERHEDE VAN DEELNEMER (Afrikaans version)

TITEL VAN NAVORSINGSPROJEK: Doeltreffende bestuur van post-operatiewe pyn bestuur van pasiente in die chirurgiese saal in die Windhoekse Sentrale Hospitaal Namibië
HOOF ONDERSOEKBEAMPTE: Mej. Maano Nelao Oletu Mika
ADRES: Windhoek Sentrale Hospitaal, Ooievaar Straat, Windhoek Noord
KONTAK NOMMER: 061 203 3160

Ek wil u graag uitnooi om deel te neem aan 'n navorsings studie. Dit is baie belangrik dat u die informasie hier aangeheg noukeurig lees om sodoende te verstaan wat die doel daarvan is en wat van u verwag word voor u besluit om deel te neem. U is welkom om vrae en verduidelikings te vra ten opsigte van enige aspek van hierdie informasie wat u nie heeltemal verstaan nie.

Deelname aan hierdie studie is vrywillig en mag ter enige tyd afgebreek word. Neem asseblief kennis, dat tydens hierdie studie, by alle etiese riglyne en beginsels soos in die Internasionale Verklaring van die Helsinki en Namibiese Nasionale Ondersoek Beginsels beskryf, gehou sal word. Die studie is deur die Universiteit van Namibië, die Ministerie van Gesondheid en Sosiale Dienste asook die Sosiale Etiese Dienste Kommittee goedgekeur. Goedkeuring is ook van die Mediese Superintendent van die Windhoek Sentrale Hospitaal verkry.

Wat behels die studie?
Doel van hierdie studie is om oor 'n periode van drie maande vas te stel hoe effektief die beheer van pyn na 'n operasie tussen pasiënte is wat in die chirurgiese saal in die Windhoek Sentrale Hospitaal opgeneem is. 'n Verpleegster sal die pyn meet volgens drie pyn stelsels, meetbaar 24 uur en 48 uur na die chirurgiese operasie.

Verduidelik die gebruik van enige medikasie waar van toepassing.
Hierdie studie is nie doel om medikasie aan pasiënte te voorsien nie. Alle etiese riglyne en beginsels soos in die Internasionale Verklaring van Helsinki en die Namibiëse Nasionale Navorsing van Etiek moet egter gedurende hierdie studie gevolg word.

Pasiënte wat matige tot intensiewe pyn gedurende die pyn ondersoek verduur, sal voorsien word met pyn stillers soos deur die WHO aanbeveel.

Hoekom is u uitgenooi om deel te neem?

Jy is uitgenooi om deel te neem omdat jy ‘n volwasse pasiënt is (ouderdom > 18 jaar) wat ‘n chirurgiese operasie gehad het. Daar is ‘n totaal van 75 ander deelnemers wat ook deelneem aan die studie.

Wat sal jou verantwoordelikheid wees?

Jou enigste verantwoordelikheid is, om die Verpleegster op hoogte te hou van jou pyn sodat dit volgens die drie verskillende pyn maatstawwe gemeet kan word. Dit sal 24 uur en 48 uur na die operasie gedoen word.

Wat is my voordeel deur deel te neem aan die ondersoek?

Voordeel van deelname aan hierdie studie vir jou is soos volg, dat die ernstigheid van u pyn bekend sal wees en dat u Dokter/verpleegster kan help om dit te verlig. Verder mag die uitslag van hierdie studie lei tot die verbetering in die beheer van pyn by pasiënte na ‘n chirurgiese operasie.

Is daar enige risiko verbonde deur jou deelname aan hierdie studie?

Risiko verbonde tydens deelname aan hierdie studie is die ongemak tydens die ondervraging van die verpleegsters.

Watter alternatiewe het jy indien jy weier om deel te neem?

Sou jy weier om deel te neem sal dit nie die standaard van u sorg beïnvloed nie.

