RADIOLOGICAL PATTERN OF UPPER LIMB FRACTURES AMONG PATIENTS ATTENDING MUHIMBILI ORTHOPAEDIC INSTITUTE FROM AUGUST 2016- FEBRUARY 2017

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By

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A Dissertation Submitted in Partial Fulfillment of the Requirement for the Degree of Master of Medicine (Radiology) of Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The under signed certify that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; "***Radiological patterns of upper limb fractures among patients attending Muhimbili Orthopedic Institute***", in (partial) fulfillment of the requirement for the degree of Master of Medicine (Radiology) of the Muhimbili University of Health and Allied Sciences.

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Dr. Mechris Mango

(Supervisor)

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Date

DECLARATION AND COPYRIGHT

I, **Tawfeeq I Sangey**, hereby declare that this **dissertation** is my 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 …….

ACKNOWLEDGEMENT

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DEDICATION

This work is dedicated to my lecturers and colleagues at MUHAS. Thank you for making learning interesting and memorable.

To my beloved Sangey family for supporting and encouraging me.

ABSTRACT

INTRODUCTION

The upper extremities are the second most common musculoskeletal injuries following lower extremities in the emergency department. Over the past few years due to economic and demographic variation, prevalence of upper extremities fractures has increased with simultaneously increase in relative mortality. The study aimed to describe fracture patterns of upper extremity long bones and its associated mechanism of injuries.

METHODOLOGY

This was a hospital based descriptive cross sectional study, conducted at MOI from August 2016 to February 2017. A structured questionnaire was used to collect clinical information and radiologic findings from radiographs were extracted. SPSS (version 20) was used for data analysis, Chi-square test was used and P-value of 0.05 was considered statistically significant.

RESULTS

A total of 210 patients participated in the study. Male to female ratio was 2.6:1. Majority of fractures were observed in age group 0-15. Fall from height and slip were the common mechanisms of injuries observed in age group 0-15 and RTA was observed in young adults age group 16-30 and 31-45. Radius was the most frequently fractured bone (39.3%) and humerus was the least fractured (26.7%). Distal segments of both radius and ulna were most commonly fractured with prevalence of 57.1% and 51.5% respectively. For humerus, middle segment was commonly fractured at 41.3%. Simple transverse fracture pattern was the most prevalent (51.8%), followed by oblique fractures (28.6%), comminuted fractures (11.8%) and the least common was segmental fractures (1.8%). Humerus fracture was significantly associated with RTA (p=0.019) and significantly not associated with sport (p=0.0032).

The radius fracture was significantly associated with RTA (p=0.001), sports (p= 0.002) and slip (p=0.005). Ulna fracture was not significantly associated with any mechanism of injury.

CONCLUSION

Children 0-15 years were commonly involved, mainly due to fall from height or slip. Humerus fractures were associated RTA and significantly not associated with sports. Radius fractures were associated with RTA, sports and slip. No injury mechanism associated with ulna fractures.

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LIST OF ABBREVIATION

RTA	Road Traffic Accident
MOI	Muhimbili Orthopaedic Institute
MNH	Muhimbili National Hospital
USA	United State of America

CHAPTER ONE

INTRODUCTION

The upper extremities are the second most common musculoskeletal injuries following lower extremities in the emergency department with prevalence ranging from 20.5% to 41.1%(2,3,4,5). Other studies have documented higher incidence of upper extremities than lower extremities with 56.6% in India and 60% in Eastern Ethiopia.(5,6).

A study done in MOI, the upper extremities prevalence was 14.3% among motor cycle crash in 2012(7). RTA contributes significantly to the burden of musculoskeletal injuries in Tanzania mainly due to motorcycling, which is now an emerging mode of transportation.(8)

The magnitude of the force varies from high energy impact such as RTA, fall from height and abusive strike to the low energy impact such as fall from a standing position or less (9,10). Therefore, the more complex fracture pattern the greater the energy required to produce the fracture.(10)

Fracture classifications are used to guide treatment, estimate prognosis, and hence predict the risk of complications. (11) The most frequently used classification systems for shaft fracture was proposed by Muller AO according to location was proximal third, midshaft and distal third.(12)Moreover a fracture pattern can further be classified by its morphology into transverse, oblique, spiral, spiral-wedge or segmental. (10,13).

