EVALUATION OF THE EFFECTIVENESS OF ORAL MORPHINE FOR PAIN CONTROL IN PATIENTS WITH CARCINOMA OF THE CERVIX AT OCEAN ROAD CANCER INSTITUTE

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MMed (Clinical Oncology) Dissertation

Muhimbili University of Health and Allied Sciences.

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By

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A dissertation submitted in Partial Fulfillment of the Requirements for the Degree of Masters of Medicine (Clinical Oncology) of the Muhimbili University of Health and Allied Sciences.

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May, 2014

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance of dissertation entitled **Evaluation of the effectiveness of oral morphine for pain control in patients with carcinoma of the cervix at Ocean Road Cancer Institute-**in a (partial) fulfillment of degree in MMED Clinical Oncology at Muhimbili University of Health and Allied Science

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Dr. K . Maunda

Supervisor

_____

Date

DECLARATION AND COPYRIGHT

I, **Dr. Hellen Robert Makwani,** declare that this **dissertation** is my own original work and that it has not been presented to any other university for a similar or any other degree award.

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To all who has contributed to my success and for all that I have achieved in my course of study, may the almighty GOD bless them all.

DEDICATION

To my parents, bothers and sisters, for the values they installed in me that continued to guide me in my life.

To my Husband for his love, hard working and support to our family.

To our children Maryanne Maxmillan and Millan Maxmillan for the joy they bring into our life.

ABSTRACT

Morphine is a drug which is grouped in the category of opioids. There are several forms of morphine one being in liquid form which is taken orally. It is used to relieve moderate to severe pain that does not respond to non opioids specifically the NSAID's. However morphine is highly addictive once used incorrectly can lead into side effects such as constipation, drowsiness, abdominal cramps, excessive sweating and even weight loss.

Objective

The objective of this study is mainly to investigate the effectiveness of oral morphine in the control of pain in cancer patients specifically patients with carcinoma of the cervix who form the majority of patients attended at ORCI. Also to assess the level of pain of the majority of patients seen at ORCI and the most common side effects of morphine that the patients experience. This will lead to the relationship between level of pain, morphine dosage and the side effects encountered.

Methodology

The study was conducted at ORCI which is located along Indian Ocean. It is a teaching and referral Hospital and approximately 230 staffs are enrolled. Approximately 5500 cancer patients visit our hospital per year.

This is a prospective hospital based cohort study which has been conducted for three months focusing on the patients response to morphine specifically patients who have not shown response to NSAID's. The patients with carcinoma of the cervix who have been assessed for pain before treatment have been included in the study and whole patients with other gynaecological malignancies and cancer of the cervix patients who have started radiation or chemotherapy have been excluded from the study. Dose titrations after careful pain assessment have been performed as to keep patients free from pain.

Data was collected by using structured questionnaires and then analyzed by SPSS version 21 software. The total budget for the study was Tshs 1,560,000.

Findings

The research findings among 93 patients investigated (36.6%) were observed to be of age group 50-59 as the majority. (62.4%) were of primary education and among the group (72%) were married and the leading zone was Lake zone covering (27%).The disease stage IIB were mostly seen with (50.5%) of the total studied group.

Before morphine administration (54.8%) had moderate pain covering more than half of the population. After morphine administration (80.6%) had no further pain. The commonest side effect was constipation (69.6%), drowsiness (48.9%) and sweating (27.7%)

Discussion

The above findings are consistent with several studies done worldwide that supports that morphine is effective in control of pain and should be titrated according to patients responsiveness to pain (21,25,30).The study further shows that reducing morphine does not have significance in constipation as it may be caused by other factors like locally advanced disease to the pelvis example rectal involvement.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
AJCC	American Joint Committee on Cancer
CNS	Central Nervous System
FIGO	International Federation of Obstetrics and Gynecology
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
STI,s	Sexually Transmitted Infections
UICC	Union Against Cancer
WHO	World Health Organization
ORCI	Ocean Road Cancer Institute
NSAID's	Non Steroid Antinflammatory Drugs
MUHAS	Muhimbili University of Health and Allied Sciences

CHAPTER ONE

BACKGROUND TO THE RESEARCH PROBLEM

1.0 INTRODUCTION

Pain is how the brain interprets information of stimuli from a certain part of the body, through an impulse that is sent through the nerve pathways to the brain. There are two types of pain, acute and chronic pain; the former being of short duration including pain of acute injuries, post traumatic pain and the later being pain signifying an ongoing condition like back pain and cancer pain.(1)

About half of all patients with malignant cancer experience chronic pain that diminishes their quality of life specifically in end stage of the illness. This pain can be effectively controlled in 80 to 90 percent of cases using WHO treatment guidelines for pain control Worldwide there are 10 million new cases of cancer and 6 million deaths per year. WHO published first cancer pain relief in 1986 and designed a ladder of which would be useful. As seen in the Irish study to be effective to date (2). The pain of malignancy can be managed differently; mild to moderate pain with non opioids and moderate to severe pain with opioids together with antidepressants. Steriods may be added in cases of swelling or edema. Pain can also be managed by psychological means, massaging, radiation therapy and surgically by the removal of nerves and/or tumor that compresses the nerves (3).

WHO advices to start with non opioids to the maximum recommended dose before opioids are initiated. Opioids are used in a step ladder fashion starting with weak ones like hydrocodone with acetaminophen and then proceeding to the strong opioids like morphine in combination with antidepressants whenever needed. Pain management needs an interdisciplinary approach with a palliative care team and should be individualized according to pain tolerance of the individual patient (4, 5)

1.0.1 PAIN ASSESSMENT

A complete history and a thorough physical examination was perfomed, with emphasis to location, intensity, radiation, aggravating factors, timing and quality of pain.Most patients were assesed and almost all complained of lower abdominal pain radiating at the back and perineum.A pain scale which measures a patient's pain intensity based on self-report, observational or physiological data was established. Pain scale which was used is visual analog scale by using five fingers which is a five point scale. 0 - no pain at all, 1 mild pain, 2 moderate pain,3 severe pain,4 very severe pain and 5 overwhelming pain.. Patients were asked to point the finger which is thought to be compared with the pain they experience. Pain was graded and effective dosage prescribed.(7)

1.0.2 CARCINOMA OF THE CERVIX

Carcinoma of the cervix is the third most commonly diagnosed cancer and fourth leading cause of cancer death in females worldwide, accounting for 9% (529,800) of the total new cancer cases and 8% (275, 100) of the total cancer deaths among female in 2008. More than 86% of these cases and deaths occur in developing countries, representing 13% of female cancers (8). Histological, 80% are squamous cell carcinomas and 20% are adenocarcinoma (9).

