USE OF CLINICAL RISK FACTORS IN THE ASSESSMENT OF FRACTURE RISK AND ITS APPLICATION IN SCREENING FOR OSTEOPOROSIS AT MUHIMBILI ORTHOPAEDIC INSTITUTE

A HOSPITAL-BASED CROSS SECTIONAL DESCRIPTIVE STUDY

By

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A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Medicine (orthopaedic and Traumatology) of the Muhimbili University of Health and Allied Sciences (MUHAS)

MAY, 2011

CERTIFICATION

The undersigned certifies that he has read and hereby recommends the examination of dissertation entitled ***"Use of Clinical risk factors in the assessment of fracture risk and its application in screening for osteoporosis at Muhimbili orthopaedic institute"*** in partial fulfillment of the requirements for the award of the degree of Master of Medicine (Orthopaedic and Traumatology) of Muhimbili University of Health and Allied Sciences.

_____

Dr Robert Mhina
(Supervisor)

Date:…….

DECLARATION AND COPYRIGHT

I, **Goodluck Lema,** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature: _____ Date: _____

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ACKNOWLEDGEMENT

I thank God, the Almighty, for the gift of a healthy life.

I wish to express my sincere thanks to my Supervisor, Dr. Robert Mhina, for his invaluable time to guide and assist me with this dissertation work right from proposal development to the end.

Special thanks to the entire staff of the Muhimbili Orthopaedic Institute (MOI), MUHAS for accepting my dissertation title and offering me the necessary support throughout my term as a resident in the Department. I am equally indebted to Prof Lawrence Museru, executive director of Muhimbili Orthopaedic Institute (MOI), who despite his limited time he found time to go through my study, correcting and supporting me, Dr C.N. Mcharo Acting Medical Director and Senior lecturer MUHAS, Dr K.S Nungu lecturer MUHAS, Dr A.D.A Kinasha consultant Neurosurgeon and Senior lecture MUHAS, Prof J.F Kahamba consultant neurosurgeon and senior lecturer MUHAS, Dr S. Sharif consultant orthopaedic surgeon and Head of firm B at MOI. I acknowledge the contribution of Dr S. Swai and Dr E. Ndalama both Orthopaedic and trauma Surgeons at MOI.

I would like to extend my sincere gratitude to Dr Silver Faya consultant orthopaedic surgeon and senior lecture at the Aga khan Hospital Dar es salaam who despite of his special interest in this topic encouraged and offered me the necessary support.

Many thanks to Dr Elia John, Dr Germana Leyna, Ms Rose Mpembeni, Ms Kandida and Dr Joel Malissa for helping me out with the data handling and eventual analysis, their guidance is highly appreciated.

Thanks to all the patients who accepted to participate in this study as they are the forefront of every part of this work. If not for their acceptance this work would not have been

accomplished. Last but not least, I wish to express my extreme gratitude to my sister Happiness Lema and my Brother Isaack Lema for their constant assistance and moral support.

DEDICATION

This dissertation is dedicated first to my mother the late Rose Mlay. She was a lovely mother I ever knew, may the Lord comfort her forever. Secondly to my father Sariandumi David Lema, the father who has always been there to guide, encourage, and help us overcome every challenge in life. Lastly but not least to my brother Isaac Lema, my sisters Mapendo Lema, Happyness Lema, and my uncle Dr Joseph Mwanga, you gave me strength to go on.

ABSTRACT

Title: Use of Clinical risk factors in the assessment of fracture risk and its application in screening for osteoporosis at Muhimbili Orthopaedic Institute (MOI).

Objective: To determine the Clinical Risk Factors used in the assessment of fracture risk and their application in the screening for osteoporosis at Muhimbili Orthopaedic Institute (MOI).

Methods:

This was a cross – sectional hospital based study conducted at Muhimbili Orthopaedic Institute from March to December 2009.

Results

A total of 20,038 trauma patients were managed at Muhimbili Orthopaedic Institute during the study period. Among this 560 patients met criteria for this study and were enrolled. Males were 42.9% (240) and female were 57.1% (320) with mean age 53 (SD ± 11) years. Of 560 patients 5.5% (31) had no clinical risk factors for osteoporosis. Males above 60 years had more clinical risk factors for osteoporosis 32.9% than the younger ones 7.6% (p = 0.001). The same was observed in females [46.2% versus 2.1% (p = 0.001)]. More females 64.5% (60) had osteoporotic fractures than males 35.5% **(**33) (p = 0.116). Independent risk factors for fractures observed in this study were age more than 60 years, body mass index less than18.5%kg/m^2, cigarette smoking, physical inactivity and excessive alcohol intake.

Clinical risk factors strongly associated with osteoporotic fractures in female were underweight (low BMI), Age, heavy cigarette smoking, allergic to milk, amount, duration, and type of alcohol consumed. While in males underweight (low BMI), Age, and sedentary life style (sleeping during the day) were significant associated with osteoporotic fracture.

Prevalence of osteoporosis as analyzed by FRAX index tool was 21.3%. Out of 560, 6.8% (38) patients with 10 years probability of major osteoporotic fractures and 14.5% (81) patients with 10 years probability of hip fractures were identified. Females have high probability of osteoporosis hip fractures than males, 16.9% and 11.3% respectively.

Conclusion and Recommendation

The proportion of adult who are attending or admitted to MOI with (WHO) risk factors for osteoporosis is high. There was a positive correlation of WHO Risk factors for osteoporosis with occurrence of osteoporosis and osteoporotic fractures. Clinical Risk Factors of osteoporosis through the FRAX tool, which have been used for fracture prognostication and screening for osteoporosis in absence of BMD is suitable in Muhimbili Orthopaedic Institute. Application of this tool enables us to identify individual at high risk of disabling fractures, thereby allowing careful allocation of expensive treatments to individuals most in need without using BMD determination test.

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LIST OF ABBREVIATIONS

BMC.....Bone Mineral Content

BMD.....Bone Mineral Density

BMI.....Body Mass Index

CI……...Confidence Interval

CRFs.....Clinical Risk Factors

DALYs.....Disability Adjusted Life Years

DEXA.....Dual Energy X-ray Absorptiometry

EMD.....Emergency Department

EMRC.....Endocrinology Metabolism Research Centre

EPIDOS.....Epidemiologie de L' osteoporose

FRAX…….Fracture Risk Assessment

HRT.....Hormone Replacement Therapy

IOF.....International Osteoporosis Foundation

KCMC.....Kilimanjaro Christian Medical Centre

Mil.....Millions

MOI.....Muhimbili Orthopaedic Institute

MUHAS....Muhimbili University of Health and Alliance Services

OPD…….. Outpatient Department

OR.....Odds Ratio

OT……..Orthopaedic and Traumatology

SD……..Standard Deviation

SPSS……...Statistical Package for the Social Sciences

PMO.....Post Menopausal Osteoporosis

SERMS.....Selective Estrogen Receptors Modulators

SIOP.....Steroid Induced Osteoporosis

UK.....United Kingdom

USA .....United State of America

USD.....United State Dollar

WHO.....World Health Organization

CHAPTER ONE

1. INTRODUCTION AND LITERATURE REVIEW

1.1. 1.Definition and Epidemiology of Osteoporosis

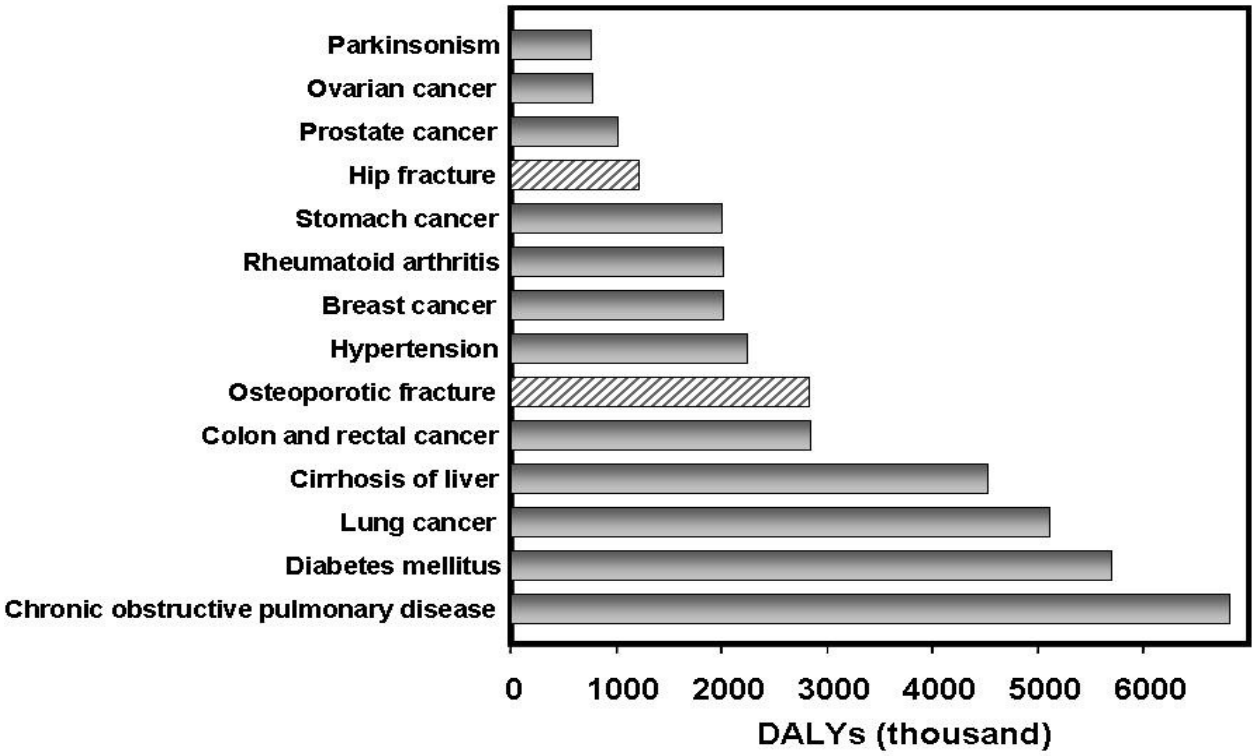
In 1994, the WHO defined osteoporosis as a "disease characterized by low bone mass and micro-architectural deterioration of bone tissue, enhanced bone fragility and an increase in fracture risk"[1, 2, 3] Osteoporosis occurs primarily as a result of normal ageing, but can arise as a result of impaired development of peak bone mass (e.g. due to delayed puberty or under-nutrition) or excessive bone loss during adulthood (e.g. due to estrogen deficiency in women, under nutrition, or corticosteroid use) [1, 2, 3.] The most serious consequence of osteoporosis is a fragility fracture defined by the WHO as "a fracture caused by injury that would be insufficient to fracture normal bone with the result of reduced compressive and/or torsional strength of bone" [4.] The most common sites of these fragility fractures are the hip, spine, proximal humerus and wrist. The clinical consequences of osteoporosis are the result of these fractures with their attendant morbidity and mortality [4.]

Osteoporosis is a systemic skeletal disease that up until a few years ago was considered as a normal part of the aging process. Intensive research over the last 10 years has lead to the realization that this is not only a treatable but also a preventable disease [3, 4.] Osteoporosis is a silent disease which is under diagnosed and thus under treated [3, 4.] Many patients seek attention only when they develop a fragility fracture, by which time the disease is severe or well established[3, 4.]