Transverse fractures run approximately right angles to the long axis of the affected bone, Oblique fractures runs diagonally across the diaphysis with short blunt fracture usually

ending at a 45° angle with no vertical segment (10). They are located mostly on the impact aspect indicating even greater shear forces than tension forces.(10).

Spiral fractures are caused by rotational forces on the bone; it has a long sharp pointed ends and vertical segments in contrast to oblique (10). Spiral patterns are highly associated with abusive trauma and incautious trauma like tripping while running.((14).

Segmental fracture is when multiple fractures leave diaphyseal portions separated from the proximal or the distal ends and comminuted fracture is the one in which more than two fragments are generated at the fractured site.(10)

LITERATURE REVIEW

Upper limb fractures prevalence has bimodal distribution, most commonly seen in children under 15 years and in elderly above 50 years(1,15,16). Young adults of age group 15-40 years are at greater risk for upper extremities fracture due to RTA. (3,4,5,6)

Upper limb fractures occur more commonly in males than female.(3,4,5,6,11) However, rates are higher in males than females from childhood to about 50 years of age and are higher in females than males above 65 years of age.(15,18,19)

The nature of the injuring force determines pattern of the bone fracture. Certain types of fracture pattern are associated with specific related complications for example transverse and spiral fractures had a significantly higher occurrence of radial nerve palsy $p < 0.001$.(20)

The most common fracture pattern is transverse fracture followed by oblique, comminuted and the least is spiral.(2,4). In another study highest prevalence was for comminuted, transverse and oblique pattern in a decreasing order.(3)

Humerus fracture accounts for 3% of all orthopedic fractures.(14) Most common site of humerus fracture is proximal followed by middle and distal.(16,17,18,19) Proximal fractures occur commonly in older patients and distal fractures occur in children and the most common mechanism are falls and RTA.(16,17,18,19) A significant correlation of fall with humerus fracture p-0.000 has been reported.(26) In another study the was no significant association of humerus fracture with falls and RTA p-0.619.(19)