Wie sal toegang he tot jou mediese verslag? (Waar van toepassing)

Slegs die Hoof Ondersoekbeampte, en persone wat die informasie kollekteer, sal toegang tot die aangetekende informasie hê. Jou privaatheid en persoonlike informasie sal deur ‘n wagwoord beveiligde, persoonlike rekenaar en rugsteunflits met ‘n wagwoord, in ‘n toesluitbare kabinet, binne die kantoor van die hoof ondersoekbeampte bewaar word, wat gedurende die dag veilig is. Geen persoonlike identifikasies sal gedokumenteer word nie. ‘n Unieke kode sal aan jou toegeken word. Alle informasie ten opsigte van hierdie studie sal vir die doel gebruik word.

Wat sal gebeur by ‘n onwaarskynlike besering as ‘n direkte gevolg gedurende hierdie ondersoek?

Die genoemde studie hou geen risiko of nadelige gevolge vir jou in nie.

Sal jy betaling ontvang om aan hierdie studie deel te neem of is daar enige koste aan verbonde?

Geen betaling sal gemaak word om deel te neem en daar sal ook geen koste aan verbonde wees nie.

Is daar nog enige informasie wat jy sou benodig om te doen

Jy kan Mej. Maano Nelao Oletu Mika kontak by 061 – 203 3160 indien jy enige verdere vrae of probleme ondervind.

Jy kan die Sentrum vir Navorsing en Publikasies kontak by +264 61 206 3061; pclaassen@unam.na, indien jy enige beswaar en ontevredenheit ondervind wat nie behoorlik deur die ondersoekbeampte aangespreek is nie.

Jy sal ‘n afskrif en toestemmingsvorm van hierdie informasie ontvang.

APPENDIX E: Ouyelele wunasha nomapekaapeko (Oshiwambo version)

Oshipalanyole shoproyeka oyo tayi pekaapekwa: omapekaapeko o ndodo yo nghene omiti do uyehame hadi kwafele moku ninipika ouyehame konima yetando mosaala yovanhu ovo opo vadi koshitandelo moshipangelo shepangelo sha Central, moWindhoek, Namibia

Edina lo mupekaapeki: Ms. Maano Nelao Oletu Mika

Ondjukifi: Windhoek Central Hospital, Ooievaar Street, Windhoek North

Onhomola yongodi: 061 203 3160

Nefimaneko oto shivwa opo wu holole omadilaadilo oye momapekaapeko atumbulwa metetekelo. Oto indilwa nee wu kale wa manguluka moku shi ninga. Onghee osha fimana wu leshe nawa ouyelele awushe wa pewa omanga ino ninga omatokolo oku kufa ombinga. Ngeenge opena oshinima inashi yela, pula opo wu fatu lulilwe ove wu kale wa yelelwa nawa. Ehololo madilaadilo loye momapekaapeko oludi eli itali dengele, nowu na yo oufemba woku kala ino kufa ombinga sheli kolelela komaliudo oye. Omilandu adishe dopalutu oda wanifwapo ngaashi sha ufwa ko nghatu yopombada oyo hayi ifanwa (International Declaration of Helsinki and Namibian National Research Ethics). Omapekaapeko aa okwa kwashilipalekwa yoo kou Ministeli woundjolowele nonghalo nawa oshoyoo komukulunhu woshipangelo sha Central, Movenduka.

Omapekaapeko aa oku nasha nashike?

Omapekaapeko aa oku nasha noku konaakona nghene omiti do uyehame hadi kwafele moku ninipika ouyehame konima yetando mosaala yovanhu ovo opo vadi koshitandelo moshipangelo shepangelo sha Central, moWindhoek, Namibia. Ota a ka ningwa oule weemwedi nhatu. Omupangi ote ke ku pula wu tengeneke ondodo yo uyehame woye oikando ili itatu ta longifa oiyelekifo/oimetifo youwehame ili itatu ya yooloka eevili 24 konima yetando oshoyo eevili 48 konima yetando.

Momapekaapeko aa otamu ka yandjwa mbela omiti koonaku kufa ombinga?

Moku ninga omapekaapeko kwetu katuna elalakano lokupa ovakufi mbinga omiti. Ashike ngenge otwa didilike kutya wumwe womwaavo va kufa ombinga okuna ondodo youyehame uhapu, ohatu kaya meenghundafana nova pangi oshoyo oondokotola opo vemu shangele omiti doku ninipika ouyehame ngaashi shaufwa

konghatu yopaunhu. (International Declaration of Helsinki and Namibian National Research Ethics)

Omolwashike to shivwa ukufe ombinga?