Osteoporosis affects more than 8.9 million fractures annually worldwide, of which more than 4.5 million occur in the Americas and Europe. The lifetime risk for a wrist, hip or vertebral fracture has been estimated to be in the order of 30% to 40% in developed countries – in other words, very close to that for coronary heart disease [3,4]. Osteoporosis is not only a major cause of fractures, it also ranks high among diseases that cause people to become bedridden with serious complications. These complications may be life threatening in elderly people. In the Americas and Europe osteoporotic fractures account for 2.8 million disability-adjusted life

years (DALYs) annually, somewhat more than accounted for by hypertension and rheumatoid arthritis [4,] but less than diabetes mellitus or chronic obstructive pulmonary diseases (Fig. 1.1). Collectively, osteoporotic fractures account for approximately 1% of the DALYs attributable to non communicable diseases

Figure 1: Burden of diseases estimated as disability-adjusted life years (DALYs) in 2002 in the Americas and Europe combined (The World health report 2004)



In Switzerland, osteoporotic fractures account for more hospital bed days than myocardial infarction and stroke [5.]

The osteoporosis problem is of greater importance in developing countries since there is an increase of life expectancy [6.] Most of the studies on osteoporosis and hip fractures have been carried out in developed countries and it was previously thought that Africans had a low prevalence of osteoporosis. Emerging evidence suggests that osteoporosis is on the increase in African populations [6.] Amongst the African American population it has been noted that osteoporosis is under-recognized and under-treated [8.] African American women are also more likely than white women to die following a hip fracture and that diseases more prevalent in the

African American population, such as sickle-cell anemia and lupus, can increase the risk of developing osteoporosis [8.] All these factors mitigate against the long held notion that osteoporosis is only a concern for Caucasian and Asian populations [8.] This misperception can delay prevention and treatment in black people who do not believe they are at risk for the disease. Scientific studies amongst Africans and African Americans highlight the risk that this population faces with regard to developing osteoporosis and osteoporotic fractures. The risk for hip fracture doubles approximately every 7 years as African American women age [8.] In a study done in South Africa it was demonstrated that the osteoporosis underlying femoral neck fractures in black Africans is high [9.] Ascorbic acid deficiency, iron overload (found in traditional liquor), and alcohol abuse contributed to this severe osteoporosis [9.] In Cameroon it was found that about 10% of all fractures in the above 50 age group in urban Cameroon were low energy hip or wrist fracture consistent with the view that bone fragility is likely to be a problem in Cameroon [9.]

In the Middle East, the burden of this disease is expected to increase, considering the steady growth of the ageing population. More particularly, in Iran alone, according to the Endocrinology and Metabolism Research Centre (EMRC), two million people are at the risk of fracture, thus establishing osteoporosis as one of the main health problems in Iran [10.]

The economic costs associated with osteoporosis and fragility fractures are overwhelming. The combined annual costs of all osteoporotic fractures have been estimated to be $20 billion in the USA and about $30 billion in the European Union [11.]

In Lebanon osteoporosis represents a heavy financial burden. The direct cost of hip surgery is 9,000 USD, per patient per hip fracture. Taking into consideration that the minimum income level of the Lebanese population is 200 USD per month it is obvious that by this income most of the patients can't afford the cost of surgery. In Iran, according to the Ministry of Health, the annual cost of hip fractures is between 8mil and 16mil USD [10.]

From a public health perspective, hip fractures are consistently considered to be the most important type of osteoporosis-related fractures [12-16.] In Europe, of the 3.79million osteoporotic related fractures which occurred in 2000, 0.89million were hip fractures. It also has been

estimated that 179,000 men and 611,000 women will experience a hip fracture in Europe each year [17, 18]. In Canada, almost 30,000 hip fractures occur each year, and it has been estimated that one Canadian sustains an osteoporosis-related hip fracture every eighteen minutes [19, 20].

By the year 2030, the number of hip fractures is expected to quadruple. Americans at the moment experience more than 1.5 million osteoporotic fractures each year, 300,000 of which are hip fractures, and it has been estimated that the number of hip fractures in the United States may double or triple by 2040. [21, 22] Mortality rate associated with this hip fractures ranges from 10% to 20% [23]. Among the survivors, half will require assisted walking and one-quarter will require long-term nursing home care [24]. Hip fractures account for most of the medical costs related to osteoporosis [25]. Several studies have demonstrated that the occurrence of one osteoporotic fracture increases the probability of a second fracture [26, 27], and it has been reported that patients with a history of hip fracture have a greater risk of having another hip fracture [28]. Following the first hip fracture the rate of a second hip fracture in women increases six fold, from 3.6 to 22 per 1000 person-years [28]. Furthermore, the risk of recurrent fractures begins to increase within the first months and year after the index fracture [29]. Therefore, focusing attention on patients with a hip fracture may be an important step toward a significant reduction in the burden of osteoporosis and subsequent fractures in society [30]

1.1.2 Risk Factors

Because of the morbid consequences of osteoporosis, the prevention of this disease and its associated fractures is considered essential to the maintenance of health, good quality of life and independence in the elderly population. In May 1998, the 51st World Health Assembly requested the Director-General to formulate a global strategy for the prevention and control of noncommunicable diseases [31, 32]. A scientific group meeting subsequently reported on the prevention and management of osteoporosis [33]

Osteoporosis has been operationally defined on the basis of bone mineral density (BMD) assessment. Non-invasive methods, such as bone densitometry, provide a measure of the bone mineral content (BMC) of a region expressed as grams of bone mineral, or bone mineral

density (BMD) expressed as grams of mineral per unit projected area of the bone. BMD is a predictor of fracture but bone size, shape and micro architectural features of bone are not captured by the measurement. Thus although the measurement does identify a high-risk group it is not sensitive. About 50% of persons who sustain fractures actually have osteopenia (BMD value between -2.5 SD and -1 SD) or normal BMD. A decline in BMD with age increases bone fragility because it reflects the progressive loss of bone mass and changes in the architecture of the bone such as cortical thinning, cortical porosity, thinning and loss of trabeculae with loss of continuity of trabeculae. Bone loss is progressive and is not associated with symptoms until a fracture occurs – the main clinical feature of osteoporosis. According to the WHO, the fractures are "caused by injury that would be insufficient to fracture normal bone" [4]. In other words, a fragility fracture can result from minor trauma, such as a fall from a standing height or less.

WHO criteria, defined osteoporosis as a BMD that range from 2.5 standard deviations or more below the average value for young healthy women (a T-score of <-2.5 SD) [3, 31]. This criterion has been widely accepted and, in many member states, provides both a diagnostic and intervention threshold. The most widely validated technique to measure BMD is dual energy X-ray absorptiometry (DEXA), and diagnostic criteria based on the T-score for BMD are a recommended entry criterion for the development of pharmaceutical interventions in osteoporosis [32-34]. Since therapy trials in osteoporosis usually require a low BMD value as an entry criterion drugs are available for use in patients below a given BMD threshold. The implication is that BMD should be assessed before treatment is considered.

There are, however, several problems with the use of BMD tests alone in diagnosing osteoporosis and thus determining treatment threshold. Firstly these tests are expensive and not widely available in many developing countries. [7] Furthermore these tests alone are not optimal for detection of individuals at high risk of osteoporotic fracture. Over most reasonable assumptions, the tests have high specificity but low sensitivity [3]. In other words, the risk of fracture is very high when osteoporosis is present, but by no means absent when BMD is normal. Indeed there are good proportional of osteoporotic fractures that will occur in individuals with a normal BMD test [34]. Thus, the potential impact of widespread testing of

BMD on the burden of fractures is less than optimal. This is one of the reasons why many agencies do not recommend population screening of BMD [3, 35, 37]. . It is against this background that the WHO with other International organizations such as International Osteoporosis Foundation, the National Osteoporosis Foundation (USA), the International Society for Clinical Densitometry and the American Society for Bone and Mineral Research developed algorithms for fracture risk assessment that were sufficiently flexible to be used in the context of many primary care settings, including those where BMD testing was not readily available [3]. The developed program is able to identify and validate clinical risk factors that can be used in diagnosis and prognostication of osteoporosis, either alone or in combination with bone mineral tests.

The choice of risk factors examined was governed by availability of data, and the ease with which the risk factors might be used in primary care. [3, 31, 32] Potential risk factors were examined by a series of meta-analyses using Poisson models for each risk factor in each of the study cohorts and for each sex [3, 31, 32]. Covariates examined included age, sex, glucocorticoid use, secondary osteoporosis, family history of fragility fracture, prior fragility fracture, smoking, excess alcohol consumption, BMD, time since assessment and the covariate itself, e.g. to determine whether BMD or body mass index (BMI) are equally predictive for fracture at different levels of BMD or BMI. Results from the different studies were merged using the weighted _-coefficients [3, 31, 32].

1.1.3 Model synthesis

A further step was then to merge these meta-analyses of each risk factor so that account could be taken of the interdependence of the risk factors chosen, and therefore the risk provided by any combination of risk factors, with and without the additional use of BMD.

The prediction of hip fracture and other osteoporotic fractures was based on the assessment algorithms (FRAX) which includes clinical risk factors alone or the combination of clinical risk factors plus BMD. The WHO Fracture Assessment Tool (FRAX) available online at www.shef.ac.uk/FRAX/ enables clinicians to determine 10 year fracture probabilities of hip and major osteoporotic fractures (clinical vertebral, forearm, hip and proximal humerus) with

or without BMD measurements. These probabilities are calculated from WHO clinical risk factors for osteoporosis and are country based. This model is based on longitudinal population cohort studies on these clinical risk factors and is categorized for country use depending on the prevalence of osteoporosis. For countries without the model, the authors advocate use of a country that closely mirrors the local prevalence. Prevalence figures for Tanzania are not available, but it is considered to be a low prevalence country like most sub-Saharan countries. However as hip fractures rates increase, in sub-Saharan countries, the need to find out the prevalence becomes paramount to avoid under diagnosing osteoporosis. If the FRAX tool is adapted to countries with higher prevalence, fracture probabilities are higher. The intervention threshold decision varies from country to country and is based on the willingness of a country to pay for recommended treatments. The treatment intervention level in the US FRAX model is 10 year hip fracture risk probability >3% or a 10 year all major osteoporosis related fracture probability of >20%. [11]

The FRAX algorithms are therefore suitable for men and women. Clinical risk factors developed in FRAX have the same ability to screen for osteoporosis and predict future fractures as BMD.

A recent public survey was conducted in Lebanon in order to determine risk factors for osteoporosis and osteopenia in the Lebanese female population [37]. The sample was composed of 551 post-menopausal women aged 61 +/- 8.9 years old and with at least one risk factor for developing osteoporosis. These women had no history or evidence of systemic disease. They were also not on treatment for osteoporosis. Significant clinical risk factors observed were low physical activities 55%, familial history of osteoporosis or hip fracture 35%, suffered from loss of height or kyphosis 35%, an early menopause 25%, heavy smoking (>10 cigarettes per day) 24%, underweight 23%, history of rheumatoid or thyroid disease16%, history of chronic use of corticosteroids 12%, and chronic use of alcohol 6%. The mean number of risk factors reported was 6 ± 3. The results show that the more risk factors the patient has, the lower the BMD. Among patients with one risk factor, 25% of them had normal BMD. Among patients with 2-3 risk factors 21-14% had normal BMD while 8% of those with more than 3

risk factors had normal BMD [37].

In a meta analysis study done in Europe to review recent literature regarding relationships among age, weight or body mass index (BMI), bone mineral density (BMD), maternal history of fracture, or personal prior history of fracture and fragility fractures in women with postmenopausal osteoporosis (PMO) 68 articles were reviewed. It was revealed that the risks associated with the evaluated clinical risk factors (CRFs) were high and significant [38]. Prior fracture was a strong predictor of fracture and increased the risk up to 18 times. Each standard deviation below the referent mean for BMD was associated with an increased fracture risk of up to 4.0 times; maternal fracture history increased risk 1.3-2.9 times. Age (per 5 year increment) increased risk by 1.2-5.0 times; low weight or BMI inconsistently showed a 0.5-3.0 times greater risk [38].