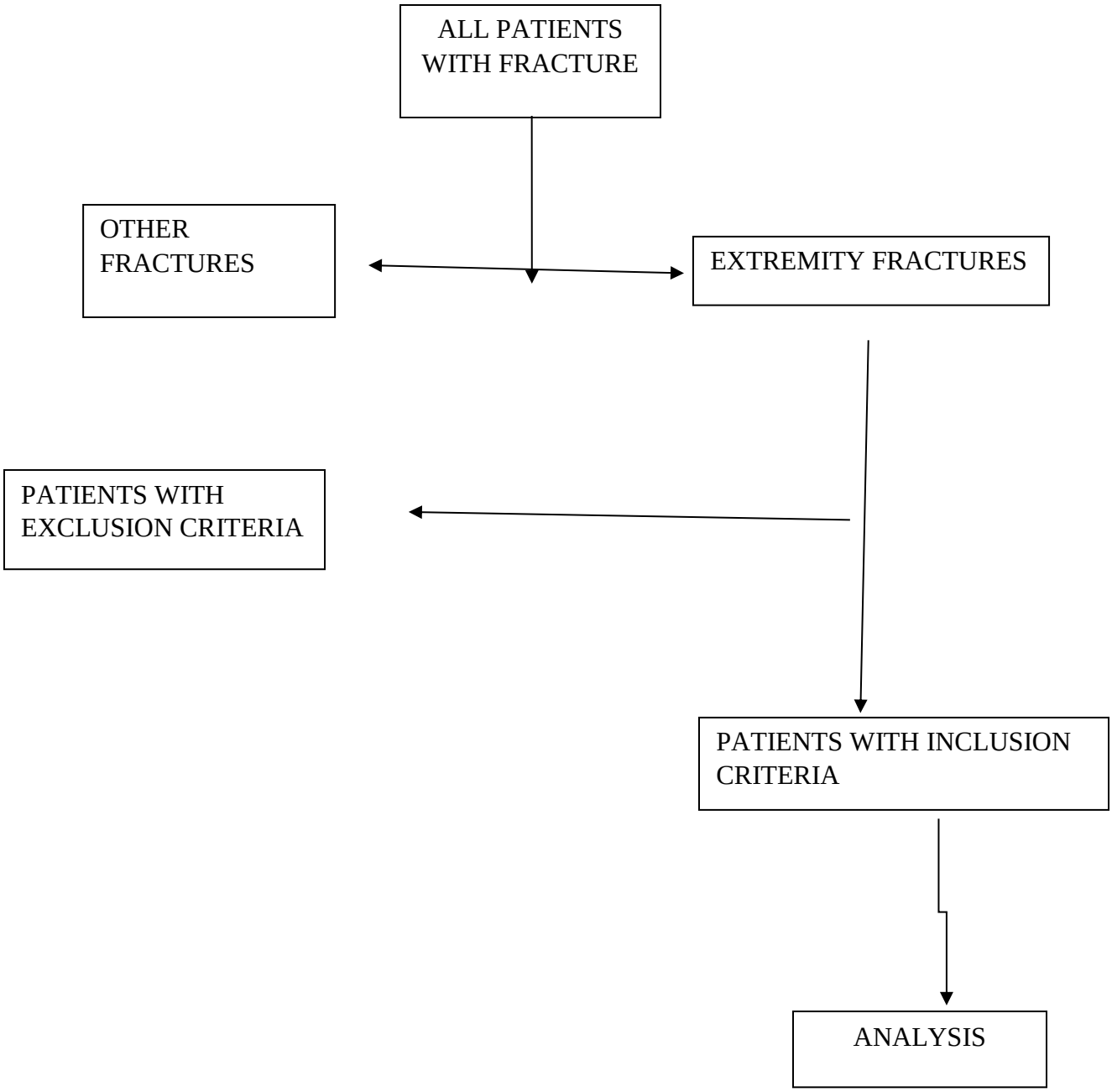
Radius fracture occur most commonly at its distal ends, the most common type of fracture accounting for (23% - 25%) and (17% - 18%) in pediatrics and elderly population respectively.(12,22)

A study done in India showed the prevalence of radius according to site of fracture, distal (69.3%) was most common followed by middle (23.4%) and least was the proximal (7.3%).(17)

Sports related distal radius fractures occur in young population compared with the classic fragility fracture caused by falls seen in children and elderly.(21,22,23)

Ulna fracture occurs least among upper extremities fractures (3,4,30). In another studies it appears second most common following radius fracture.(5,17) Prevalence of shaft of ulna is 3.06% - 4.4%.(4,30) Distal ulna is the most common site with prevalence of 47.5%, followed by mid (39.9%) and proximal (12.5%).(17) Similar trend was seen in another study, distal 50%, middle 15% and proximal 2.5%.(4) In several studies ulna fracture occurs along with radius fracture at its distal end.(3,4,5)

CONCEPTUAL FRAMEWORK



PROBLEM STATEMENT

Road traffic injuries in Tanzania are an important public health problem.(8,31,32). A study done in 1998 showed RTA were responsible for 56% of admission in MNH.(31) The proportion of motor cycles injuries among RTA was found to be higher ranging from 53.4% to 66.3%. (8,31) The upper limb fracture being the second most common injury site with 14.3%.(7)

Tanzania with a dynamic change in socio – economic status, has seen an increase in motor cycle usage both as a commercial means of transportation and private. Motor cycle injuries and especially upper limb fractures are expected to increase. The fracture patterns may be specific to injury mechanism and hence predicting prognostic outcome such as complication like radial nerve palsy and vascular injuries. It will also influence the fracture management and treatment in future.