The most common presenting early stage symptoms are foul-smelling vaginal discharge and abnormal vaginal bleeding, including postcoital bleeding, intermenstrual bleeding, or postmenopausal bleeding(10). FIGO, in collaboration with the World Health Organization (WHO), and TNM system of the International Union Against Cancer (UICC) and the American Joint Committee On Cancer (AJCC) is used for staging of the disease depending on the extent of the disease whereby stage one disease is confined to the cervix, stage two the tumor extends to the pelvic wall with involvement of upper one third of vagina ,stage three where lower two third of vagina is involved and sometimes the kidney involvement resulting into hydronephrosis or non functioning kidneys and stage four beyond the true pelvis to involve the rectum and distant organs(11. There are several risk factors associated with carcinoma of the cervix including having many sexual partners, early sexual activities before

18 years, having sexually transmitted diseases (STIs) such as Chlamydia, HIV and syphilis together with a weak immune system and cigarette smoking(2).

1.0.3 How Does Pain in Cancer of Cervix Patients Occur

Pain in carcinoma of the cervix patients is due to locally advanced disease that has invaded the nearby tissues with invasion of the nerves, local pressure to the pelvic organs and metastasis to bones particularly pelvic bones and rarely the long bones bones(13,14). Arterial occlusion, specifically of iliac arteries and that of lymphatic channels result in painful non pitting edema of the lower limbs .(15) Radiotherapy has also been implicated in causing radionecrosis resulting into fracture of the bones.

1.0.4 What is Morphine?

Morphine was named by a British doctor in 1898. Is an opiate analgesic psychoactive drug and is considered to be the prototypical opioid, used to relieve severe or agonizing pain and suffering by acting directly on the (CNS). However, it is highly addictive and its abuse has been reported. A study conducted by Japanese researchers who injected morphine into mice concluded that 10mg of morphine, twice a day for as little as five days, exhibited drug withdrawal symptoms. Despite its addiction and withdrawal symptoms today morphine is a popular powerful drug in control of cancer pain.

There are some uncommon side effects encountered when taking oral morphine such as abdominal or stomach pain, blurred vision, itching and numbness with pricking sensations, colour blindness especially yellow and blue, chest discomfort, confusion, cough, decrease urination, dizziness, headache, increased sweating, loss of appetite, nausea and vomiting, sweating and chills, and sometimes wheezing and constipation. In case of drug overdose constricted, pinpoint or small pupils, decrease responsiveness, fever, increased blood pressure, thirst, muscle spasms, and weight gain. Common side effects are cramps, constipation, drowsiness, excessive sweating and weight loss(16).

1.2 LITERATURE REVIEW

In a study done by Lawne Park et al, who reviewed several studies on the side effects of morphine despite its analgesic effect, the commonest side effect was constipation and minor transient sedation which are tolerable (17). Its effectiveness outweighed the side effects and has therefore recommended that patients should be counselled on its benefits than the side effects.

Another study done in China compared transdermal fentanyl with oral morphine in treatment of cancer pain where a cohort of 32 studies with 2651 patients were included; the remission rate between fentanyl and oral morphine was 86.6% and 88.31% and oral morphine was found to have less side effects compared to transdermal fentanyl. Out of 32 cohort studies, 6 supported that transdermal fentanyl improved quality of life of the patients. In conclusion both were found to have the same efficacy with the former having less side effects and better quality of life (18).

In another study aimed at those who responded to morphine and those who did not respond, it was revealed that those who responded to oral morphine had high plasma concentration of oral morphine and were the ones who suffered adverse effects; implying that adverse effects are associated with high plasma concentrations which indicates the effectiveness of oral morphine in relation to plasma level (19, 20).

The efficacy of oral morphine versus the intravenous form was compared in study by Rana et al whereby 62 patients with end stage cancer. It was fond that intravenous was superior to oral form of morphine for immediate pain relief despite of its superiority it is recommended within 24 hours and substituted with oral morphine to avoid unnecessary side effects .

It is seen that in the management of a patient with cancer pain there is no standard dose to be prescribed, dosage should be titrated to patients with less side effects and review patients within 24 to 36 hours, though the compliance in some patients is very poor that requires supervision and bearing in mind that neuropathic pain and sometimes bone pain do not

respond to morphine .Carefully pain evaluation with investigations should be performed so as to avoid unnecessary overdosage (21).

To show the evidence that oral morphine is the first choice for moderate to severe pain randomized clinical trial with its side effects was done and still morphine is the choice in management of moderate to severe pain. As it was conducted in Uganda in 1993 which aimed at showing the evidence that oral morphine is the first choice despite other forms were given as a substitute, it was fond other forms of morphine to be very expensive compared to oral morphine that it is non affordable in developing countries(22).

Another study was done in India and education to care givers was given specifically the doctors and nurses before morphine was administerecvh b/'-d. The study showed that only 50% of the patients achieved adequate pain relief and after education was given on how to prescribe morphine 80% was effective and the study concluded that educating the health workers has an impact on correct prescription to patients. Careful titration of doses is necessary for the effective control of pain (23).

A study which was done in Italy in 2006 by G Apolone et al aimed on the evaluation of patterns and quality of pain care in cancer patients, it used a standard measure of pain management index which compared the most potent anaelgesics prescribed on cancer patients, history was taken before and after usage of the anaelgesics, the outcome measures were the pain characteristics and this was a cross sectional study design. WHO level III opioids were prescribed among which was oral morphine. Only 53% used morphine correctly and the rest did not. The conclusion of the study was palliative care education is needed so as to improve the patients standard of life (24).

Another study was done in Korea by Howard et al in 2008 and during that time 12 million people were diagnosed with cancer per year and 7.6 million deaths occurred of which 75-90% had metastatic disease. It aimed on finding the effectiveness of oral morphine on patients with metastatic disease .T he findings were NSAID's and steroids had better outcomes with bone

metastasis than oral morphine and the conclusion was that opioids specifically oral morphine do not cause relief on bone pain (25).

Another study which was done by Robert N et al airmed on gender aspect on the use of opioids. The study showed that both men and women demonstrated similar degrees of drug related behaviours, though it was thought due to women emotion, more side effects could be developed due to morphine misuse (26).