Fracture risk assessment was done in 2005 older people who were living in age care facilities by using clinical risk factors. Among these male were 473 and females 1,532. The mean age was 87.7 years with SD 7.1 years. Fractures were ascertained for 2 years from baseline during a mean follow-up of 1.64 years, 401 fractures occurred in 338 participants. Significant independent clinical risk factors for fracture were institution type, balance, history of previous fracture, cognitive function, number of medications, and weight [39]

An assessment tool for predicting fracture risk on older women, a set comprised of seven variables of clinical risk factors that included age; BMD T-score, fracture after age 50 years, maternal hip fracture after age 50, weight less than or equal to 125 pounds (57 kg), smoking status, and use of arms to stand up from a chair were used to predict fracture risk in post menopausal women. The fracture index was shown to be predictive of hip fractures as well as vertebral and non vertebral fractures.[40]

A study done in Europe in 1995 to assess risk factors for hip fracture in white women revealed the following, maternal history of hip fracture doubled the risk of hip fracture and these increase in risk remained significant even after adjustment for bone density. Women who had gained weight since the age of 25 had a lower risk. The risk was higher among women who had previous fractures of any type after the age of 50, were tall at the age of 25, rated their

own health as fair or poor, had been treated with long-acting benzodiazepines or anticonvulsant drugs, ingested greater amounts of caffeine, or spent four hours a day or less on their feet. [41]

Steroid induced osteoporosis (SIOP) arises due to use of glucocorticoids analogous to Cushing's syndrome and involving mainly the axial skeleton. The synthetic glucocorticoid prescription drug predniselone is a main culprit and after prolonged intake. Some professional guidelines recommend prophylaxis in patients who take equivalent of or more than 30 mg hydrocortisone (5.0 mg of prednisolone), especially when this is in excess of three months duration.[42] Alternate day use may not prevent this complication.[43]

Barbiturates phenytoin and some other enzyme-inducing antiepileptics - these probably accelerate the metabolism of vitamin D. [44]

L-Thyroxine over-replacement may contribute to osteoporosis in a similar fashion as thyrotoxicosis does this can be relevant in subclinical hypothyroidism.[45]

The most important reason for Orthopaedic surgeons to play an active role in the assessment and management of patient with fragility fractures is that a previous fracture is one of the strongest risk factors for new fractures [46]

Many published studies have shown that most women who sustained a fragility fracture are not appropriately diagnosed and are not started on treatment for the secondary prevention of osteoporosis. [47] It was revealed that only 2.8% of 1162 women over 55 years with Cole's fractures had a bone density measurement within six months after the fracture. [47]

An analysis of the records of 1654 patients in the Netherlands one year after an Osteoporotic fracture found that only 15% were taking any medication[Including calcium, vitamin D, selective Estrogens receptor modulators {SERMS}, hormone replacement therapy{HRT}, biphosphonate or fluoride] for osteoporosis. [48]

A recent survey of 3500 Orthopaedic surgeons from France, Germany, UK, Italy, Spain and New Zeeland highlighted the lack of training in osteoporosis for Orthopaedic surgeons. This

result in low referral rate of patient for BMD testing and there is also lack of awareness about their own national societies that deal with osteoporosis. [49]

Some of the factors which may have contributed to the reluctance of Orthopaedic surgeon to get involved in the evaluation of osteoporosis are lack of sufficient knowledge and understanding. Another reason may be that, Osteoporosis evaluation is complex and time consuming and that prevention strategies are also not effective. [50] It is imperative therefore for orthopaedic surgeons to play an active role in assessment of osteoporosis and management of fragility fracture as this is one of the strongest of predictor of risk factors for a new fracture.

1.2.0 PROBLEM STATEMENT

Osteoporosis is an emerging non-communicable disease in the developing world. Though traditionally communicable diseases carried the larger chunk of health budgets in the developing world, it is increasingly recognized that non-communicable disease like osteoporosis will be one of the coming scourges in Sub- Saharan Africa. In East Africa and Tanzania in particular there is scarcity of recent published data to show the impact of osteoporosis in society. Most of the studies on osteoporosis and hip fractures have been carried out in developed countries and it was previously thought that Africans had a low prevalence of osteoporosis.[6] Emerging evidence suggests that osteoporosis is on the increase in African populations.[6] Amongst the African American population it has been noted that osteoporosis is under-recognized and under-treated. [8] Scientific studies amongst Africans and African Americans highlight the risk that this population faces with regard to developing osteoporosis and its incident fractures. The risk for hip fracture doubles approximately every 7 years as African American women age. [8] A woman's risk for a fracture of the hip is equal to her combined risk for breast, uterine, and ovarian cancer, and the morbidity and mortality associated with fractures of the hip are staggering. [51, 52] Mortality rate in the first year after a fracture of the hip has been shown to increase considerably compared with the expected rate,

depending on the age of the patient at the time of the fracture, the gender of the patient, and the presence of co morbidities. [23] Using a population based model of the impact of osteoporosis over a lifetime, it was estimated that 10 percent of postmenopausal women older than fifty years of age who sustain a fracture of the hip become permanently functionally dependent in activities of daily living and 19 percent need long-term nursing-home care. [52] In a sample of seventy-five patients who were sent for rehabilitation training after a fracture of the hip, it was found that twenty-two (29 %) died and less than a third of the survivors returned to baseline functional status. [53]Although the risk of fracture in men is lower, it is certainly not inconsequential, and men are more likely to die after a fracture about the hip.[54]

One of the challenges faced by African societies in developing countries is diagnosis of osteoporosis. BMD have been used as a gold standard for diagnosing osteoporosis through dual energy X-ray absorptiometry (DEXA). However as pointed earlier these tests are expensive, not widely available in many developing countries, and have high specificity but low sensitivity. [3, 7] The WHO in conjunction with the International Osteoporosis Federation (IOF) have designated WHO clinical risk factors for osteoporosis that can be used for diagnosis and prognostication of osteoporosis either alone or in combination with bone mineral tests. [3] Clinical risk factors of osteoporosis through the FRAX tool were used in diagnosis of osteoporosis and for fracture prognostication in absence of BMD (T-score) determination in this study. Study result will enable to find the aptness of FRAX in the local setting and hence providing a local assessment tool for osteoporosis in MOI. FRAX application will justify identification of individual at high risk of disabling fractures, thereby allowing careful allocation of expensive treatment to individuals most in need without using BMD.

1.3. RATIONALE

The magnitude of patients with osteoporotic fractures and its sequel in Muhimbili Orthopaedic Institute is not known. The role of various risk factors in development of osteoporotic fractures in the local setting is unknown. There is no evidence of any study been done in Tanzania to assess the magnitude of osteoporosis and osteoporotic fractures using World Health Organization, clinical risk factors In this study the role of various factors associated with osteoporotic fractures in patients admitted at MOI will be assessed. Clinical risk factors revealed to be associated with osteoporosis and osteoporotic fractures in the studied population will set a base line data for developing a local assessment tool for osteoporosis.

1.4.0 OBJECTIVES

1.4.1. Broad Objective

To determine the Clinical Risk Factors used in assessment of fracture risk and their application in the screening for osteoporosis at Muhimbili Orthopaedic Institute (MOI)

1.4.2. Specific objectives

1. To determine proportion of adult who are attending or admitted to MOI with (WHO) risk factors for osteoporosis
2. To determine the (WHO) Clinical Risk Factors among patients with osteoporotic fractures
3. To apply the WHO fracture risk assessment tool (FRAX) to predicting 10years osteoporotic fractures probability in the study population

CHAPTER TWO

2. 1.0. METHODOLOGY;

2.1.1. Study design

This was a hospital based cross-sectional descriptive study

2.1.2. Study site

This study was conducted at Muhimbili Orthopaedic Institute (MOI). MOI is an autonomous institute, and also a referral teaching hospital located in the city of Dar es salaam with an estimated population of about 3.5million. MOI consist among other departments; Orthopaedic and Traumatology, Neurosurgery, and Pediatric orthopaedic departments. All orthopaedic trauma patients and neurosurgical patients are received by MOI emergency department. Patients with orthopaedic problems are seen at outpatient clinics while those with osteoporotic fractures are admitted for further treatments.

2.1.3. Study population

Patients attending outpatient's clinics, emergency department and those admitted in the wards, aged 40 years and above between March 2009 and December 2009. Age of the patient was verified in the identification card, voter's card, and if this was not available then verbal information from patient sufficed.

2.1.4. Sampling technique

Inpatients were consecutively selected from admitting wards, emergency department on a daily basis. In outpatient clinics, on each clinic day patients aged 40 years and above attended with orthopaedic problem, and those with fragility fractures and met inclusion criteria were included in the study.

2.1.5. Inclusion criteria

i) Patient aged 40 years and above
ii) consent to participate

2.1.6. Exclusion criteria

i) All patients below 40 years

ii) Patient with fractures from causes other than osteoporosis (i.e. involved significant energy/force, tumors)

iii) Patients who were too sick to interview

iv) Patients who did not consent

2.1.7. Sample size

The estimated sample size was derived from the following formula.

$$n = \frac{Z^2 P (1-P)}{d^2}$$

Where n = sample size,

P = expected prevalence or proportion, in this study population p is taken to be 44.5% which is proportion of patients with osteoporosis

d = precision (in proportion of one; if 5%, d = 0.05).

Z = is percentage point of normal distribution corresponding to the level of significance for 5% significance level Z= 1.96

Using above formula

$$n = \frac{(1.96)^2 0.445 (1-0.445)}{(0.05)^2}$$

$$n = 380$$

Using the above formula the minimum sample size was 380. A total of 560 patients were

recruited

2.2.0. Definition of terms for this study

2.2.1. Osteoporosis

The FRAX thresholds used for diagnosis of osteoporosis are outlined below.

• 10 Year Major Osteoporotic Fracture Probability >20% - model 1

• 10 Year Hip Fracture Probability >3% - model 2

All patients with Osteoporotic fractures as agreed by a panel of specialist and consultant orthopaedic and Traumatology based on x-rays presented in the morning presentation. Osteoporotic fractures (Low energy trauma fractures) were due to trivial impact resulting in these fractures. These groups included fractures sustained after slipping and falling and those where the patient realized they had a fracture without antecedent trauma.

2.2.2. WHO Clinical Risk Factors

W.H.O. clinical risk factors for osteoporosis prevalent in the study population were determined. The clinical risk factors, identified from previous meta-analyses shown in annex were used to determine their relation with osteoporosis. [4, 14, 15] Patients were assessed for 10 years probability of osteoporotic fractures using WHO FRAX index.

• Age

• Sex

• Low body mass index (BMI) (<18.50 kg/m2).

• A prior history of fracture

• A parental history of hip fracture

• Use of oral glucocorticoids

• Rheumatoid arthritis

• Secondary causes of osteoporosis

• Current tobacco smoking

• Daily alcohol intake of 3 or more units =24g.

A prior history of fracture and parental history of fracture were determined by the patients' recollection from their history. The use of oral glucocorticoids was considered positive, if the client had been exposed to oral glucocorticoids for more than 3 months at a dose of prednisolone of 5mg daily or more (or equivalent doses of other glucocorticoids). This was confirmed in the patients' medical record. Cigarette smoking has a dose dependent effect, i.e. the higher the exposure, the greater the risk. Cigarette smoking of 10 cigarettes pieces or more per day was taken as a standard required by FRAX tool used in this study. A patient's rheumatoid arthritis diagnosis was confirmed from the medical record where the clinicians' diagnosis of rheumatoid arthritis was confirmatory.