RATIONALE

The rapid increased use of motorcycles particularly in urban areas has been implicated as one of the major contributing factors to road traffic injuries, therefore identification of the precise pattern of injury, target groups involved and correlation to the mechanisms antecedent to the injury is important to appropriately manage these cases as well as institute preventive strategies.(33)

The aim of this study is to provide epidemiologic description of patterns of the upper limb fracture. Also it is equally expected to determine the association between the fractured bone and the mechanism of the injury.

This study will be used by the hospital management as a basis for forecasting resources needed for management and treatment of such type of injuries.

The study will also help in the accomplishment of the MMed Radiology Degree Program at MUHAS.

RESEARCH QUESTION

What are the radiological patterns of upper limb fractures among patients seen at (MOI) between August 2016 and February 2017?

OBJECTIVES

Broad Objective: To determine the patterns, distribution and associated factors of upper limb fractures among patients attending at MOI from August 2016 to February 2017.

Specific Objectives:

1. To determine the demographic data (age & sex) of patients with upper limb fractures among patients attending at MOI from August 2016 to February 2017.
2. To determine the patterns and distribution of the upper limb fractures among patients attending at MOI from August 2016 to February 2017.
3. To determine association between mechanism and upper limb fractures among patients attending at MOI from August 2016 to February 2017.

CHAPTER TWO

METHODOLOGY

Study Design

This is a hospital based descriptive cross sectional study.

Study Population

This study involved all patients referred to MOI causality department with traumatic upper limb fractures and undergoing radiographic evaluation during the study period.

Study Area

The study was carried out at the casualty department of MOI, it is the only tertiary hospital offering orthopedics and neurosurgery service located in Dar es Salaam, Tanzania, which also serves as a teaching hospital for MUHAS. The patients were referred from municipal hospitals, neighboring regional hospitals or self-referral. The casualty department of MOI admits an average of 26 patients per day.

Data collection tools and methods

A structured questionnaire was used to collect personal and clinical information including social demographic and mechanism of injury from each consenting participant. Orthogonal x-ray films (AP and Lateral) were generated by Philips Optimus and interpreted by both researcher and radiologist in charge.

Duration of the study

Data for this study will be collected over a period of seven months, from August 2016 to February 2017.

Sample Size

The sample size was calculated using the following formula (Creative Research Systems, 2015):

$$n = \frac{Z^2_{\alpha/2} P(1-P)}{E^2}$$

Where: n = sample size, P = estimated prevalence or proportion of patients presenting with lower extremity fractures at MOI, E = error margin which is 0.05, and $Z\alpha_{/2}$= 1.96.

A study at done at MOI on motor traffic accidents calculated its sample size assuming a prevalence of 14.3%(, Bryson Mcharo 2012). Therefore, this study made the same assumption to calculate the minimum sample size required for the current study. So;

$$\mathbf{n} = \frac{(\mathbf{1.96})^{\mathbf{2}} \times \mathbf{0.14} \times (\mathbf{1} - \mathbf{0.14})}{(\mathbf{0.05})^{\mathbf{2}}} = \mathbf{188}$$

Then assuming a 10% non-response rate, the final minimum sample size became 206.

Inclusion criterion

All patients with the fracture of humerus, radius and ulna are eligible for inclusion in the current study.

Exclusion criteria

Those who will refuse.

Sampling Technique and Procedure

All patients who met the inclusion criteria were consecutively enrolled into the study after giving a written consent. For those patients with altered level of consciousness, their next of kin had given consent on their behalf and for the children, consent from the parents / guardian was obtained.