The study which was conducted in Israel by Freud T et al considered opioids specifically morphine as a corner stone of cancer pain relief, it assessed opioids use for the period of six years from 2001 to 2006 among cancer patients who were under Clait Health Services in Israel, during the study the purchase of morphine in 2001 was only 7.5% and from 2002 to 2006 the purchase increased dramatically to 9.9%.It concluded that pain is more at the late stage of life in cancer patients and that was the reason of increase in morphine purchase and morphine helps in improving the standard of life because the patients who used morphine only once died earlier than those who used it regularly(27).

Also a study done by Merchadante S et al aimed on presenting how opioids are effective in palliative care unit, it recruited home palliative care programmes, Oncology department, hospitals and emergency units. Basic information of patients on admission and during discharge was recorded. The study concluded that patients use more morphine on discharge than in hospitals which attracts education to patients on correct use of morphine so as to prevent the side effects. Carefully monitoring is needed (28).

Another study which was done in French by the African Pediatric Oncology group which contributed to good prognosis of pediatric cancers in Africa mainly the Sub Saharan Africa.It used questionnaire to both doctors and nurses, among all who were questioned only 6 physicians had received a specific training. They used morphine which was available in 5 and 8 pilot units, among the cancer patients, 62.5% used it incorrectly due to poor knowledge and among the group 50% had developed the side effects though the majority had pain at diagnosis and at relapse but pain was controlled during discharge. The study showed that oral morphine

is effective in control of cancer pain, but careful titration is required so as to prevent the side effects (29).

The study which was done in UK by the national collating Center for cancer by the department of health in 2008 focused on the WHO pain ladder aimed on correctly use of opioids specifically oral morphine so as to reduce dosing errors and care during the last days of life. It concluded that correctly titration of morphine is essential for the well being of cancer patients so as to improve the standard of life (30).

1.3 PROBLEM STATEMENT

There is inadequate access to treatment for terminal ill patients suffering from chronic severe pain and this should be taken as a serious health problem requiring access to management of chronic diseases such as cancer of the cervix. This is supported by a study that was done in French in 1986, WHO guidelines recommended that in 50% of the cancer patients morphine insufficiently controls pain (31).

There are major deficits in knowledge of health care professionals regarding the mechanisms of pain and its management. Chronic pain is highly stigmatized in the society and most countries have no national policy regarding the management of pain as a health problem, including an inadequate level of research and education. Pain Medicine is not recognized as a distinct specialty with a unique body of knowledge and defined scope of practice founded on research and comprehensive training programs. WHO estimates that 5 billion people live in countries with low or no access to controlled medicines and have no or insufficient access to treatment for chronic pain.

There are severe restrictions on the availability of opioids and other essential medications, critical to the management of pain. This leads to unnecessary sufferings of the patients with chronic pains who are then stigmatized in their societies they live. However there was a study which was done in rural Uganda, Kenya and Malawi which recruited 33 patients, 27 family cares, 36 staffs and 29 leaders, and the observation of 12 patients in a palliative unit was performed and it concluded that palliative care can be delivered effectively but in order to achieve it effectively public health support is required (32).

At ORCI pain is the main cause of morbidity and mortality in most of our cancer patients. The challenge is how we asses pain before we prescribe morphine and it should be taken at individual bases without relying on the stage of the disease. The patients are instructed to keep their medicine by themselves after every four hours, Most of them are illiterate that they can't instruct themselves correctly as it is required and this should be corrected to avoid unnecessary complications. The system should be changed and morphine should be taken under nurses instruction, clinicians should perform thorough pain assessment regardless of the

stage of the disease. Not only that but also some of the patients do fear the side effects and hesitate using morphine as prescribed. Majority of them think that constipation is caused by taking oral morphine but is not always the case because sometimes may be due to advanced disease and infiltration of rectal mucosa.

Lack of knowledge about morphine as a drug that relieves patients sufferings is essential with correct prescription, correct usage and its side effects attracts me to conduct this study at ORCI. There has been no systematic study at ORCI that evaluated the use of oral morphine in controlling pain specifically in carcinoma of the cervix patients.

1.4 JUSTIFICATION OF THE STUDY AND RATIONALE

In developing countries such as Tanzania, strategies to improve morphine prescription are essential as what challenges us is how to assess pain and at what concentration the patient can respond to pain. Previously we used to prescribe morphine 5mg concentration in 5mls four hourly and 10mg during the night. The challenge is, pain is very difficult to tolerate once the plasma level is reduced or declined at all within those four hours. Automatically the patient wakes up, saying that 10mg should be given during the night is absolutely wrong and ideally the therapeutic window declines after every four hours. So morphine should be prescribed 4hourly in 24 hours.

Another challenge is how to get an appropriate therapeutic window that maximizes pain control with our patients with less side effects. In our setting we concentrate only on improving quality of life by pain reduction without seeing at what concentration do our patients respond well, we usually assume that all the patients can control their pain by 5mg in 5mls concentration without reviewing the concentrations according to the patients response.

There was no scientific research that was done at **ORCI** to evaluate how morphine is effective in control of pain in carcinoma of the cervix patients. This study looked on the effectiveness of oral morphine in pain control in the patients with carcinoma of the cervix with the common side effects encountered with the patient. All the patients were started on a baseline of 2.5mg concentration increasing the concentration to see how each patient responded to the respective concentration . Absence of research studies and information on pain assessment and morphine prescription according to patients' pain level attracted a need to conduct this kind of study, which later will attract other studies on different types of malignancy that will improve the quality of life to our cancer patients.

This will depend on the type of cancer with minimal side effects, with good adherence and finally will result into good prognosis.

1.5 OBJECTIVES OF THE STUDY

1.5.1 BROAD OBJECTIVE

To determine the effectiveness of oral morphine in pain control in carcinoma of the cervix patients diagnosed at ORCI from January to March 2014 and its side effects.

1.5.2 SPECIFIC OBJECTIVES

i. To determine the social demographic characteristics and disease profile among carcinoma of the cervix patients.
ii. To determine the level of pain experienced by the patients with carcinoma of the cervix at ORCI before the start of morphine and after the treatment.
iii. To determine the effectiveness of oral morphine in controlling level of pain among patients with carcinoma of the cervix at ORCI.
iv. To determine the side effects of morphine.
v. To determine the relationship between dose of morphine and the side effects among carcinoma of the cervix patients.

1.6 HYPOTHESIS

Null hypothesis: morphine is not effective in the control of pain among cancer of the cervix patients.

Alternative hypothesis: morphine is effective in the control of pain among cancer of the cervix patients.