2.3. Data collection methods

A structured questionnaire (Appendix I) was used for data collection. WHO fracture assessment tool available on line at www.shef.ac.uk /FRAX was used to calculate 10 Year Major Osteoporotic Fracture Probability >20% and 10 Year Hip Fracture Probability >3% Probabilities are calculated from WHO clinical risk factors for osteoporosis and are country based. Prevalence figures for Tanzania are not available, but it is considered to be a low prevalence country like most sub-Saharan countries. For countries without the model like Tanzania, the authors advocate use of a country that closely mirrors the local prevalence. The USA modal FRAX for black without BMD was used as black in USA was shown to have low prevalence, and share the same race with the study population.

2.4. Study Procedures

Data were filled in structured questionnaire by investigator, from patients who consented to participate in the study. Information on socio demographic characteristics that included age, sex, level of education, check list for risk factors, employment status was obtained by interviewing the patients. Measurement of weight and height were taken using calibrated weighed scale in kilogram and in centimeter respectively and were taken at OPD clinic, EMD and in the wards. BMI was calculated using (Kg/m^2)

-BMI categories

-Under weight = 18.49

-Normal = 18.50-24.99

-Overweight = 25-24.9

-Obesity = 30 or greater

A unit of alcohol (one oz.) was taken to be equivalent to 8g of ethanol (UK standard drink). In term of volume one oz. = 30ml, a standard glass of beer is 360 ml, a bottle of beer ranges from 250ml- 500ml depending on the type of beer. For local brew a bottle of soft drink (Coca or Pepsi) 350ml or 500ml bottle of "Konyagi", or "chibuku'' were used to estimates the units of alcohol consumed. For whisky and wine standard glass for whisky and wine were used to estimates the units of alcohol consumed, fig 2 below The FRAX ask for 3 or more units = 24g



Fig 2

The units were later converted to metric value, i.e. 12oz = 360mls. (Oz- A unit of volume capacity in the US customary system used in liquid measure equal to 29.57≈ 30millimeter)

2.5. Data entry, cleaning and analysis

Data was checked daily for completeness and consistency thereafter was entered into a statistical soft ware SPSS version 16. Data were cleaned before being transferred to Stata version 10 for analysis. Continuous variables were summarized by calculating mean and standard deviation. The difference between means was assessed by using t-test. Binary variables were frequencies and differences between proportions examined using Chi square test. To assess factors associated with fracture crude odds ratio (OR) were calculated. Multiple logistic regressions were done to control for potential confounders. Adjusted OR with 95% CI were presented. The analysis was two tailed. P value of less than 0.05 was considered

significant.

2.6. Ethical consideration

The study received ethical clearance from the Research and Publication committee of MUHAS and Orthopaedic and Traumatology department of MOI. Patients were included after informed verbal and written consent. Confidentiality was adhered to when filling the data collection sheets. Physical examinations were conducted in private and whenever needed in presence of a nurse. Those who declined consent were not in any way deprived their right to receive medical attention and advice.

2.7. Disposal of Study patients

All precautions were taken to ensure that no harm occurs to them during the course of the research. All benefits as a result of the research were provided to the patients in terms of better care of their health. Patients diagnosed with osteoporosis were offered the necessary treatment as is expected of the medical standard for patients with osteoporosis and fragility fracture the treatment included counseling and prescription of appropriate medical treatment

CHAPTER THREE

3.1. RESULTS

From March-December 2009, a total of 20,038 adult patients were seen at Muhimbili Orthopaedic Institute, among these 560 patients who consented and met study criteria were enrolled in this study. The socio demographic characteristics of the study population are shown in Table 1

Table 1; Socio Demographic characteristics of the study population

	n	%	p - value
Age group (yrs)			
40-49	264	47.1	
50-59	149	26.6	
60-69	100	17.9	
70-79	30	5.4	
80+	17	3.0	$p < 0.001$
Total	560	100	
Sex			
Male	240	42.9	
Female	320	57.1	$p = 0.116$
BMI			
Low BMI	86	15.4	
Normal	205	36.6	
Overweight	147	26.3	
Obesity	122	21.7	$p = 9.65$
Occupation			
Employed	202	36.1	
Self employed	92	16.4	
Small scale farmers	65	11.6	
Peasant	201	35.9	

3.2.Proportion of adults attended and admitted at MOI with (WHO) risk factors for osteoporosis

The mean age of study population was 53 (SD ± 11 years). 47.1% of patients aged less than 50 years were majority. There were more enrolled females than males in the study population (57.1% versus 42.9%). All of the patients were of Tanzanian nationality. The mean body mass index (BMI) was 25.51kg/m (SD ± 5.84). Table 2 summarizes numbers of patients who were observed to have WHO risk factors for osteoporosis. Majority of patients spend more than 4 hours sited during the day 48.6%, while 38.4% were alcoholic (consumed > 3 units per day). 22.5% were heavy smokers (> 10 cigarette per day). Only 2.0% of patients had Diabetes Mellitus and of 19 females who had gynecological problem which ended up with Oophorectomy, only 8(1.4%) had hormonal replacement therapy.

Table 2; WHO CRFs frequency in the study population

Risk Factors	n	%
H/o Parental fracture	94	16.0
H/o Parental - hump	28	5.0
Fragility fracture	93	16.6
< 1hr of work	94	16.8
>4hr of sitting per day	272	48.6
Sleep during day time	108	19.2
Smoking cigarette	126	22.5
Drinking alcohol	215	38.4
Not drinking milk	19	3.4

Not use Calcium tabs	34	6.1
Early menopause	96	17.1
Amenorrhea- 12month	19	3.4
Oophorectomy <50	19	3.4
Hormonal replaced	8	1.4
Estrogens use	22	3.9
Diuretics use	87	15.5
Anticonvulsant use	18	3.2
Antacid drugs use	29	5.2
Corticosteroid use	15	2.7
Diabetes Mellitus	11	2.0

All age groups had patients with CRFs for osteoporosis. 95.8% (230) of all male patients had at list one clinical risk factor. Proportion of clinical risk factors more than 6 rose from 7.6% in the age group 40-49 years, to 32.9% in patients with more than 60 years ($p < 0.001$). (Table 3)

Table 3; WHO clinical risk factors by age group in the male studied (n=240)

No of CRFs	0	%	1-2	%	3-5	%	>6	%	Total
Age – years									
40-49	**5**	**4.8**	**49**	**46.7**	**43**	**40.9**	**8**	**7.6**	**105**
50-59	**4**	**6.2**	**22**	**33.8**	**33**	**50.8**	**6**	**9.2**	**65**
60+	**1**	**1.4**	**14**	**20.0**	**32**	**45.7**	**23**	**32.9**	**70**
Total	**10**		**85**		**108**		**37**		**240**

Of the female patients, 6.6% (21) had no clinical risk factors while 93.4% (299) had at least one clinical risk factor. Proportion of clinical risk factors more than 6 rose from 2.1% in the age group 40-49 years, to 46.2% in patients with more than 60 years ($p < 0.001$). (Table 4)

Table 4; WHO clinical risk factors by age group in the female studied (n=320)

No of CRFs	0	%	1-2	%	3-5	%	>6	%	Total
Age – years									
40-49	**15**	**10.1**	**60**	**40.5**	**70**	**47.3**	**3**	**2.1**	**148**
50-59	**5**	**5.3**	**42**	**44.7**	**37**	**39.4**	**10**	**10.6**	**94**
60+	**1**	**1.3**	**9**	**11.5**	**32**	**41.0**	**36**	**46.2**	**78**
Total	**21**		**111**		**139**		**49**		**320**

3.3 Proportion of adult admitted or seen at MOI with osteoporotic fractures

From March 2009 to December 2009 a total of 2088 patients were admitted in Muhimbili Orthopaedic Institute wards. Among this 4.2% (88) were admitted due to Osteoporotic

fracture. More female had osteoporotic fracture compared to male (60 Vs 33). However statistically the different observed was not significant (P= 0.116). Univariate Analysis of the categorical WHO CRFs with Pearson Chi square in patients with osteoporotic fracture, revealed the following association. Age was significant associated with osteoporotic fracture Chi square (96.15) P< 0.001, and it was observed that risk was increasing statistically with aging. (Table 5)

Table 5; Shows Osteoporotic fractures versus sex, age groups, and Body Mass Index (BMI) cross tabulation, (n = 93)

Osteoporotic fractures against Risk factors cross tabulation				
	n	**%**	**OR**	**P – value**
Characteristics				
Sex				
Male	**33**	**35.5**		
Female	**60**	**64.5**	**0.69**	**0.116**
Age group				
40 – 49	**20**	**21.5**		
50 – 59	**19**	**20.4**		
60 – 69	**26**	**27.9**		
70 – 79	**14**	**15.1**		
80+	**14**	**15.1**	**1.39**	**< 0.001**
BMI				
Underweight	**51**	**54.8**		
Normal	**17**	**18.3**		
Overweight	**12**	**12.9**		
Obesity	**13**	**14.0**	**9.65**	**< 0.001**

***OR unadjusted odds ratio**

Low BMI (under weight) was the most common risk factor in patients with osteoporotic fracture 54.8% and was significant associated with osteoporotic fracture Chi square (134.11) P< 0.001. (Table 5)

3.4 The clinical risk factors (WHO) in patients with osteoporotic fractures associated with fractures.

Bivariate analysis was carried out for WHO CRFs against osteoporotic fracture, Age and low BMI (underweight) were significantly associated with osteoporotic fractures, [OR= 1.39(1.11-1.73)] and [OR=9.65 (2.87-32.34)] respectively. As shown in table 5 above

Table 6 depicts association between clinical risk factors and osteoporotic fracture. Association of the WHO clinical risk factors with osteoporosis was assessed by means of the odds ratio ranging from 0.06 (oophorectomy < 50) to 3.15 (smoking for > 20 years).

Heavy smoking was significantly associated with osteoporotic fracture. Patients who had been smoking a packet and more of cigarette per day for more than 20 years had significant association with fracture [OR =3.15 (1.96-5.06)]. More fractures were observed in this group than those with less duration of smoking.

Alcohol use of more than 3 units per day which started at young age in both sexes showed an increase risk of having osteoporotic fractures. The observed risk was not significant [OR =1.24 (0.79-1.95)]. When tested against sex, female patients were more likely to get fracture [OR =1.83 (1.14-2.95)] than males patients (Table 7).

Daily house works carries a less risk of osteoporotic fracture [OR = 0.55 (0.32-0.87)] while lack of physical activities as observed in those; not performing physical exercise (jogging) [OR= 1.65 (1.04-2.63)], not engaged in gardening [OR= 1.65 (1.04-2.63)], daily sleeping during the day [OR= 1.72 (1.02-2.88)], carries a great risk of osteoporotic fracture.