Data entry and management

The filled questionnaires were checked for quality, coded and entered into Statistical Package for Social Studies (SPSS program version 20). Frequency distributions will be used to describe categorical variables, and means and standard deviation for continuous variables. Chi-square test was used to test for association of categorical variables. P-value of 0.05 was considered significant.

Variables and data analysis

Outcome or dependent variable

This study will have one outcome variable, namely, upper extremity fracture patterns. This was categorical variable with sub categories as:

Patterns - Simple transverse, Oblique, comminuted, Spiral and Segmental.

Level – Proximal, Middle, And Distal.

Mechanism of injury – RTA, Sports, Slip, falls from height and Assault.

CHAPTER THREE

RESULTS

Aim of the study is to describe the epidemiology of radiological fracture patterns of upper extremity long bones and its associated risk injuries.

Descriptive results

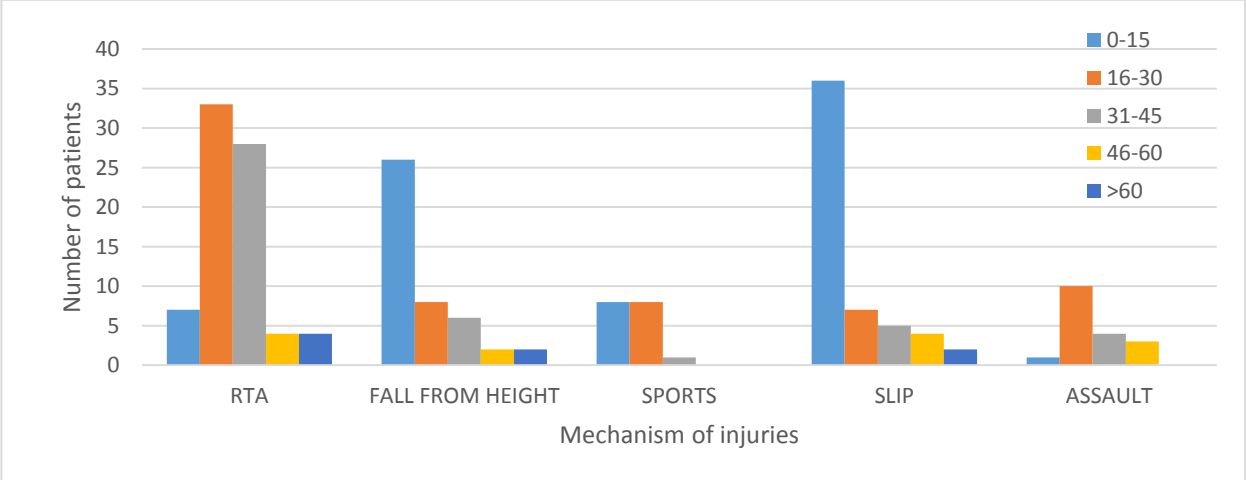
The number of participants in this study were 210 and number of bones fractured were 280 (i.e. one person had multiple bone fractures).

Table 1: The demographic characteristics (age & sex) of patients with upper limb fractures among patients attending at MOI from August 2016 to February 2017.

Sociodemographic Variables	Number of participants	Percentage (%)
Age group (years)		
0-15	78	37.1
16-30	66	31.4
31-45	45	21.4
46-60	13	6.2
>60	8	3.8
Total	210	100.0
Gender		
MALE	164	78.1
FEMALE	46	21.9
Total	210	100.0

Table 1: The number of participants in this study were 210 in which males were 164(78.1%) and females were 46(21.9%) with ratio of (2.6:1). The mean age was 24.49 years old with range of 87(2-89) years old and standard deviation of 16.5. As shown in the table above, most injuries were from age group of 0-15 years old 78(37.1%), followed with of 16-30 years old 66(31.4%).

Figure 1: The mechanisms on injury with age group of patients with upper limb fractures among patients attending at MOI from August 2016 to February 2017. N=210.