CHAPTER TWO

2.0 METHODOLOGY

2.1 STUDY AREA / STUDY POPULATION

The study was conducted at ORCI and was based on the carcinoma of the cervix patients who were referred at our institute before they commenced treatment. I chose the group because these are the leading group of patients we see at our center. ORCI is a National cancer Hospital having approximately 230 staffs and the Hospital enrolls approximately 6000 patients per year. It is also a research and teaching Hospital.

2.2 STUDY DESIGN

This was a hospital based cross sectional study design. It enrolled the patients with carcinoma of the cervix who were referred at ORCI after confirmed biopsy results as inpatients or outpatients from January to March.

2.3 SAMPLE SIZE ESTIMATION

$$N=\frac{Z^2P\,(100-P)}{\varepsilon^2}$$

Where n=minimum sample size

Z=point estimate corresponding to 95% CI which is 1.96

P=proportion of systematic improvement of moderate to severe pain at 30%

ε=margin of error (5%)

Sample size was calculated based on the estimated prevalence of symptomatic improvement rate of moderate to severe pain by oral morphine by 0.8 and 0.5 respectively among patients with cancer of the cervix, by using the double sided test, P=0.05 and power of 80% a sample

size of 79 patients was required. The sample size was increased to 100 in order to take into consideration the drop outs.

2.4.1 INCLUSION CRITERIA

Patients with carcinoma of the cervix who were assessed for pain in the wards and outpatients and did not respond to NSAIDS referred to ORCI from January to March 2014.

2.4.2 EXCLUSION CRITERIA

Patients with other gynaecological malignant tumors and those who responded to other forms of anaelgesics specifically NSAIDs.

2.5 SAMPLING TECHNIQUE

Patients with carcinoma of the cervix who were knewly diagnosed as outpatients and those who were in the wards from January 2014 to March 2014.

2.6 DATA COLLECTION

All patients who fulfilled the inclusion criteria were assessed. This was achieved by assessing those who did not respond to NSAIDs, assessment was done by a visual analog scale by using five fingers being a popular method used at ORCI. This is a subjective means of pain assessment as the patient is asked to grade the pain experienced. Morphine was then prescribed at the initial dose of 2.5mg, and then assessed after three days, those who did not respond dosage was increased to5mg and finally to7.5mg. All the required information were recorded in a standardized structured questionnaire designed for the study. Demographic characteristics such as age, residence and occupation were recorded together with the risk factors together with the stage, of the disease..Dosage prescription in timing and concentration was observed closely to analyze at what concentration did the patient responded well to pain so as to ensure that the patients are pain free.

2.7 DATA ANALYSIS / IMPLEMENTATION PLAN

The data analysis was done using the SPSS version 21 for windows. Analysis focused on the evaluation of the effectiveness of morphine in pain control in carcinoma of the cervix patients, at what concentration did the patients became pain free and had improved quality of life.

Socio-Demographic characteristics such as age, tribe, religion and the stage of the disease were summarized using frequency distribution and cross tabulation tables. Chi-square test was used to assess association between effectiveness of morphine in pain control in carcinoma of the cervix patients in relation to dosage and concentration before and after consumption of morphine.

2.8 ETHICAL CLEARANCE

Ethical clearance to conduct the study was obtained from MUHAS Ethical Committee and ORCI. Consent forms, confidentiality and deletion of names was done during study analysis. The patients who refused to be taken as part of the study were also treated and were not neglected. Care was the same between those who entered the study and those who refused to be part of the study. This was achieved by patients' interview after pains have been assessed effectively from January to March 2014.

CHAPTER THREE

3.0 RESULT

FINDINGS ANALYSIS

TABLE 1: SOCIAL DEMOGRAPHIC CHARACTERISTICS AMONG CARCINOMA OF THE CERVIX PATIENTS (N=93)

Characteristics		Frequency (n)	Percent (%)
Age (years)	Less than 40	9	9.7
	40 to 49	30	32.3
	50 to 59	34	36.6
	60 to 69	17	18.7
	More than 69	3	3.2
Education level	No formal education	35	37.6
	Primary school	58	62.4
Marital status	Single	8	8.6
	Married	67	72
	Divorced	6	6.5
	Widowed	12	12.9
Religion	Christian	55	59.1
	Muslims	38	40.9
Occupation	Housewife	27	29
	Farmer	55	59.1
	Self employed	9	9.7
	Employed	2	2.2
Number of children	Less than 4	9	9.7
	5 to 8	44	47.3
	9 to 12	20	21.5
	13 to 16	20	21.5

With respect to this research on investigating the effectiveness of oral morphine in the control of pain in cancer patients, a total of 93 patients participated in this study. Most (36.6%) were observed to be of age between 50-59 years. On the aspect of religion, 59.1% of the patients were Christians. From the study findings, in assessing education level, most of the patients had only primary education (62.4%). Majorities (72%) of the patients reported that to be married; this was represented by 72% of the respondents whereas 12.9% of the respondents were widows. With regards to occupation, More than half of them reported to be farmers, with less than 10% being self-employed. Moreover about 47.3% reported to had 5 to 8 children. Background characteristics are shown on table1 above.

Table 2: Frequency distribution table showing Residence of cervical cancer by zone

Zone	**Region**	**Frequency (n)**	**Percent (%)**
Coast and Dar-es-salaam	Dar-es-salaam	5	5.4
	Coast region	6	6.5
Total		**11**	**11.9**
Northern	Tanga	7	7.5
	Arusha	2	2.2
	Kilimanjaro	3	3.2
Total		**12**	**12.9**
Southern			
	Rukwa	3	3.2
	Iringa	1	1.1
	Mbeya	2	2.2
	Mtwara	4	4.3
	Ruvuma	3	3.2
Total		**13**	**14.0**
Lake	Shinyanga	16	17.2
	Mwanza	12	12.9
	Mara	6	6.9
Total		**34**	**27.0**
Central			
	Dodoma	9	9.7
	Singida	2	2.2
	Morogoro	6	6.5
Total		**17**	**18.4**
West			
	Kigoma	1	1.1
	Tabora	**5**	**5.4**
Total		**6**	**6.5**

Most of the patients are coming from the lake zone (27%) with Shinyanga being the most of other regions. Shinyanga and Mwanza have high prevalence of carcinoma of the cervix. Of all zones of stay, the western zone (Kigoma and Tabora) had the least number of patients presenting with cervical cancer at ORCI. The information is summarized on table 2 above.

Disease Profile

It was found out that most of the patients who were seen had developed some symptoms specifically those with stage 11B; it was followed by the stage 11A, then 111A, 111B, 1B and 1VA. With respect to the findings it was revealed that 50.5% of the respondents were diagnosed when the disease was stage 11B, 18.3% diseases stage 11A, 17.2% disease stage of 111A, 6.5% disease stage of 111B, 5.4% of the respondents' disease stage of 1B and 2.2% disease stage of 1A. Bar graph below shows the comparison.