***OR unadjusted odds ratio (table 6 below)**

Table 6; Association between Clinical risk factors and Osteoporotic fracture (n=560)

	Osteoporotic fracture		No Osteoporotic fracture			
WHO Risk factors	**risk present**	**Risk absent**	**risk present**	**risk absent**	***OR**	**95 % CI**
Smoking for > 20 yrs	39	54	87	380	3.15	1.96 -5.06
Drinking alcohol	40	53	175	292	1.24	0.79 – 1.95
H/o Parental fracture	14	79	80	387	0.86	0.46 - 1.61
Daily house works	53	40	329	138	0.55	0.32 - 0.87
Gardening	36	57	129	338	1.65	1.04 - 2.63
Daily jogging	2	91	44	423	0.20	0.04 – 0.90
Day time sleeping	25	68	83	384	1.72	1.02 – 2.88
Not drinking milk	64	29	13	454	2.40	0.89 – 6.50
Early menopause	27	30	69	194	1.13	0.72 – 2.40
Oopherectomy <50	4	56	15	245	0.06	0.01 – 0.26
Chronic use of diuretics	20	73	67	400	1.63	0.93 – 2.85
Chronic use of corticosteroids	2	91	13	454	0.76	0.17 – 3.45
Diabetes mellitus	3	90	8	459	1.91	0.49– 7.34

Patients who were not drinking milk and dairy products because they suffered allergic reaction [OR= 2.40 (0.89-6.50)] had an increase risk of getting osteoporosis.

Contrary to what has been observed in many other studies early menopause for women whose ovaries were surgically removed due to gynecological problem had lower risk of getting osteoporotic fracture [OR= 0.06 (0.01-0.26)]. Patients who were using corticosteroids (Predniselone tabs 5.0mg daily) for more than 3 months, diuretic for more than 3 months, and those with Diabetes Mellitus carries great risk of osteoporotic fracture but there was no significant association

Multivariate analysis carried out to control for sex and WHO CRFs shows underweight (low BMI), Age, heavy cigarette smoking, allergic to milk, amount, duration, and type of alcohol consumed, were significant associated with osteoporotic fracture in women

Table 7; Multivariate analysis of the association between WHO CRF and osteoporotic fracture among female

	OR	95% CI	P - values
WHO CRFs			
Underweight low BMI	10.70	3.11-36.76	0.001
Age	1.40	1.12-1.75	0.003
Cigarette smoking	3.80	1.28-11.22	0.016
Allergic to milk	0.42	0.23-0.07	0.006
Alcohol use	1.83	1.14-2.95	0.002

* OR Adjusted for sex and WHO CRFs

However in male patients underweight (low BMI), Age, and sleeping during the day were significant associated with osteoporotic fracture. (table 8)

Table 8; Multivariate analysis of the association between WHO CRF and osteoporotic fracture among male

	OR	95% CI	P-Value
WHO CRFs			
Underweight (low BMI)	11.46	4.10-31.99	0.001
Age	1.28	1.02-1.59	0.029
Cigarette smoking	3.80	1.28-11.22	0.016
Day time sleeping	3.59	1.16-11.08	0.026

* OR Adjusted for sex and WHO CRFs

3.6 The application of the WHO clinical risk assessment tool FRAX to predicting 10 year osteoporotic fractures probability in the study population

Patients with Osteoporotic fracture recorded among the study population were 93(16.6%). Of 560 patients 38(6.8%) had 10 years probability of developing major osteoporotic fractures, while 81(14.5%) had 10 years probability of developing hip fracture. Proportion of male patients with 10 years probability of developing major osteoporotic and hip fractures identified by FRAX Index were 2(0.8%), and 27(11.3%) respectively while proportion of female patients with 10 years probability of developing major osteoporotic and hip fractures identified by FRAX Index were 36(11.3%) and 54(16.9%) respectively. FRAX identify 90% and 81.8% of female and male patients admitted with hip fractures respectively.

CHAPTER FOUR

4.1 DISCUSSION

4.1.1. Socio- demographic characteristic

In this study 560 patients were enrolled, 57.1% of whom were female and 42.9% males. More than seventy three percent of patients enrolled in this study are below 60 years as majority of patients (high energy trauma patients) attended at MOI fall in this age category. Similar studies done in other part of the world had majority of studied patients above 65 years [6, 13, 29, 39, 58, 59.]

4.1.2. Proportion of adults attended and admitted at MOI with (WHO) risk factors for osteoporosis

Studies done in USA, Europe, Asia and other part of the world, reported osteoporosis to be prevalent among whites and Caucasian. [3, 4, 6, 10, 14, 17] Most of these studies were done in elderly people with mean age of 65 years [6, 13, 29, 39, 58, 59.] Contrary to that this study was done in black people considered to have low prevalence and with mean age of 53 years. It was found that all age groups had patients with clinical risk factors for osteoporosis [15, 38, 39.] The clinical risk factors more prevalent in the studied patients were physical inactivity, alcohol drinking, cigarette smoking, and familial history of osteoporotic fractures. This is in keeping with other studies [36, 41, 42, 43, 45.] Elderly patients above 60 years had more clinical risk factors for osteoporosis than young ones which are consistent with other studies [38, 58, 60]. Result show that the more risk factors the patient had the higher the risk for osteoporosis and osteoporotic fracture [37, 38, 60.]

4.1.3. Magnitude of Osteoporotic fracture

According to the WHO, osteoporosis is becoming an increasing health problem throughout the world. Increase of life expectancy in the developing countries has made osteoporosis a medical problem of importance [3, 4, 6, 10.] Hip fractures as a sequel of osteoporosis are

considered to be the most important type of osteoporotic related fractures [12-16.] A total of 2088 patients were seen and admitted in MOI wards during the study period, among these 4.2% were admitted due to osteoporotic hip fractures [56.] Patients in the older group had more osteoporotic fractures and more WHO clinical risk fractures consistent with other studies [37, 38, 39, 58, 60.] Female patients had more osteoporotic hip fractures as compared to male. This finding is consistent with other studies [17, 18.] Worldwide the cost of treating hip fractures is very high [10, 11, 25.] Medical cost of treating hip fracture is even more in developing countries where the income per capita is less than 200 USD [10, 11.]

4.1.4 The clinical risk factors (WHO) in patients with osteoporotic fractures associated with fractures

As it was revealed previously clinical risk factors for osteoporosis were more prevalent in patients with osteoporotic fracture than those without. Significant independent clinical risk factors for fracture were Age greater than 60years, low body weight (body mass index <18.5kg/m^2) cigarette smoking, previous fragility fractures, lack of physical activities and sedentary life style, the finding were consistent with other studies [28, 29, 33, 40, 58.]

There was correlation between increasing in **Age** and osteoporotic fractures observed in this study, which was in keeping with other studies [38, 40, 60.]

Low body mass index was shown to be an independent significant risk factor associated with osteoporotic fractures, while being overweight protects against osteoporosis, this was also observed in different studies [33, 41.]

Tobacco smoking inhibit the activity of osteoblast and is an independent risk for osteoporosis, this was the case in patients who had started to smoke at young age at a rate of 10 cigarettes per day [37, 61.] Smoking also resulted in an increase breakdown of exogenous estrogen, most of females patients with hip fractures in this study were heavy smokers [37, 61.]

Followed an initial low trauma fracture from a simple fall both older men and women have an increased equivalent risk of all types of subsequent fractures especially in the next 5-10 years. **A prior fragility fractures** was shown to be a strong predictor of getting another fracture and this is consistent with other studies which had revealed the same trend [26, 27, 28, 38.]

Bone remodeling occurs in response to physical stress. Weight bearing exercise improves bone

remodeling. **Physical inactivity** show significant association with osteoporotic fracture as it was revealed in this study in those who do not participate in; house activity, physical exercise like jogging, gardening and those who sleep during the day. This is consistent with other studies [39, 43, 60.]

Early menopause was a strong predictor of fragility fractures, but did not show significant association in this study as shown in other studies [37.] Osteoporosis is far more prevalent in women after menopause due to loss of the hormone estrogen. This is the case in women above 50 years of age. It was challenging for an elderly patients to remember the age when menopause start, this contributed to the lack of significant association observed. In addition to that majority of women (46.3%) consist of younger population less than 50 years, who despite having an early menopause had a few clinical risk factors for osteoporotic fractures.

Women who undergo **surgical removal of their ovaries at age below 50 years** fail to show positive correlation with osteoporotic fractures as reported in other studies [37.] This lack of association can be explained by small number of patients with osteoporotic fractures in this category.

Osteoporosis has been shown in studies to have a large genetic component. **A parental history of fracture** (particularly hip fracture) confers an increased risk of fracture [14, 30.] Lack of significant association in this study can be attributed by the fact that 84.2% of patients with fragility fractures were elderly and had poor memory of the past events, also the small number of patients (16%) admitted to have this risk factor consist of younger population.

Small amounts of **alcohol** do not increase osteoporosis risk and may even be beneficial but a high intake of alcohol leads to a significant risk of future fracture (alcohol intake greater than 3 units per day) especially at a younger age increases risk significantly as observed in female patients [7, 8, 61.]

Low dietary intake of calcium in women was a predictor of an increase risk for osteoporotic fractures. This was observed in patients who do not drink milk or dairy products at all and it's consistent with other studies [43, 61.] Male patients' failed to show this association, the difference was contributed by a small number of male patients who had fragility fractures in this category.

Prolonged use of corticosteroids is the most common cause of secondary osteoporosis. It is estimated that 30-50 % of patients on long term corticosteroids therapy will experience fractures with increase in risk of hip fracture by 2 fold in women and 2.6 fold in men. Owing to small number of patients who chronically used oral corticosteroid (0.9%), significantly association of these clinical risk factors with osteoporotic fractures was not observed as compared to other studies [42, 43, 45]

Diabetic Mellitus as the cause of secondary osteoporosis was found to have no significant association with osteoporosis as shown in other studies[42, 43, 45.] This can be explained by small number (2%) of patients with Diabetes Mellitus

4.1.5. The application of the WHO clinical risk assessment tool, FRAX to predicting 10 years osteoporotic fractures probability in the study population

Since the clinical outcome of osteoporosis is bone fracture, attention is now increasingly focused on the identification of patients at high risk of fracture rather than the identification of people with osteoporosis as defined by BMD alone. Prevalence of osteoporosis as analyzed by FRAX index tool is 21.3%. This proportion is consistent with other studies done in different part of Africa and higher than what reported from studies done in western countries in black populations which showed low proportion [7, 8, 9, 55, 62.] In their study among southern Sudanese immigrants to the USA (88 women and 55 men) Gong et al found the prevalence of osteoporosis to be 21.6% for women and 25.5% for men [40, 62.] Rogers et al found 10% prevalence of osteoporosis among 513 urban Cameroon [9,] while Sellami et al observed a prevalence of 10% in 1311 postmenopausal women in Tunisia [8.]

As observed in different studies done in different parts of the world, women are more affected than men. In this study FRAX revealed the same trend both in 10 years probability in major osteoporotic and hip fractures [40, 58, 60.] Out of 560, 38 patients with 10 years probability of major osteoporotic fractures and 81 patients with 10 years probability hip fractures were identified. These are the patients FRAX advocate that clinicians begin treatment.

CONCLUSION

- This study had shown that the prevalence of osteoporosis amongst patients managed at MOI is high. A trend is shown of a positive correlation of WHO Risk factors for osteoporosis with occurrence of osteoporosis and osteoporotic fractures amongst patients managed at MOI with hip fractures.
- In a place where DEXA is not readily accessible like MOI, treatment of osteoporosis poses a major challenge. CRFs of osteoporosis through the FRAX tool used in this study is useful in identification of individuals at high risk of disabling fractures and thereby allowing careful allocation of expensive treatment to individuals most in need without using BMD.
- The tool is sensitive inexpensive effective and easy to implement.