Oto shivwa ukufe ombinga momapekaapeko aa, osheshi oove wumwe womwaavo va wanifapo omauyelele oo a pumbiwa moku ninga omapekaapeko etu. Hano wuna eedula 18 ilo di dulifepo nowu li yoo wa tambulwa mosaala yaavo tavayi ile vadja koshitandelo. Ino pumbwa oku mbadapala osheshi haave awuke, otamu kufa ombinga navakweni veli 75.

Owa teelelwa nana wu ninge shike onga omukufi mbinga momapekaapeko oludi eli?

Oshinakuwanifwa shoye onga omukufi mbinga momapekaapeko aa oku lombwela omupangi ondodo youyehame woye oikando itatu, osheshi otaku longifwa oimetifo youyehame ili itatu ya yoolokafana. Eshi otashi ka ningwa nee konima yefiku (eevili 24) oshoyo omafiku avali (48 hours) eshi wadja koshitandelo.

Omauwa oku kufa ombinga momapekaapeko aa owashike?

Ngee owa kufa ombinga momapekaapeko omu oto ningileko yo elao osheshi ngeenge ovapangi ova yeleke ondodo youyehame woye ndee tava mono kutya owuli mouyehame uhapu, oto ka pewa omiti doku ninipika ouyehame. Omapekaapeko aa otaa kwafele yo okunduluka omikalo dipe doku ninipika ouyehameko konima yetando monakuyiwa.

Oupyakadi washike handi keli hanga muwo ngee onda kufa ombinga momapekaapeko aa?

Oupyakadi wuli po oku piyaanekwa ashike kashona noku kala pamwe ino manguluka una to pulwa kovapangi.

Ngee onda tokola okukala inandi kufa ombinga momapekaapeko oludi eli ohandi ningwa shike?

Kuna eshi to ningwa, sho itashi imbi epango loye liye komesho.

Ngee onda kufa ombinga, oolyelye tava mono omishangwa douhaku wange?

Omishangwa douhaku woye otadi monika ashike komu pekapeki oshoyo ovapangi ovo tava yeleke ondodo youwehame woye. Moku ninga omapekaapeko kwetu itatu ka longifa omadina eni, nouyelele awushe owu tau ongelwa okudilila momapekaapeko aa otawu ka tulwa mokompiuta oyo hayi kala ya pata efimbo alishe. Omupekaapeki oye awuke hadulu oku mona oyelele owu. Ouyelele awushe owu twa ongelapo otau ka longifwa ashike moinima yinasha nelihongo.

Oto ningwa ngeipi ngee owa lemana omanga uli omukufi mbinga momapekaapeko aa?

Momapekaapeko aa kamu nasha shanyika oku lemaneka omunhu.

Ngeenge onda kufa ombinga momapekaapeko omu ohandi ka pewa ofuto yonhumba ile pamwe ndi keli hange handi pulwa ndi fute oimaliwa yasha?

Ahawe, ito pewa ofuto yasha, ove kuna yo efiku wu kelihange to pulwa ufute oshimaliwa shasha omanga wuli omukufi mbinga momapekaapeko aa.

Opuna sha mbela vali shimwe nda pumbwa oku shiva onga omukufimbinga momapekaapeko aa?

Kapu nasha vali shimwe sha wedwapo. Nongeenge owe keli hanga wuna epulo ilo oupyakadi washa omanga wuli onga omukufimbinga momapekaapeko aa, oto dulu oku dengela omupekaapeki ye mwene konhomola tayi shikula; Ms Maano Nelao Oletu Mika (061 203 3160).

Oto dulu yoo oku dengelela koshikandjo shomapekaapeko noinyangadalwa konhomola eyi; +264 061 2063061; ile u tume etumwalaka kondjukifi eyi ngee opena oupyakadi wonhumba omanga wuli omukufi mbinga momapekaapeko aa. pclaassen@unam.na

Oto ka pewa nee okopi yombapila omo muna youyelele wunasha nomapekaapeko aa oshoyo ombapila yoku ku pula epitikilo opo wu ninge omukufimbinga momakonaakono

KALULO E: LIKEPE LA LIÑUSA LABAITENGI (Silozi version)

TOHO YA PATISISO: Mayemo sakata a pabalelo ya butuku bobu tiswa kasamulaho wa kupazuliwa kwa bakuli babali mwa woodi ya lipazulelo mwa Sipatela sesituna sa Windhoek Central mwa Namibia.