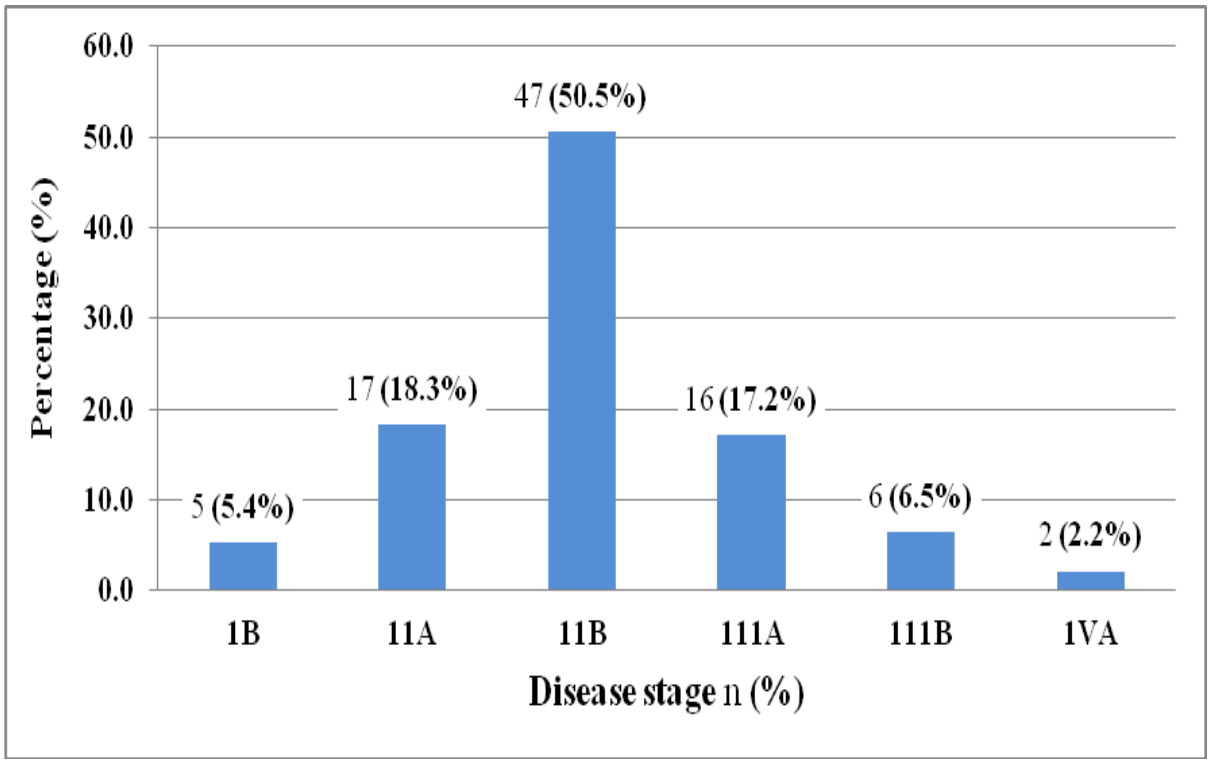


Figure1: Bar graph showing disease stage among cervical cancer patients n (%)

Level of pain before and after treatment with morphine

Before treatment with Morphine, About half of studied population had presented with Moderate pain (54.8%), twenty percent had severe pain, whereas Very severe pain and Overwhelming pain accounted for 11.8% and 12.9% respectively. None of the patients presented with either Mild pain or pain with no relief. However on comparison with level of pain after treatment, study findings shows that, most (80.6%) presented with no further pain post treatment with morphine. Less than 10% had mild pain and only one patient had moderate pain. However eight patients (8.6%) had presented with persistent pain with no relief. From these findings it suggests that Treatment with morphine offers best outcome of alleviating pain among patients with carcinoma of the cervix. Presentation of pain with no relief even after treatment could suggest disease advancement as all patients were in stage carcinoma of the cervix 111A to stage IV. Table 3 below shows the comparison.

Table 3: Comparison of level of pain perceived by patients before and after use of morphine (n=93)

Level of pain	Before treatment		After treatment	
	n	%	n	%
No pain	-	-	75	80.6
Mild pain	-	-	9	9.7
Moderate pain	51	54.8	1	1.1
Severe pain	19	20.4	-	-
Very severe pain	11	11.8	-	-
Overwhelming pain	12	12.9	-	-
No relief	-	-	8	8.6

Dosage of Morphine prescribed

Distribution of dosage of morphine prescribed to patients is shown of the pie chart below. Most of treated patients (71%) had been prescribed with lower dose of morphine (2.5mls) compared to other study participants however very few treated patients had a dose of 7.5mls of morphine. Findings also show that 7.5 mls of morphine was prescribed only to 6 patients who had overwhelming pain. Further analysis indicated that six patients who had been prescribed with 7.5 mls of morphine were in advanced stage of cervical cancer (stage IIIA, IIIB and IV) however in assessing the level of pain after treatment, about half (3 patients) presented with pain of no relief and other half had mild pain. It's clear that high dose of morphine don't offer and absolute better outcome in pain management among patients with advanced stage of cervical cancer.