The results show that, in RTA most affected age group was the young age 16-30 years old followed with age group of 31-45 years old. The figure also depicts that fall from height and slip injured most patients with age group of 0-15 years old. From the sports the age group of 0-15 and 16-30 years were injured equally**.**

Table 2: The distribution of bone fracture with fracture patterns of patients with upper limb fractures among patients attending at MOI from August 2016 to February 2017. N=280

BONE FRACTURED	FRACTURE PATTERN					
	SIMPLE TRANSVERSE	SPIRAL	OBLIQUE	SEGMENTAL	COMMINUTED	TOTAL
Humerus	18(24.0%)	12(16%)	25(33.3%)	1(1.3%)	19(25.3%)	75(26.7%)
Radius	73(66.4%)	3(2.7%)	26(23.6%)	2(1.8%)	6(5.5%)	110(39.3%)
Ulna	54(56.8%)	2(2.1%)	29(30.5%)	2(2.1%)	8(8.4%)	95(33.9%)
Total	145(51.8%)	17(6.1%)	80(28.6%)	5(1.8%)	33(11.8%)	280

Table 2: Simple transverse has the highest frequency 51.8% of all patterns. Simple transverse was most common seen in radius and ulna with prevalence of 66.4% and 56.8% respectively. Oblique pattern was common in humerus33.3%. Segmental fracture had the least frequency in all upper limb long bones.

Table 3: The distribution of fracture bone with the bone level of patients with upper limb fractures among patients attending at MOI from August 2016 to February 2017. N=280

BONE	FRACTURED LEVEL			
	PROXIMAL	MIDDLE	DISTAL	TOTAL
Humerus	17(22.7%)	31(41.3%)	27(36.0%)	75(100%)
Radius	9(8.2%)	38(34.5%)	63(57.3%)	110(100%)
Ulna	8(8.4%)	38(40.0%)	49(51.5%)	95(100%)
TOTAL	34(12.1%)	107(38.2%)	139(49.6%)	280 (100%)

Table 3: Radius was most frequently fractured (39.3%) and humerus was least fractured (26.7%). Distal segment of both radius and ulna were most commonly fractured site with

57.1% and 51.5% respectively. For humerus bone, middle segment was highly fractured 41.3%.

Table 4: The risk factors with humeral fracture of patients with upper limb fractures among patients attending at MOI from August 2016 to February 2017.

MECHANISM OF INJURY	HUMERUS FRACTURE			**Pearson's X^2**	**P-value at 95% CI**
	YES	NO	TOTAL		
RTA	35(46.7%)	41(30.4%)	76(36.2%)	5.545	**0.019**
SPORTS	2(2.7%)	15(11.1%)	17(8.1%)	4.621	**0.032**
FALL FROM HEIGHT	18(24.0%)	27(20.0%)	45(21.4%)	0.458	0.498
SLIP	16(21.3%)	38(28.1%)	54(25.7%)	1.420	0.233
ASSAULT	4(5.3%)	14(10.4%)	18(8.6%)	1.561	0.212

Table 4: The results shown that RTA (46.7%) was significantly associated with humeral bone fracture with P=0.019 and Sport 2(2.7%) was not significantly associated with=0.032 as shown in the table above.

Table 5: The risk factors with radius fracture of patients with upper limb fractures among patients attending at MOI from August 2016 to February 2017

MECHANISM OF INJURY	RADIUS FRACTURE			Pearson's X^2	P-value at 95% CI
	YES	NO	TOTAL		
RTA	28(25.5%)	48(48%)	76(36.2%)	11.530	**0.001**
SPORTS	15(13.6%)	2(2.0%)	17(8.1%)	9.533	**0.002**
SLIP	37(33.6%)	17(17.0%)	54(24.8%)	7.589	**0.006**
FALL FROM HEIGHT	23(20.9%)	22(22.o %)	45(21.4%)	0.037	0.847
ASSAULT	7(6.4%)	14(11.0%)	18(8.6%)	1.437	0.231

Table 5: The results found that there was strong significance relation between radius bone fracture with RTA 28(25.5%), Sport 15(13.6%) and slip 37(33.6%) with significance levels of P=0.001, P=0.002 and P=0.006 respectively as depicted in the table above.