MUBATISISI YO MUHULU: Mufumahali Maano Nelao Oletu Mika

KEYALA: Windhoek Central Hospital, Ooievaar Street, Windhoek North

NOMBOLO YAKWITUSISA: 061 203 3160

Nenitabela ku mi mema kuli munge kalulo mwapatisiso. Kikwabutokwa ahuli kuli munge nako yakubala litaba ze filwe fafasi fa, ili kuli muutwisise hande mutomo wa patisiso ye ni sesibatahala kwalineku lamina inge musikanga kale kalulo mwa patisiso ye. Mwa kona kubuza lipuzo ni kukupa tatuluso kuamana ni liñusa lelifilwe haiva kuna nize musautwisisi kabutungi. Buitengi bwamina mwapatisiso ye ki kakuya kabuitomboli bwamina hape mwakona kusiyela fahali kuba nikalulo mwa patisiso haiba inge muikutwa kuli hamusakona kuzwela pili ni patisiso ye. Mulemuswa kuli mwakalulo yapatisiso ye mihato ya International Declaration of Helsinki and Namibian National Research Ethics ikalatelelwa. Patisiso ye ihatisizwe katumelelano ni ba University of Namibia. Mane cwalo ni Balikolo la Makete ni Silelezo yasicaba. Bona ba Ministry of Health and Social Services Ethical Committee. Ni ka tumelelano ya yo muhulu wa sipatela se situna sa windhoek central ya Namibia.

Kana Patisiso ye kiyañi?

Patisiso yekiya ku batisisa mayemo a pabalelo ya butuku bo butisiwa ki kupazuliwa kwa bakuli baba lobalizwe mwa woodi yalipazulelo mwa sipatela sesituna sa Windhoek Central mwanako yalikweli zetaalu. Muoki ukana atatuba butungi kapa buima bwa butuku bwamina ka kusebelisa likala ze talu zabutuku. Ka lihola ze 24 ni 28 kasamulaho wakupazuliwa.

Kana kukaba ni tatuluso ya musebezi wa milyani yefiwa haiba inge kuba ni kalulo.

Patisiso ye haina kalulo yabutokwa bwa kufa liñusa leliama milyani. Kono nihaili cwalo mihato yaba, International Declaration of Helsinki and Namibian National Research Ethics ikalatelelwa mwapatisiso ye. Bakuli babakaba ni butuku bobutokwa kulilimaniswa ki milyani bakabe bafilwe milyani ya kulilimanisa butuku bobautwa, kakuya ka ba sikwata sa WHO kuamana ni mukwa wapabalelo yabutuku.

Kiñi hamu memilye kunga kalulo mwapatisiso ye?

Mu memilwe kuitenga mwakalulo ye kakuli muna nililimo za mutu ya hulile (lilimo ze 18 nikuisa kwahalimu) hape ne mubile mwakalulo yakupazulwa. Batu kaufela babakaitenga mwa kalulo ye kiba mashumi asupile kabaketalizoho (75).

Musebezi wamina kiufi mwapatisiso ye?

Musebezi wamina feela ikaba waku bulelela muoki kuli butuku bwamina buutwahala cwañi, imi butuku boo buka alulwa fa zikala zetalu za butuku (butuku mbicani, butuku ahulu, butuku kufiteleza). Patisiso yabutuku ika ezahala hasekufitile lihola ze 24 ni 28 kuzwa fa nako yakupazulwa kwamina.

Bunde bwa kuitenga mwapatisiso ki bufi?