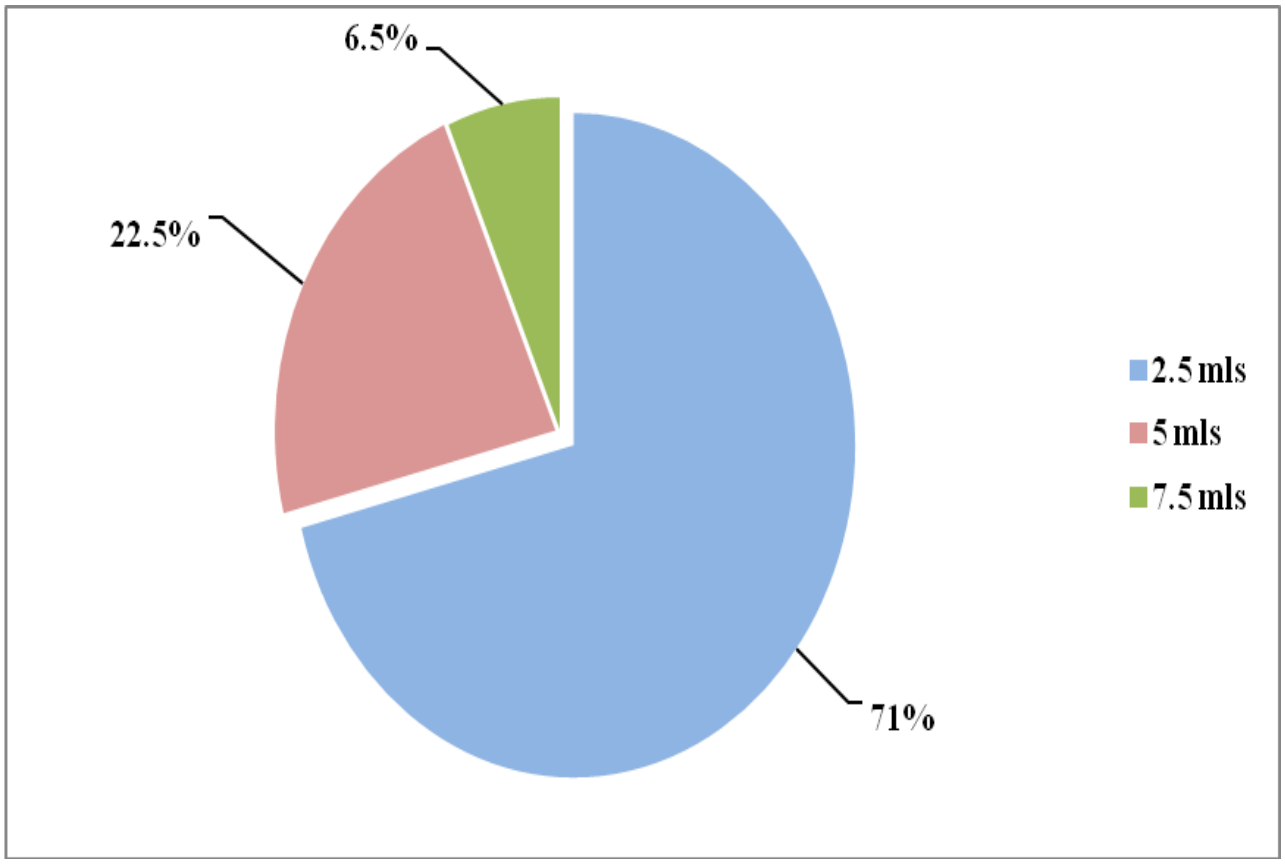


Figure 2: Pie chart showing Morphine dosage prescription

Morphine side effects

Analysed side effects of morphine have indicated that constipation was the commonest (69.6%) of all. One third of studied carcinoma of the cervix patients presented with excessive sweating after the use of morphine whereas 48.9% had experienced drowsiness. Further analysis was carried out to investigate the effects of high dose of morphine used with the increase in side effects. For the case of constipation, study findings suggest that there is increase in proportion of patients with constipation within comparing patients who had received 2.5mls of morphine (63.1%) and those who had received 5mls of morphine (85.7%). On the other hand patients who had received 7.5mls of morphine, 83.3% had constipation. The observed proportion is higher compare to those who had received lowest dose (2.5mls) but a bit lower compared to patients treated with 7.5mls. The observed difference was not statistically significant ($p = 0.089$).

Table 4: Distribution of side effects of morphine with dosage of morphine used

	Amount of morphine				
Complications	**2.5 mls**	**5 mls**	**7.5 mls**	***p*- value**	**Total**
Constipation					
Yes	41 (63.1)	18 (85.7)	5 (83.3)		**64 (69.6)**
No	24 (36.9)	3 (14.3)	1 (16.7)	0.089	**28 (30.4)**
Excessive sweating					
Yes	18 (27.7)	10 (47.6)	3 (50)		**31 (33.7)**
No	47 (72.3)	11 (52.4)	3 (50)	0.125	**61 (66.3)**
Drowsiness					
Yes	25 (39.7)	14 (66.7)	5 (83.3)		**44 (48.9)**
No	38 (60.3)	7 (33.3)	1 (16.7)	0.018	**46 (51.1)**
Total	**65 (71)**	**21 (22.6)**	**6 (6.5)**		**93 (100)**

Excessive sweating

The effect of dosage of morphine on excessive sweating was also studied. Less than one third (27.7%) of all patients treated with 2.5mls of morphine experienced excessive sweating. On the other hand, those who received 5 mls had higher proportion (47.6%) of patients who experienced excessive sweating compared to the previous group. About half of patients treated with 7.5 mls of morphine had excessive sweating which is nearly twice the proportion of those who had received the lowest dose (2.5%) but a bit higher compared to patients received 5mls of morphine. There is a steady increase of proportion of patients who experienced excessive sweating as a side effect with increase in dose of morphine used however the observed difference is not statistically significant ($p = 0.125$).

Drowsiness

Drowsiness was experienced in about 48.9% of all patients treated with morphine. About 39.7% of those received 2.5mls of morphine had experienced drowsiness, whereas 66.7% of those received 5mls of morphine developed drowsiness and more than three quarter of patients treated with 7.5 mls of morphine experienced drowsiness. These results suggest the significant increase in proportion of patients with drowsiness with increase in dosage of morphine used. The observed difference was found to be statistically significant ($p = 0.018$).

CHAPTER FOUR

4.0 DISSCUSSION

This chapter presents the study findings based on ninety three (93) patients at ORCI who participated as respondents. The study aimed at 100 patients of which seven (7) patients did not turn up. The chapter further provides the discussion on the findings in relation to the research objectives. The study aimed mainly at investigating the effectiveness of oral morphine in the control of pain in cancer patients specifically patients with carcinoma of the cervix who form the majority of patients, an attempt has thus been made among others to determine the effectiveness of oral morphine in controlling level of pain among patients with carcinoma of the cervix at ORCI and to determine the side effects of morphine. The socio-demographic data were assessed separately, age being one of them. From these findings it can be viewed that most of the elderly women have carcinoma of cervix patients this is because among the ninety three (93) patients, 87.09% of these respondents were of age between 40-69 years while only approximately 13% of the patients were of age between 30-39 and above 70 years.

This finding is consistent with other studies done worldwide as it was seen in the study (12) of American college of obstetricians and gynaecologysts which explained that inorder to acquire cervical cancer a patient should be sexually active and this is regarded as earlier exposure to sex though the outcomes can be seen later in life. From this study I can see the assosciation with the age above 50 years of and lesser were found below 50 years of age following the incubation period of HPV. Level of education in our set up has been considered as majority seen had low level of education because according to this research there were no patients who had above secondary school education. There might be some relationship between the spread of this disease and the general level of awareness obtained and experienced through education. (Table 1) The level of education may have significant relationship with the presence of carcinoma of cervix in the society.