4.3; RECOMMENDATION

- FRAX tool to be used as identification tool for high risk patients for osteoporosis and osteoporotic fractures and initiation of treatment at MOI. For this to be carried out effectively special clinics for patients at high risk of osteoporosis and osteoporotic fractures are recommended. The clinics can be done once per week or twice in a month.
- Management of osteoporosis need multidisplinary approach therefore other specialties will be involved in order to include those patients at high risk of secondary osteoporosis. This tool can be used as a guideline to initiate medication so as to prevent osteoporosis and its sequel in this group.
- Most patients can’t afford the medications for osteoporosis because their expensive. Ministry of Health should be involved through Medical Store Department to see the possibility of subsidizing the price as in other medication such as ant malarial. National Health Insurance should also be involved to include medication for osteoporosis in their drugs list.
- Orthopaedic surgeons should play an active role in assessment of osteoporosis and management of fragility fracture as this is one of the strongest of predictor of risk factors for a new fracture.

- There is a need to raise awareness among young surgeons and doctors to recognize osteoporosis as a disease.

STUDY LIMITATIONS

- FRAX index tool couldn't use all significant risk factors for osteoporosis observed in this study.

REFFERENCES

1. NIH Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy. "Osteoporosis prevention, diagnosis, and therapy". JAMA 2001; 285:785-795.
2. Kanis JA. Assessment of fracture risk and its application to screening for postmenopausal osteoporosis: synopsis of a WHO report. WHO Study Group. Osteoporosis Int 1994; 4:368-381.
3. Assessment of fracture risk and its application to screening for postmenopausal osteoporosis. Report of a WHO Study Group. Geneva, World Health Organization, 1994 (WHO Technical Report Series, No. 843).
4. The world health report 2004: changing history. Geneva, World Health Organization, 2004.
5. Cummings SR, Melton LJ. Epidemiology and outcomes of osteoporotic fractures. Lancet 2002; 359: 1761–67.
6. Cooper C, Campion G, Melton LJ III. Hip fractures in the elderly: a world-wide projection. Osteoporosis Int 1992; 2:285-289.

7. WHO Scientific Group on the Assessment of Osteoporosis at Primary Health Care level. Summary Meeting Report. 5-7 May 2004. Brussels Belgium
8. National Institutes of Health Osteoporosis and Related Bone Diseases ~ National Resource Center. Osteoporosis and African American women. Available from URL: http:// www.niams .nih.gov/Health_info/Bone/Osteoporosis/Background/default.asp
9. Roger MF, Zebaze D, Seeman E. Epidemiology of hip and wrist fractures in Cameroon, Africa. Osteoporosis International 2003; 14: 301-305
10. Endocrinology and Metabolism Research Center. Teheran, Iran.
11. Sambrook P, Cooper C. Osteoporosis. Lancet 2006; 367: 2010–18.
12. Melton LJ 3rd. Who has osteoporosis? A conflict between clinical and public health perspectives. J Bone Miner Res. 2000; 15:2309-14.
13. Haentjens P, Autier P, Barette M, Boonen S, Belgian Hip Fracture Study Group. The economic cost of hip fractures among elderly women. A one-year, prospective, observational cohort study with matched-pair analysis. Belgian Hip Fracture Study Group. J Bone Joint Surg Am. 2001; 83:493-500.
14. Reginster JY, Gillet P, Gosset C. Secular increase in the incidence of hip fractures in Belgium between 1984 and 1996: need for a concerted public health strategy. Bull World Health Organ. 2001; 79:942-6.
15. Kannus P, Niemi S, Parkkari J, Palvanen M, Vuori I, Jarvinen M. Hip fractures in Finland between 1970 and 1997 and predictions for the future. Lancet. 1999; 353:802-5.
16. Dubey A, Koval KJ, Zuckerman JD. Hip fracture epidemiology: a review. Am J Orthop. 1999; 28:497-506.
17. Kanis JA, Johnell O. Requirements for DXA for the management of osteoporosis in Europe. Osteoporos Int. 2005; 16:229-38.
18. Melton LJ 3rd, Gabriel SE, Crowson CS, Tosteson AN, Johnell O, Kanis JA. Cost-equivalence of different osteoporotic fractures. Osteoporos Int. 2003; 14:383-8.

19. Goeree R, O'Brien B, Pettitt DB, Cuddy L, Ferraz M, Adachi J. An assessment of the burden of illness due to osteoporosis in Canada. J Soc Obstet Gynaecol Can. 1996; 18(7 Suppl):15-24.

20. Papadimitropoulos EA, Coyte PC, Josse RG, Greenwood CE. Current and projected rates of hip fracture in Canada. CMAJ. 1997; 157:1357-63.

21. Riggs BL, Melton LJ 3rd. The worldwide problem of osteoporosis: insights afforded by epidemiology. Bone. 1995; 17(5 Suppl):505S-511S.

22. Gullberg B, Johnell O, Kanis JA. World-wide projections for hip fracture. Osteoporos Int. 1997; 7:407-13.

23. Cummings SR, Black DM, Rubin SM. Lifetime risks of hip, Colles', or vertebral fracture and coronary heart disease among white postmenopausal women. Arch Intern Med. 1989; 149:2445-8.

24. Edwards BJ, Perry HM 3rd. Age-related osteoporosis. Clin Geriatr Med. 1994; 10:575-88.

25. Ray NF, Chan JK, Thamer M, Melton LJ 3rd. Medical expenditures for the treatment of osteoporotic fractures in the United States in 1995: report from the National Osteoporosis Foundation. J Bone Miner Res. 1997; 12:24-35.

26. Ribot C, Tremollieres F, Pouilles JM, Albarede JL, Mansat M, Utheza G, Bonneu M, Bonnissent P, Ricoeur C. Risk factors for hip fracture. MEDOS study: results of the Toulouse Centre. Bone. 1993; 14 Suppl 1:S77-80.

27. Ross PD, Genant HK, Davis JW, Miller PD, Wasnich RD. Predicting vertebral fracture incidence from prevalent fractures and bone density among non-black, osteoporotic women. Osteoporos Int. 1993; 3:120-6.

28. Cummings SR, Nevitt MC, Browner WS, Stone K, Fox KM, Ensrud KE, Cauley J, Black D, Vogt TM. Risk factors for hip fracture in white women. Study of Osteoporotic Fractures Research Group. N Engl J Med. 1995; 332:767-73.

29. Nguyen TV, Eisman JA, Kelly PJ, Sambrook PN. Risk factors for osteoporotic fractures in elderly men. Am J Epidemiol. 1996; 144:255-63.

30. Klotzbuecher CM, Ross PD, Landsman PB, Abbott TA 3rd, and Berger M. Patients with prior fractures have an increased risk of future fractures: a summary of the literature and statistical synthesis. J Bone Miner Res. 2000; 15:721-39.
31. The world health report 1997: conquering suffering, enriching humanity. Geneva, World Health Organization, 1997.
32. Resolution WHA51.18. Noncommunicable disease prevention and control. In: Fifty-first World Health Assembly, Geneva, 11 –16 May 1998. Volume 1. Resolutions and decisions, annexes. Geneva, World Health Organization, 1998 (WHA51/1998/REC/1).[i]
33. Prevention and management of osteoporosis. Report of a WHO Scientific Group. Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 921).
34. Kanis JA et al. The diagnosis of osteoporosis. Journal of Bone and Mineral Research, 1994, 9:1137–1141Schroder HM, Petersen KK, Erlandsen M. Occurrence and incidence of the second hip fracture. Clin Orthop Relat Res. 1993; 289:166-9.
35. Guidelines for preclinical and clinical evaluation of agents used in the prevention or treatment of postmenopausal osteoporosis. Rockville, MD, Food and Drug Administration, Division of Metabolism and Endocrine Drug Products, 1994.
36. Committee for Proprietary Medicinal Products. Note for guidance on postmenopausal osteoporosis in women. European Agency for the Evaluation of Medicinal Products, London, 2001 (CPMP/EWP/552/95 rev. 1)
37. Kamel HK, Hussain MS, Tariq S, Perry HM, Morley JE. Failure to diagnose and treat osteoporosis in elderly patients hospitalized with hip fracture. Am J Med. 2000; 109:326-8.
38. Lafleur J, Mc Adams Marx C, Kirkness C, Brixner D, Clinical risk factors for fracture in postmenopausal osteoporotic women; review of recent literature. Ann pharmacother.2008 mar, 42(3) 375-86
39. Jian Sheng Chen, Judy M. Simpson, Lya M.March, Ian D. Cameron, Robert G Cumming, Stephen R. Lord, Markus J. Seibel and Philip N. Sambrook. Fracture risk

assessment in fail older people using Clinical risk Factors. Age and Ageing 2008 37(5): 536 – 541

40. Black DM, Steinbuch M, Palermo L et al (2001). An assessment tool for predicting fracture risk in postmenopausal women. Osteoporosis Int 12:519–528
41. Steven R, Cummings, Michael L Nevitt, warren S. Browner, Katie Stone Kathleen M, Fox Kristine E. Ensrud, Jane Cauley, Dennis Back, Thomas M. Vogt, for the study of osteoporosis fractures research Group; risk Factors for hip Fracture in white women; march 1995: 332 (12): 767 – 774
42. Simonelli, C et al. (July 2006). "ICSI Health Care Guideline: Diagnosis and Treatment of Osteoporosis, 5th edition" (PDF). Institute for Clinical SystemsImprovement.http://www.icsi.org/osteoporosis/diagnosis_and_treatment_of_osteoporosis__3.html. Retrieved 2008-04-08.
43. Kohlmeier, Lynn Kohlmeier (1998**).** "Osteoporosis - Risk Factors, Screening, and Treatment". Medscape Portals. http://www.medscape.com/viewarticle/427342**.** Retrieved 2008-05-11.
44. Ebeling PR (2008). "Clinical practice. Osteoporosis in men**".** N Engl J Med 358 (14): 1474–82. doi: 10.1056/NEJMcp0707217. PMID 18385499**.**
45. Tucker KL, Morita K, Qiao N, Hannan MT, Cupples LA, Kiel DP (2006). "Colas, but not other carbonated beverages, are associated with low bone mineral density in older women: The Framingham Osteoporosis Study". Am. J. Clin. Nutr. 84 (4): 936–42. PMID 17023723.
46. Klotzbuecher CM, Ross PD, Landsman P, Abbott TAI, Berger M, Patients with poor facture has an increased risk of future fractures: a summary of the literature and statistical synthesis. J. bone Joint Surg Am 2000: 15:721 – 39
47. Freedman KB, Kaplan FS, Biller WB, Strom BL, Lowe RA, Treatment of Osteoporosis; are physicians missing an opportunity? J. Bone Joint Surg am 2000: 82 – A: 1063 – 70.
48. National Osteoporosis Foundation. Physicians guide to prevention and treatment of osteoporosis. Excerpta Medica, 1998

49. Dreinhofer KE, Anderson M, Feron JM et al, Multinational Survey of Osteoporotic fracture management. Osteoporosis Int. 2005: 16 Suppl 2: 544 – 553

50. Report / Technology Assessment No. 28 (Prepared by the Oregon Health and Science University Evidence-based Practice Center under contract No. 290-97-0018). Rockville, MD, Agency for Healthcare Research and Quality, 2002(AHRQ Publication No.

51. Cooper, C.: The crippling consequences of fractures and their impact on quality of life. Am. J. Med., 103(2A): 12S-17S, 1997.

52. Chrischilles, E. A.; Butler, C.D.; Davis, C.S.; and Wallace, R. B.: A model of lifetime osteoporosis impact. Arch. Intern. Med., 151: 2026-2032, 1991.