Bunde bwakuba mwapatisiso kibwakuli mufuta wabutuku bwamina ukazibahazwa kumuoki kapa muwoki yomutuna yabizwa Dokota, mi mukafumana lituso zende za kulilimanisa butuku bwamina kwa Baoki kaputako. Pumano mwapatisiso ye ikatusa kumbweshefaza mayemo apabalelo yabutuku kwa bakuli babakataha mwa mulaho wamina. Kuzwafo likalabo zeka fiwa likatusa tatuluso ye katusa kundeefaza mibabalelo yaku fukuza butuku bwa bakuli babazwa mwalipazulelo.

Kana kukaba ni bumaswe bobukona kutiswa ka kuitenga mwa patisiso ye?

Bumaswe feela mwa patisiso ki bwa kuli, mukona kusaikutwa hande hamunze mubuzwa lipuzo kwa baoki kuamana ni butuku bomuutwa kalinako ze mukatatubiwanga.

Haiba inge muhana kuitenga mwa patisiso ye, kukaezahakañi kumina?

Ni hamusaitengi mwapatisiso hakuna kufukuza mayemo apabalelo yamakete amiba.

Kimani yalumelezwi kubona likalabo zemufile?

Likalabo zamina lika bonwa feela ki yomuhulu wababatisisi ni babaitengile kwakushimba likalabo zamina (muoki). Mayemo amina akapatiwa, kaufela zeamana ni patisiso zika bulukiwa mwa kompiyuta yekona ku kwalulwa feela kanombolo ye zibilwe feela kimubatisisi. Mabizo amina ana kubelekiswa mwapatisiso ye, muitomboli kaufela uka zibahazwa feela ka nombolo yeketilwe ki mubatissisi. Linombolo zeo lika cincana kakuya kamuitomboli, imi kaufela ze ama patisiso

zikabulukiwa kalinombolo zeo. Ze fumanwi mwapatisiso zikasebeliswa feela ki mubabatisisi.

Kukayezahalañi haiba inge kuba nikolofalo bakeñi sa kuitengaa mwa patisiso yeo?

Tomo ya patisiso yeo haina kubeya bupilo bwamina mwabutata kapa kutisa likolofalo.

Kana kukaba ni lituwelo kwa baitomboli kapa kukaba ni tifo yebatahala mutu haitenga mwapatisiso ye?

Hakuna lituwelo ze kafiwa hape hakuna tifo ye kabatahala kwa baitengi.

Kana kuna nizemwi zeniswanela kuziba kapa kueza?

Mukona kulizeza bo mufumahali Maano Nelao Oletu Mika fa nombolo ye: 061 203 3160 Haiba inge muba nilipuzo kapa kufitelwa kibutata kuamana ni patisiso ye.

Mukona ku lizeza Senta yalipatisiso ni lipatalazo (Centre for Research and Publications) fa nombolo ye: +264 061 2063061; pclaassen@unam.na haiba muna ni pilaelo yesika talelezwa ki mubatusisi.

Mukafumana pepa yaliñusa labaitengi ni pampili yemuswanela kusaina liswayo lamina, kuli mubuluke bupaki bwakunga kalulo mwa patisiso ye.

YI TJANGWA YO MU HAMENI MO. (Rukwangari version)

EDINA LYE LIRONGO: Nonkondo do ku tarera kukora po ku mana kutaghura vaveli, mo si pangero sa Ghurumende so sinene mo venduka.

MULIRONGO ESI SIRUGANA: Ms. Maano Nelao Mika

EVANGO: Sipangero saghurumende sosinene movenduka

Telefona: 061 203 3160

Ose kuna hara tumu zigide muyahamenemo me lirongo elitunakulironga. Mulyo Ghunene asi mu guse ruveze murese nawa eyi twa tjanga yipo muzuvilire nawa, sitambo selirongo esi tuna kurugana. Eyi muna ku dira kuzuvilira ku pura tupu efatururo. Kuhamena molirongo eli nyamweni tupu nsene mwahara. Nkenye apa nomu tokwera asi mwahara ku hage ka ku hamena melirongo eli. Sure Zonene za Namibia (UNAM), Ghurumende zo ghukanguki no yi pangero (Ministry Of Health and Social Services), mberewa zo mukondi go sipangero so sinene movenduka (Windhoek Central Hospital Superintends Office), nomberewa nadi nye edi twa tumbagura datu pulisire turugane elirongo eli. Melirongo omu tatu ka kwama nye no veta do International Declaration of Helsinki ntani no veta da Namibia National Research Ethics.