As it has also been seen that Carcinoma of cervix seems to be in most individuals who are married. There is a relationship between being in marriage and the prevalence of this disease. However it has been seen that most of the patients are not formally employed, This is represented with 59.1% being farmers and 29% being housewives and the rest 9.7% being either self employed or employed. This reflects their education background and thus their level of awareness on various issues.

This is consisten with the study (33) which studied the impact of the socio demographic factors,115 patients were enrolled. Near 72% presented late while 28.04% with early disease. Chi square test revealed (P=0.01),(0.001),(0.0001)being low monthly income, unsatisfactory hygiene and low education respectively.

Patients with fewer number of children had less chance of obtaining carcinoma of cervix because only 9.7% of the reported cases had the number of children between 0-4.This was consistent with a study done in Jamaica by Catherine H et al (34) which explained low birth intervals is associated with higher exposure of HPV and the findings were statistically significant with(P=0.001).

With respect to disease profile, the findings revealed that 50.5% of the respondents seek medical attention when the symptoms show up mostly when the disease was at stage 11B showing that most patients seek medical attention after the symptoms show up as explained with D et al(33).

Dose prescription was done to whole patients with the baseline of 2.5mls of morphine and after careful pain assessment the dose was increased to 5mls and the highest being 7.5mls depending on response of morphine to pain and it was irrespective of the stage of the disease as pain is subjective and pain tolerance differs. It was noted that also some of the patients who had advanced disease responded to 2.5mls of morphine. This was consistent with the studies (21, 25,30) which explains that supervision and pain assessment is essential when prescribing morphine adequately. Some did not even respond to 7.5mls of morphine and were found to have advanced disease whereby it was noted that those patients had locally advanced disease which might involve the pelvic bone. Howard et al (25) explains that morphine does not relief

bone pain and thus should be treated with NSAIDs with steroids. Taking into account that pain is subjective and should be titrated to the level required starting with little amount.
Before the use of morphine patients had moderate to severe pain in one way or another and after the use of Morphine it was found out that most of the patients experienced no further pain. This was almost proved by 80.6% of the patients. This is evidenced with the study (23) by Barath B et al. Apart from that, nine point seven percent (9.7%) of the respondents claimed to have mild pain whereas 8.6% of the respondents had no relief and only 1.1% had moderate pain. Those who had not responded to morphine were regarded as patients who had locally advanced disease involving the pelvis and further pelvic x ray should be done to confirm as morphine does not relieve pain in bones.

Of all the side effects studied constipation was the main one despite the reduction of amount of morphine, reducing the amount does not have significance on constipation. This is also observed in our study whereby majority of the patients 69.9% experienced this side effect despite the reduction of dosage. T his was statistically not significant as constipation may not be caused by morphine alone as some other factors such as locally advanced disease and irrational use of morphine may be the cause. This is consistent with the study that was done by Lawne Park et al (17) which reviewed several studies on the side effects of morphine despite its anaelgesic effects the main side effect was constipation, therefore patients should be counseled on its benefit than the side effect.

Concerning drowsiness as it was seen in the study, it seems that increasing the dosage of morphine has significant increase in drowsiness as the higher the dosage of morphine the higher the toxicity. This is due to increase in plasma concentration of morphine which makes the patient drowsy. This was consistent with other studies (21,22,23) which reviewed the side effects showing that drowsiness is mainly due to higher doses of morphine with addictive effect. This was significant with the study as increase in the dosage of morphine has significance increase in level of drowsiness, the higher the dose the higher the level of drowsiness.

CHAPTER FIVE

4.0 CONCLUSION

This chapter explains the effectiveness of oral morphine as was previously demonstrated in 93 patients among 100 patients who presented for the study. More than 80% had pain relief.

From this study it has been observed that Morphine is effective in controlling and reducing the level of pain in cancer patients because before the use of morphine all patients had pain ranging from moderate to overwhelming pain and after using morphine 80.6% had no further pain.

4.1 STUDY STRENGTH AND LIMITATION

4.1.1 STRENGTH

This was a prospective hospital based cohort in which the author was involved in data collection and personally entered and analyzed the data in order to assure authenticity and completeness of data collected as well as the results obtained.

4.1.2 LIMITATIONS

Being a hospital based study; some information obtained from the study cannot be generalized into the exact population.

4.2 RECOMMENDATIONS

Patients should be started with a baseline of 2.5mls of morphine once qualify to do so despite of the stage and level of pain encountered as pain is subjective.

For all patients who do not get relief with morphine pelvic x ray should be done to rule out local bone involvement than further proceeding with prescribing morphine. If pelvic x- ray confirms local bone involvement patients should be treated with NSAID's together with corticosteroids so as to relieve bone pain as morphine does not relieve bone pain.

Staff education and regular follow up of patients taking oral morphine are very crucial in order to prescribe morphine adequately and avoid further side effects which may reduce quality of life of our patients.

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APPENDIXES

APPENDIX I: CONSENT FORM (ENGLISH VERSION)

Consent to participate in the study of effectiveness of morphine in pain management in carcinoma of cervix patient at ORCI and its adverse side effects will be prepared as follows,

Dear Madam,

I am Hellen Makwani, I'm working at ORCI and need to conduct a research on effectiveness of oral morphine in pain management in cervical cancer and its common side effects. The study will be helpful in making your treatment better during the whole course of treatment and you will be pain free. I need your participation in this study so as to increase quality of service here at our hospital and please be free to participate and ask me questions whenever you are in doubt.

Purpose of the Study

We are recruiting patients who are either in the wards or as outpatients that have been assessed for pain and seen that are eligible to start morphine which will be titrated to the level that a patient is comfortable from pain. The patients referred to ORCI from June to October. We want to determine the effectiveness of morphine in pain control in carcinoma of the cervix patients and its side effects.

Participation

Those who will participate will be interviewed on some questions related to the research. Patients will be initially assessed for pain if are eligible to start morphine and they will be given morphine once eligible and the side effects that may arise from morphine usage will be documented according to the patient.

Confidentiality

All information collected will be confidential and will be used for the purpose of this study for future better care and treatment of the cancer patients in monitoring of the side effects during the treatment.

Benefits and Risks

All patients that will participate in the study will have close follup that in case of any adverse effects monitoring will be the priority so as to ensure good adherence and decrease the sufferings and improve standard of life. The information will assist in improving treatment care and minimizing the patients sufferings with the unwanted side effects that will ensure patients adherence to be improved and hence increase in quality of life.