53. Jette, A. M.; Harris, B. A.; Cleary, P.D.; and Campion, E. W.: Functional recovery after hip fracture. Arch. Phys. Med. and Rehab., 68: 735-740, 1987

54. Poór, G.; Atkinson, E. J.; O'Fallon, W. M.; and Melton, L. J., III: Determinants of reduced survival following hip fractures in men. Clin. Orthop., 319: 260-265, 1995

55. VanderJagt DJ, Damiani LA, Goodman TM, et al. Assessment of the skeletal health of healthy Nigerian men and women using quantitative ultrasound. Bone 2004 Aug; 35(2): 387-94.

56. Statistic unit at Muhimbili Orthopaedic Institute (MOI) 2009

57. Muhimbili Orthopaedic Institute (MOI) Annual report July 2007- June 2008

58. Mc Grother CW, Donaldson MM, Claytai D, Abram KR, Clarke M, Evaluation of a hip Risk Score for assessing elderly women the Melton Osteoporotic fracture (MOF) Study; Osteoporosis Int. 2002 Jan; 13 (1): 89 – 96

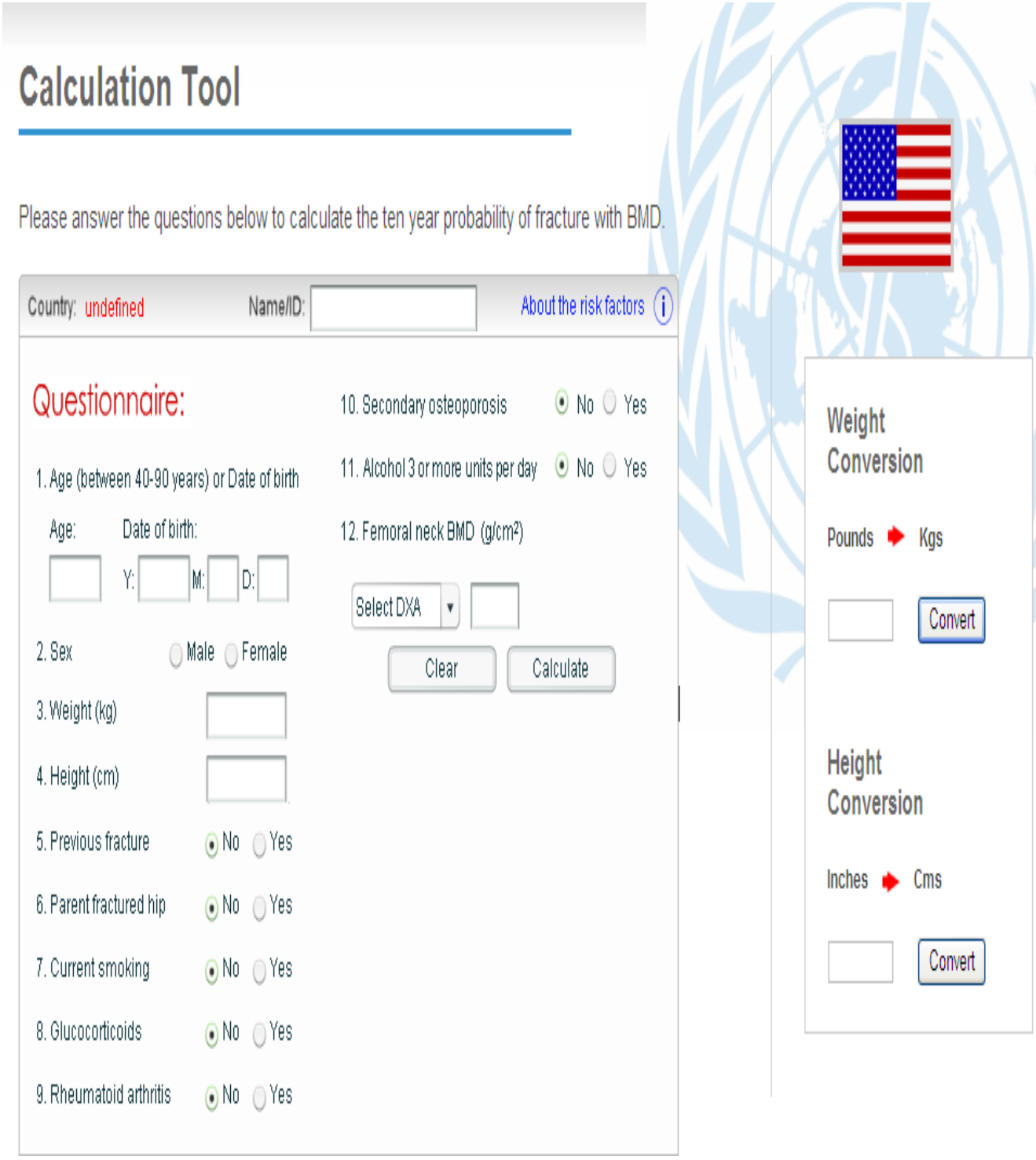
59. Kamel HK, Hussain MS, Tariq S, Perry HM, Morley JE. Failure to diagnose and treat osteoporosis in elderly patients hospitalized with hip fracture. Am J Med. 2000; 109:326-8.

60. J. A. Kanis O. Johnell, A Oden, H. Johansson, and E. Mc Closkey FRAX and the Assessment of Fracture probability in men and women from the UK; osteoporosis Int. 2008 April, 19 (4); 385 – 397

61. Nieves JW (1 May 2005). "Osteoporosis: the role of micronutrients." **.** Am J Clin Nutr 81 (5); 1232S-1239S. PMID 15883457. Available; http://www.ajcn.org/cgi/content/full/81/5/1232S**.**

62. Gong G,Haynatzki G, Haynatzka V,Kosoko-Lasaki S,et al. Bone Mineral Density of Recent African Immigrants in the United States. Journal of The National Medical Association 2006 May;98(5): 746 – 752

ANNEX 1: W.H.O. FRACTURE ASSESSMENT TOOL (FRAX)



QUESTIONNAIRE

1. Identification
    - Serial no……. Age……
    - Participant Phone……. Sex……
    - Hospital REG NO…….. Race…….
    - Name of participant…….. Tribe……
    - Date…… Occupation……
    - Weight…… Education…….
    - Height…… BMI……..

2. {i} Have any of your parents been diagnosed with a broken bone after a minor fall, at age 40 and above other than bone tumor or infection?

    {a} Yes

    {b} No

{ii} did either of your parents have a dowagers' hump"? Not caused by TB or bone tumor, at age 40 and above

    {a} Yes

    {b} No

{iii} Have you ever broken a bone or bones after a minor fall as an adult on which under normal circumstance you wouldn't

    {a} Yes

    {b} No

{iv} Do you fall frequently or do you have a fear of falling because

You are frail?

    {a} Yes

    {b} No

V. Do you have gait and balance disorder?

    {a} Yes

{b} No

3. Is your level of physical activity less than one hour per day?

{a} Yes

{b} No

{ii} Do you engaged yourself with any of these activities

a) House work
b) Garden
c) Walking
d) Running
e) Weight lifting
f) Sports
g) Others mentioned

{iii} How long do you work per day?

a) Less than one hour
b) More than one hour

{iv} How long do you sit or rest per day?

a) less than 4 hours
b) more than 4 hours

Do you have a tendency to sleep during the day every day?

a) Yes
b) No

4. Dou you currently or have you ever smoked cigarette or chewing tobacco?

a) Yes
b) No

{ia} If yes which one?

a) Smoking cigarette
b) Chewing tobacco

{ii} If yes how many packets per day

{iii} For how long have you been smoking cigarette?

{iv} for how long have you stop smoking cigarette?

5 (a) Dou you regularly drink alcohol? a) Yes b) No

(b) If yes which among this?

a) Beer or cider
b) Wine
c) Spirit
d) Local brew {specify}
e) Mixing

(c) How much

a) Beer< 2 bottle per day ,> bottle per day
b) Wine 1 glass per day,> 1 glass per day
c) Spirit 1 glass > 1 glass
d) Local brew 1 bottle, > bottle

6. Are you allergic to milk or dairy products?

a)Yes

b) No

(ii)Are you currently or have you been on any calcium medication?

a) Yes
b) No

7. for women

{i} At what age did you see your last menstrual period?

{ii} for women over 45 years

- Did your menopause occur before the age of 45?

  {a} yes

  {b} No

{iii} Have your periods ever stopped for 12 conservative months or more? {Other than

pregnancy, menopause or hysterectomy}

{a} Yes

{b} No

{Iv} Were your ovaries removed due to gynecological problem?

{a} Yes

{b} No

{v} if yes at what age?.....

{vI Are you taking hormonal replacement therapy?

a) Yes

b) No

{vii} If yes which one...

7(a) did you receive any of this drug currently or on the past few years?

- Estrogen
- Diuretics
- Corticosteroids
- Thyroid hormone
- Anti convulsion agents
- Anti acids
- Sleeping aids and anxiolytic drugs

7(b) for how long have you being receiving?

a) 3 month and more

b) less than 3 month

8. Do you have any of the following diseases?

a) Diabetic mellitus

b) Rheumatoid arthritis

c) Hyperthyroidism

DODOSO

Weka alama ya vema [√] kwenye jibu sahihi au jaza jibu katika nafasi zilizoachwa wazi.

1. Utambulisho

Namba ya dodoso.....	Umri.....
Namba ya Simu.....	Jinsia.....
Jina la mshiriki.....	Utaifa.....
Tarehe.....	Kabila.....
Uzito.....	Elimu.....
Urefu.....	BMI.....

2. (i) Je kuna mzazi wako yeyote ambaye alishawahi kuvunjika mfupa / mifupa katika umri mkubwa (zaidi ya miaka 40), kutokana na kuanguka au kuteleza? (Sio saratani ya mifupa au TB)

   {a} Ndiyo ( ) {b} Hapana ( )

   (ii) Je kuna mzazi wako yeyote mwenye kibiongo? (sio kutokana ma ajali au TB ya mifupa iliyopelekea kuvunjika mifupa ya mgongo)

   {a} Ndiyo ( ) {b} Hapana ( )

   (iii) Je umeshawahi kuvunjika mfupa / mifupa baada ya kuanguka katika umri mkubwa (zaidi ya miaka 40)? (kuvunjika ambako katika hali ya kawaida mtu mwingine asingevunjika)

   {a} Ndiyo ( ) {b} Hapana ( )

   (iv) Je baada ya umri wa miaka 40, unaona urefu wako umepungua zaidi ya sentimita 3?

   {a} Ndiyo ( ) {b} Hapana ( )

   (Kama anakumbuka urefu wako uliopita utaje)

   .....

(v) Je unakawaida ya kuanguka mara kwa mara, (zaidi ya mara 1 katika mwaka ulipita) au una woga wa kuanguka kwasababu una udhaifu?

{a} Ndiyo ( ) {b} Hapana ( )

(vi) Je unapotembea unachechemea au kupepesuka?

{a} Ndiyo ( ) {b} Hapana ( )

3. (i) Je huwa unajishughulisha na nini kila siku, kuanzia asubuhi mpaka jioni?

(a) Kazi za nyumbani {a} Ndiyo ( ) {b} Hapana ( )

(b) Kazi za bustani {a} Ndiyo ( ) {b} Hapana ( )

(c) Kutembea {a} Ndiyo ( ) {b} Hapana ( )

(d) Kukimbia {a} Ndiyo ( ) {b} Hapana ( )

(e) Kunyanyua vitu vizito (mazoezi ya viungo)

{a} Ndiyo ( ) {b} Hapana ( )

(f) Michezo {a} Ndiyo ( ) {b} Hapana ( )

(g) Nyinginezo, tafadhali zitaje.....

(ii) Je ni muda gani unatumia kufanya kazi?

(a) Chini ya saa moja ( )

(b) Zaidi ya saa moja ( )

(iii) Je unatumia muda gani kupumzika kwa siku?