Eli elirongo lyo kuhamena sinke?

Melirongo omu, tatuka lironga no nkondo do ku tarerera kukora, makwedi gatatu (3months) kutunda po ku taghura muveli, mo sipangero so sinene sa Ghurumende mo Venduka (Windhoek Central Hospital).

Mu nersa Na guza, ntani Na tjanga mo buke ghunene wo kukora, naruganesa yiviha yoku kora yitatu po, novili no murongo mbali nane (24) hrs, no novili nomurongo ne Na ntantatu (48hrs) konyima zo ku mutaghura.

-Nsene poghuli Mutji, faturura yi rugana yo gogo mutji.

Elirongo eli kapi lya Kara no sitambo, soku gava mutji kova veli, Mara mo kurugana elirongo eli tatu ka kwama veta va tura po va , International Declaration Of Helsinki na Namibia National Research Ethics .Melirongo omu, va veli ava nava likida kukora ko hansako ntani kukora ghunene, kwaku va korangida va nwe no pera doku gusa po kukora, kukwama po si viha sa WHO .

Yisinke eyi vana mu zigidire mu hamene melirongo omu?

Ose kwamu zigida muhamene melirongo omu morwa one vaveli wova kurona wono

mvura kupitakana murongo na ntantatu. Vaveli wo kusika ko no murongo ntambali na ntano (75) nava hamenamo melirongo eli.

-yinke nayi kara yi rugana yeni melirongo omu?

Yi rugana yeni yelike yo ku tantera mu nersa asi kukora kokusika kupi muna kuzuva,ogu natu gusa kurugana yiviha yitatu, novili noro mbali nane (24hrs) ntani novili rone na ntantatu (48hrs) , konyima zokumu taghura.

Kuvura mugwaneko ghuwa me lirongo eli ndi?

Uwa nomuka gwanamo Melirongo eli, tatukadivanye ghunene wokukora oghu muna kuzuva, eyi nayika vatera ndokotora gweni a ghumu verure ghusimbu, Ntani yigwana natu gwana mo melirongo omu nayi katu vatera moku tarera kukora oku ava zuvu vaveli po ku mana kuva taghura.

-Yidona musinke ya karamo mo kuhamena melirongo eli?

Yidona yakaramo moku hamena melirongo omu, kuvura muka pire Kuli zuva nawa apa namu pura gera mapuro mu nersa.

Nsene kapi nomu pura ku hamena mo melirongo eli, nonzira dimwe musinke hena no mu kara nado?

Nsene no mu nyoka ku hamena namo melirongo eli, kapi nayika tjindja omu nava mu vatera kosi pangero

Yilye na vura kumona yitundwa yelirongo eli.

Mu lirongo esi sirugana go mu kondi ntani ava nava hamenamo mo ku gusa mbudi zo vaveli.mbudi nazinye ezi natu guza ngatu zi ruganensa tupu melirongo lyeli.kwato mbudi zo mu veli ezi natu tulika. Mbudi zeni nazinye ezi natu gusa, natuzitulika mo komputa, tu zi paterere.

Yinke nayi horoka nsene muveli na remana mukonda zo kuhamena melirongo eli?

Eli elirongo kapi Lina kara noyi ninke yoku remeka muntu,

Po ku mana ku hamena mo lirongo eli nava mu futa ndi? Ndi ku hamena

Melirongo eli nava mu futisa ndi?

Vaveli ava nava hamena melirongo eli, kapi nava va futisa ntani hena kapi nava va futa.

Poyili simpe yimwe mwa kona kudiva ndi mwakona kurugana.

a. Kuvura ku kotoghona ngodi za Ms Maano Nelao Oletu Mika po ngodi zo 0612033160 Nsene mwakara no mapuro ndi Nsene no muligwanekera no maudigu.

b. Kuvura ku toghona ngodi zo Centre for Research and Publication po +2640612063061; pclaassen@unam.com.na , nsene mwakara no mapuro ndi ghudigu kava dililire ku faturura nawa valirongi eli elirongo.

c. Nomu gwana mbudi zelirongo eli nazi nye, muzi tulike nawa