All patients will start with lower dosage of morphine and will be titrated on patient's bases with good control of the side effects.

Voluntary participation & Right to withdraw

Your participation is voluntary and you have the right to discontinue from participating in our study at any time. However your decision to withdrawal will not affect your right to treatment and care.

Contact Persons

If you have questions about this study OR in case of any information about your information about your rights as a participant in this study, please contact;

The Principal Investigator

1. Dr. Hellen Makwani, Resident, Clinical Oncology Department,Tel 0715393203.
2. Dr. Khamza Maunda, Senior lecturer and Supervisor, Clinical oncology Department .Tel 0784200274
3. Dr. Julius Mwaiselage, Coordinator, Clinical Oncology Department.Tel 0784764412
4. Chairman of MUHAS IRB, Prof M. Mushi.

I.....

Have understood the above information and my questions have been answered to my satisfaction. I agree to take part in this study.

Name of the participant; …….....

Signature of the participant: …….....

Date of signed consent: …….....

APPENDIX II: CONSENT FORM (SWAHILI VERSION)

Fomu ya ridhaa ya utafiti kwa wagonjwa wenye saratani ya shingo ya kizazi wenye maumivu makali ambao wanatumia dawa ya maumivu ya morphine na madhara yake katika taasisis ya Saratani ya Ocean Road.

Utambulisho.

Habari za saa hizi

Jina langu ni Hellen Makwani ni daktari katika Taasisis ya Saratani ya ocean Road. Ninafanya utafiti kuangalia jinsi gani dawa ya maumivu ya morphine inavyokusaidia kuondokana na adha ya maumivu ya kansa ya shingo ya kizazi na madhara yake. Nitakueleza kuhusu utafiti huu kisha nitakuomba ridhaa yako kushiriki katika huu utafiti.

Tafadhali uwe huru kuuliza swali lolote.

Malengo ya Utafiti

Utafiti huu unafanyika kwa wagonjwa wote walioko kwenye tiba ya saratani ya shingo ya kizazi ambao wako wodini na wanaohudhuria kliniki ambao hawajaanza tiba ya mionzi ili kuona ni jinsi gani dawa ya morphine inawasaidia na kupunguza madhara yake wakati wanaitumia.

Ushiriki katika Utafiti

Watakaokubali kushiriki katiki utafiti tutawahoji maswali kadhaa kuhusu madhara waliyopata kutokana na dawa ya maumivu ya morphine.

Usiri

Taarifa zote tutakazopata kuhusu wewe ni siri na zitatumika tu kwa ajili ya utafiti huu na huduma bora kwako. Hakuna mtu mwingine zaidi ya wanaohusika na utafiti huu na wahudumu wa afya watakaohudumia atakayesoma au kupata maelezo yako.

Faida

Kupitia utafiti huu washiriki wote watapewa matibabu bila kuchelewa. Pia watapata fursa ya kupata ushauri wa afya zao muda wowote wakati wa utafiti kwa kuwasiliano na daktari mhusika katika utafiti.

Natumaini kuwa taarifa zote zitakazopatikana kutokana na utafiti huu zitasaidia kuboresha huduma na kupunguza madhara yanayotokana na dawa ya maumivu ya morphine na kuboresha huduma kwa kutoa kiwango sahihi cha dawa kwa muda sahihi ili kuwapunguzia wagonjwa adha ya maumivu ya saratani.

Hutapata hasara yoyote kwa kushiriki katika utafiti huu.

Iwapo utakua na swali lolote kuhusu utafiti huu unaweza kuwasiliana na

1. Mtafiti mkuu Dr. Hellen Makwani, Mwanafunzi, Idara ya Clinical Oncology.
2. Dr. K. Maunda, Senior Lecturer,Idara ya Clinical Oncology,MUHAS Tel no:0784200274.

3.Dr Julius Mwaiselage ,Mkuu Wa Idara ya Utafiti wa magonjwa ya Saratani .

Appendix III: Questionnaire (English Version)

1. Patients ID

2. Age

3. Address

4. Religion

5. Level of education a. no formal education b. Primary c. Secondary d. College / university e. Others

6. a. Marriage type

i. Monogamy

ii.Polygamy

7.Relationship

b. Cohabitating c. Single d. Divorced e. Widowed

8. Occupation

a. House wife b. Peasant c. Self employed d. Employed

8. stage of the disease

a. IA b. IB c. IIA d. IIB e. IIIA f. IIIB g. IVA h. IVB

9. Pain assesment

a. Mild pain b. Moderate pain c. Severe pain d.very severe pain e. overwhelming pain

10. Dosage prescription of morphine a. 2.5mls b. 5mls c. 7.5mls

11. Side effects of morphine

a. constipation

b.drowsiness

c.excessive sweating

d.none

12. Assesment of pain before morphine prescription

a.mild pain

b.moderate pain

c. severe pain

d.very severe pain

e.overwhelming pain

13. Assesment of pain after morphine prescription

a.no pain

b.mild pain

c.moderate pain

d. severe pain

e.very severe pain

f.overwhelming pain

g.no relief

APPENDIX IV : QUESTIONNAIRE (SWAHILI VERSION)

1. Namba ya faili la mgonjwa
2. Umri

3. Mahali anapoishi

4. Dini

5. Kiwango cha elimu

   a. Sijasoma

   b. Elimu ya msingi

   c. Elimu ya sekondari

   d. Chuo

   e. Nyingine

6. Hali ya ndoa

   a. Sijaolewa

   b. Nimeolewa

   d..nimeachika

   e.mjane

7.mfumo wa ndoa

   i. Ndoa ya mke mmoja

   ii. Ndoa ya mke zaidi ya mmoja

8. Unafanya kazi gani ?

a. Mama wa nyumbani b. Mkulima c. Kazi binafsi d. Nimeajiriwa

8. Hatua ya ugonjwa

a. IA b. IB c. IIA d. IIB e. IIIA f. IIIB g. IVA h. IVB

9. Kiwango cha dawa unachotumia a. 2.5mls b. 5mls c. 7.5mls

10. Kiwango cha maumivu a. Kidogo b. Maumivu makali c. Maumivu makali sana d.yasiyovumilika

11. Madhara ya dawa

a.kukosa choo

b.hali ya kulewa

c.hali ya kutoka jasho sana

d..hakuna madhara

12. Makadirio ya maumivu a. Kabla ya kutumia dawa b. baada ya kutumia dawa.