(a) Chini ya saa nne ( )

(b) Zaidi ya saa nne ( )

(iv) Je una kawaida ya kulala kila siku mchana?

{a} Ndiyo ( ) {b} Hapana ( )

4. (i) Je unavuta au ulishawahi kuvuta sigara au kumumunya ugoro?

{a} Ndiyo ( ) {b} Hapana ( )

(ia) Kama ndiyo, ni ipi?

{a}sigara {b} ugoro

{ii} Kama ndiyo sigara ngapi kwa siku?.....

(iii) Je ni kwa muda gani umekuwa ukivuta sigara.....

(iv) Kama umeacha ni kwa muda gani?.....

5. (i) Je una kawaida ya kunywa pombe?

{a} Ndiyo ( ) {b} Hapana ( )

(ii) Kama ndiyo, ni aina gani ya pombe katika hizi zilizoorodheshwa hapa chini?

(a) Bia (taja aina).....

(b) Mvinyo (taja).....

(c) Pombe jamii ya "Whisk" ( )

Pombe jamii ya "Brandy" ( )

Pombe jamii ya "Konyagi" ( )

Pombe jamii ya "Viroba" ( )

(d) Pombe za kienyeji (taja).....

(e) Mchanganyiko (taja, kwa mfano bia na whisky, kienyeji na bia nk.).....

(iii) Kiasi gani cha pombe unakunywa?

- **Kwa pombe jamii ya bia**

(a) Chini ya bia moja kwa siku ( )

(b) Bia moja kwa siku ( )

(c) Zaidi ya bia moja kwa siku ( )

- **Kwa pombe jamii ya mvinyo**

(a) Robo glasi kwa siku ( )

(b) Glasi moja kwa siku ( )

(c) Zaidi ya glasi moja kwa siku ( )

- **Kwa pombe jamii ya whisky**

(a) Robo glasi kwa siku ( )

(b) Glasi moja kwa siku ( )

(c) Zaidi ya glasi moja kwa siku ( )

- **Kwa pombe za kienyeji**

(a) robo au nusu ya; chupa ya soda, bia, konyagi, chibuku, au glasi kwa siku
( )

(b) chupa moja ya; soda, bia, konyagi, chibuku au glasi moja kwa siku.
( )

(c) Zaidi ya chupa moja ya; soda, bia, konyagi, chibuku au glasi moja kwa siku
( )

- **Kwa pombe mchanganyiko**

(a) Robo au nusu glasi kwa siku ( )

(b) Glasi moja kwa siku ( )

(c) Zaidi ya glasi moja kwa siku ( )

(iv) Je ulianza kunywa ukiwa na umri gani? Tafadhali utaje.....

(v) Je bado unakunywa au umeacha?

{a} Nakunywa ( ) {b} Nimeacha ( )

6. (i) Je una 'aleji' ya maziwa au vyakula vilivyotengenezwa kwa maziwa?

{a} Ndiyo ( ) {b} Hapana ( )

(ii) Je unatumia vidonge vya kalisiamu? (Calcium)

{a} Ndiyo ( ) {b} Hapana ( )

7. Kwa wanawake

(i-a) Je ni katika umri gani umeacha kuona siku zako? Tafadhali taja.....

(i-b) Bado unapata siku? {a} ndiyo

(ii) Je siku zako zimewahi kusimama kwa muda wa mwaka mmoja? (Bila kusababishwa nautumiaji wa dawa za uzazi wa mpango, ujauzito au kuondolewa kizazi)

{a} Ndiyo ( ) {b} Hapana ( )

(iii) Je ulishawahi kufanyiwa operesheni ya kuondoa vifuko vya kubebea mayai ya uzazi (ovaries) kwa sababu ya magonjwa ya kizazi, chini ya umri wa miaka 50?
{a} Ndiyo ( ) {b} Hapana ( )

(iv) Kama ndiyo je ulipewa dawa aina ya "hormone"? (Dawa za kuzuia mimba/ majira au jamii yake)
{a} Ndiyo ( ) {b} Hapana ( )

(v) Je ni katika umri gani? Taja.....

(vi) Je unatumia dawa za "hormone"? (Dawa za kuzuia mimba /majira au jami yake)
{a} Ndiyo ( ) {b} Hapana ( )

(vii) Kama ndiyo, je ni aina gani? .....

8. (i) je unatumia au umeshatumia dawa hizi?
   - Estrogen {a} Ndiyo ( ) {b} Hapana ( )
   - Diuretics (Dawa za kutibu presha{a} Ndiyo ( ) {b} Hapana ( )
   - Conticosteroids (Dawa za pumu) {a} Ndiyo ( ) {b} Hapana ( )
   - Thyroid hormone (Kuvimba kwa shingo mbele) {a} Ndiyo( ) {b} Hapana ( )
   - Anti convubian agent, mfano Tegretoz Phenobabitone (Kifafa, kushtukashtuka, maumivu ya kichwa ya muda mrefu)
     {a} Ndiyo ( ) {b} Hapana ( )
   - Anti acid (dawa za vidonda vya tumbo) {a} Ndiyo ( ) {b} Hapana ( )
   - Sleeping aids and anxiolytic drugs (Dawa za usingizi au hali ya wasiwasi)
     {a} Ndiyo ( ) {b} Hapana ( )

   (ii) kama ndiyo ulitumia dawa hizi kwa muda gani?
   (a) Miezi 3 na zaidi ( )
   (b) Chini ya miezi 3 ( )

9. Je unaugua mojawapo ya magonjwa haya?(a) Ndiyo (b) Hapana

   (i) Kisukari ( )

   (ii) Ugonjwa wa kukakamaa viungo (Rheumatoid arthritis) ( )

   (iii) Ugonjwa wa kuvimba tezi la shingo (Hyperthyroidism) ( )

CONSENT FORM

Title of the study

The use of Clinical Risk Factors in assessment of fracture risk and its application to screening for osteoporosis in Muhimbili Orthopaedic Institute (MOI)

Purpose

The aim of this study is to determine Clinical Risk Factors as a tool for screening of osteoporosis and assessment of fracture risk in Muhimbili Orthopaedic Institute (MOI). The proportion of patients with osteoporosis and osteoporotic fracture will be determined. All patients with risk factors for development of osteoporotic fractures will be identified taught about preventive measures and treatment will be offered. The aim is also to study on the kind of management given to patients with osteoporosis and osteoporotic fractures in our center prior to this study. I intend to enroll about 560 patients and I would be grateful if you will agree to participate in this study. Once you agree you will be asked some questions your person particular and health, measurements will be taken and whenever necessary investigations will be done on which participants and investigator will discuss and agree to each other.

Procedure

In this study W.H.O risk factors identified from individual patient will be used to calculate 10 years probability of major osteoporotic and hip fractures using FRAX index. Measurement will be taken using tap measure and calibrated weighed scale, measured in centimeter and weight using weighing scale in kilogram and were taken at OPD clinic, EMD and in the

wards. BMI was calculated using (Kg/m^2). Those who will be found to have risk for osteoporotic fracture treatment will be offered.

Risk and discomfort

No risk for you to participate in this study while taking measurements for patients all measures will be taken to make sure that you don't get hurt

Benefit

Agreed to participate in this study will assist us to identify patients at risk of suffering from osteoporotic fractures. It will enable us to come up with our own practical guidelines on identification of osteoporoses and prediction of osteoporotic fractures, preventive measures and management guideline on the patients attending in our institute.

Confidentiality

Your medical record will not be disclosed to any one unless you consent to it if need be.

Participation

Your participation in this study is voluntary and therefore any decision you made will be respected.

Signature

If you agree to participate in this study, I request you to sign or press your finger print below

Signature of subject ……..Date

Signature of investigator ……..Date

FOMU YA RIDHAA

Huu ni waraka wa kuomba ruhusa ya kushiriki katika utafiti iitwayo The use of Clinical Risk Factors in assessment of fracture risk and its application to screening for osteoporosis in Muhimbili Orthopaedic Institute (MOI)

Dhumuni

Lengo kubwa la kufanya utafiti huu ni kuangalia tabia hatarishi zinazosababisha watu kupata ugonjwa wa uchakavu na udhaifu wa mifupa (Osteoporosis) unaopelekea watu kuvunjika kwa urahisi katika hali ambayo kwa kawaida wasingevunjika aidha kwa kujigonga kidogo au kwa kuanguka na kuweza kuwagundua wale walio na ugonjwa huo.. Hali hiyo inawapata zaidi watu katika umri mkubwa haswa wanawake na kuwapelekea kuwa tegemezi na kufariki mapema. Ukubwa wa ugonjwa huu miongoni mwa jamii utajulikana na idadi ya wale walio katika hatari ya kuvunjika itagundulika. Wale walio katika hatari ya kuvunjika watapatiwa matibabu na kushauriwa wafanye nini ili kujiepusha na tatizo hilo kwa huko mbeleni. Pia katika utafiti huu tutaangalia aina ya matibabu yanayotolewa kwa wagonjwa wenye tatizo hili na wale waliovunjika katika taasisi ya mifupa ya MOI. Nina lengo la kuandikisha watu wazima 560 wenye umri wa miaka 40 na kuendelea, watakaohudhuria MOI kwa matibabu. Nitafurahi kama utaitikia wito huu na kushiriki, ukikubali tutakuuliza maswali mbali mbali kuhusu mwenyewe na afya yako. Utapimwa urefu na uzito na kuchukuliwa vipimo vinginevyo pale itakapobidi kwa ridhaa yako.

Utaratibu

Utakapoingia katika utafiti huu tabia hatarishi zinazopelekea mifupa kuvunjika haraka zitakazogunduliwa kwa kutumia vigezo vya Shirika la Afya duniani zitatumika kugundua wale walio katika hatari ya kuvunjika mifupa katika kipindi cha miaka 10 ijayo kwa kukotoa tabia hizo kwenye kipimo kiitwacho ‘’FRAX index’’. Urefu na uzito wa mshiriki utapimwa kwa kutumia futi kamba katika sentimeta na uzani katika kilogramu kwa meta ‘’square^2 ‘’ Hii itafanyika katika clinics, kitengo cha huduma za dharura na kwa wale watakaolazwa. yatawekwa kwenye kumbukumbu. Matibabu na ushauri utatolewa kwa wale watakaokutwa na hatari ya kuvunjika..

Madhara

Hakuna madhara yeyote kwa wewe kushiriki katika utafiti huu, uangalifu mkubwa utachukuliwa ili usiumie. wakati wa kuchukua vipimo.

Faida

Ikiwa utakubali kushiriki utakuwa umetusaidia sana kufaya utafiti huu kwa kutuwezesha kutambua wale wote wenye ugonjwa huu wa udhaifu na uchakavu wa mifupa na wale walio katika hatari ya kuvunjika mifupa. Hii itatusaidia kutengeneza utaratibu utakaofaa katika mazingira yetu utakaotuwezesha kuwagundua wagonjwa wenye tatizo hili, jinsi ya kulizuia na utaratibu mzima wa kutoa matibabu kwa wale wagonjwa watakaogunulika hapa MOI.

Usiri

Maelezo ya afya yako hayatakuwa bayana kwa watu wengine mpaka wewe mwenyewe utoe ridhaa.

Uhuru wa kujitoa

Uamuzi wowote wa kushiriki katika utafiti huu ni wa hiyari, kwa hiyo uamuzi wowote utakaoamua utaheshimiwa

Sahihi

Kama utakubali kushiriki, tunaomba uweke saini au dole gumba

Sahihi ya muhusika …… tarehe ……..

Sahihi yangu …… tarehe ……..