Table 6: The risk factors with ulna fracture of patients with upper limb fractures among patients attending at MOI from August 2016 to February 2017.

MECHANISM OF INJURY	ULNA FRACTURE			Pearson's X^2	P-value at 95% CI
	YES	NO	TOTAL		
RTA	31(32.6%)	45(39.1%)	75(36.2%)	0.951	0.329
SPORTS	9(9.5%)	8(7.0%)	17(8.1%)	0.443	0.506
SLIP	23(24.2%)	31(27.0%)	54(25.7%)	0.205	0.650
FALL FROM HEIGHT	21(22.1%)	24(20.9%)	45(21.4%)	0.047	0.828
ASSAULT	11(11.6%)	7(6.1%)	18(8.6%)	2.002	0.157

Table 6: There is no significant association between fracture of ulna and any of the mechanism of injury as shown in the table.

CHAPTER FOUR

DISCUSSION

The upper extremity injuries are a relevant part of all emergency department attendance as well as hospital admission due to trauma in MOI (Tanzania).

In present study males had more upper extremities fractures than females with male to female ratio of 2.6:1. This is similar to previous studies(3,4,5,6). This may be due to males are exposed to engaging more in greater risk occupational activities such as motor cycling and sports(34)

Children (0-15yrs) had more upper extremity fractures than other age groups. This is similar to previous studies(1,16,25). This is because children below 15 years are physically active and are prone to falls (26,27,29).Also young people below 30years presented with slightly more fractures than elderly. This is because people aged below 30years involved in sports which exposes them also to upper extremities fracture(26,27,29). Upper extremity fractures in the age group of 16 – 45 years were commonly caused due to RTA just as it adheres with other studies.(3,4,5,6,26). In our study we had less participants aged >65 years.

Radius was most frequently fractured (39.3%) with its distal site being frequently involved (57.3%)and humerus was least (26.7%) fractured bone, a similar trend was seen in other studies.(3,5,17). This is because more than 2/3rd of the fractures were due to low energy trauma (fall, slip and sports) resulting to an injury on the outstretched hand while falling.(9,27).In respect to fracture level of humerus bone, preponderance of distal over proximal could be explained by greater prevalence of children in our study incongruent with previous study.(23)

The most common fracture pattern was simple transverse followed by oblique, comminuted, spiral and segmental in descending order, similar patterns were reported in other studies(2,4). Transverse pattern is the most frequently observed because of low energy impact on a bone creates weaker tensional force than compression force.(10,14)

And also transverse pattern is most likely to occur on a bone due to elasticity of immature children bone (14). Increase in number of Transverse fracture were due to direct trauma in many cases(2) Moreover, from our study majority victims were children and most fractures were due to low energy forces.

From the index study regarding mechanism of injury, humerus fracture was statistically associated with RTA consistent with other studies. Another study reported no significant correlation between mechanism and humerus fracture. (36) Meanwhile the radius fracture is statically associated with RTA p=0.001, sports p= 0.002 and slip p =0.006.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATION

CONCLUSION

Children 0-15 years were commonly involved mainly caused by fall from height and slip. Increase in number of Transverse fracture pattern were due to direct trauma in many cases. Humerus fractures were associated RTA and significantly not associated with sports. Radius fractures were associated with RTA, sports and slip. No injury mechanism associated with ulna fractures**.**

RECOMMENDATION

A detailed study should be conducted for each anatomical bone and specific age group. Diagnosis is often straightforward, but certain patterns of injury may be more complex and elude detection. Always review at least two orthogonal views e.g. AP and Lateral are important**.**

STUDY LIMITATION

This study was done in one tertiary hospital and data was collected over a short period of time so the findings may fail to reflect the true picture of upper extremities fracture pattern.

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APPENDIX I: QUESTIONNAIRE

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
SCHOOL OF MEDICINE - DEPARTMENT OF RADIOLOGY
P.O.BOX 65001 MUHIMBILI
DAR ES SALAAM
TANZANIA

Identity number …….

NO.	QUESTION AND EXPLANATIONS	RESPONSE		SKIP
Q1	Age (in years)			
Q2	Sex	Male	1	
		Female	2	
Q3	What is your highest level of education?	Never been to school	1	
		Primary	2	
		Form four	3	
		Form six	4	
		Other, (specify)_____	5	
Q4	Residence	_____		
Q5	Occupation	_____		
Q6	Mechanism of injury	Road traffic Accident	1	
		Fall from height	2	
		Sports	3	
		Slip	4	
		Assault	5	

Q7	Place of injury	Road 1 Home 2 School 3 Work 4 Others 5		
Q8	Number of upper extremity fractured		1 2 3	
Q9	Which side of the body bone fractured	Rt Lt Both	1 2 3	
Q10	Type of injury:	Close fracture	1	
		Open fracture	2	
Q11	Which bone was fractured	humerus Radius only Ulna only Radio -ulna	1 2 3 4	
Q12	Fracture pattern	Simple tranverse Spiral Oblique Segmental Communited	1 2 3 4 5	
Q13	Level of the fracture	Proximal 3rd	1	
		Middle 3rd	2	
		Distal 3rd	3	
Q14	What was the radiological diagnosis fracture pattern	_____		

APPENDIX II: INFORMED CONSENT FORM (ENGLISH VERSION)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS, MUHAS

INFORMED CONSENT FORM

ID-NO. ☐☐

Consent to Participate ina Study

My name is Dr.Tawfeeq Sangey; I am working on this research with the objective of Describing the radiological patterns of upper limb fractures among patients presenting at MOI from August 2016 to March 2017.

Purpose of the study

The study is conducted in partial fulfillment of the requirementsfor the degree of Master of radiology. There are few studies done in East Africa including Tanzania, and therefore this study aims at addressing a detailed description and characterization of upper limb fractures presenting to casualty departments along with public health measures such as injury prevention, resource allocation, and training priorities, child and occupational hazard

What Participation Involves

If you agree to participate in the study, you will be interviewed in order to answer a series of questions in the questionnaire prepared for the study and you will be asked to provide the x-ray film you did incase it is not found in the computers, and you will be able to ask whatever you wish to know about your injury etc.

Confidentiality

Information collected from you will be kept confidential. Your name will not be written on any questionnaire or in any report/documents that might let someone identify you. Your name will not be linked with the research information in any way. All information collected on forms will be entered into computers with only the study identification

number. Confidentiality will be observed and unauthorized persons will have no access to the data collected.

Right to Withdraw and Alternatives

Taking part in this study is voluntary. You can stop participating in this study at any time, even if you have already given your consent. Refusal to participate or withdrawal from the study will not involve penalty.

Benefits

This study will help you and me and the nation as a whole to know what are the pattern of injury in certain groups so as to be aware and hence not to miss these important fractures for the best management and outcome.

Whom to Contact

If you ever have questions about this study, you should contact the Principal Investigator, Dr. Tawfeeq I Sangey, of Muhimbili University of Health and Allied Sciences, P. O. Box 65001, Dar es Salaam. If you ever have questions about your rights as a participant, you may call

Prof Said Aboud, Chairperson of the Senate Research and Publications Committee, P. O. Box 65001, Telephone : 255 22 2152489 Dar es Salaam and Dr Mechris Mango who is the supervisor of this study (Tel. +255 754022576).

Signature:Do you agree?

Participant agrees ……..Participant does NOT agree …….

I ……. have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant …… Signature of Research Assistant ……