FUNCTIONAL OUTCOME OF OPERATIVE MANAGEMENT OF HUMERAL SHAFT FRACTURES

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN ORTHOPAEDIC SURGERY OF THE UNIVERSITY OF NAIROBI

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DECLARATION

I, **DR. PETER MUNENE GICHUNGE**, hereby declare that this thesis is my own work and has not been presented for the award of a degree in any other University.

This research was carried out at P.C.E.A Kikuyu Hospital's Orthopedic and Rehabilitation centre and Kenyatta National Hospital's orthopedics clinics, wards and the Accident and Emergency Department.

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CERTIFICATE OF AUTENTICITY

This is to certify that thesis is the original work of the author.

This research was carried out at P.C.E.A Kikuyu Hospital's Orthopedic and Rehabilitation centre and Kenyatta National Hospital's orthopedics clinics, wards and the Accident and Emergency Department

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ABSTRACT

BACKGROUND

Fractures of the humeral shaft are common, accounting for approximately 3% of all orthopaedic injuries according to a study by World Health Organization[1], and result in a significant burden to society from lost productivity and income. These humeral shaft fractures have traditionally been regarded as benign, with high percentage of primary healing with conservative methods. However loss of reduction in the plaster cast invariably leads to malunion. Surgery is however indicated in some of these patients for optimum outcome. With improved implant design and surgical technique, operative management of humeral shaft fractures has increasingly become accepted[2, 3].

Most of the studies have used fracture union as the major determinant of the outcome and very few studies have examined the functions at the shoulder and elbow.

PURPOSE

To study functional outcome of operative management of humeral shaft fractures

VARIABLES TO BE EVALUATED

Age of the patient, etiology/cause of trauma, time and place of injury, occupation of the patient, associated injuries (e.g. neuro-vascular status, tendon injury), pain, instability, activities of daily living, motion and function.

STUDY DESIGN

Prospective Analytical Study

SETTING

Kenyatta National Hospital and PCEA Kikuyu Hospital Orthopedic surgery wards, clinics and casualty

STUDY DURATION

1st April 2013 to 1st April 2014

METHODS AND MATERIALS

Purposive sampling method was used to select 45 patients who sustained humeral shaft fractures requiring surgery. A thorough history and clinical examination was done. Age of the patient, etiology/cause of trauma, time and place of injury, occupation of the patient, associated injuries were recorded in a trauma sheet.

Patients who presented to hospital immediately after injury and requiredsurgery had careful pre-operative planning done. Blood investigations were taken and pre-operative review done by anaesthetist. Surgery was done under general anesthesia and prophylactic antibiotics were administered in all cases. Treatment consisted of a standard posterior triceps-splitting approach to the humerus. The radial nerve was identified and protected for the duration of the procedure. A dorsal 3.5mm or 4.5mm DCP plate was utilized. A minimum of eight cortices of fixation above and below the fracture site were obtained.

Postoperatively, anteroposterior and lateral radiographs were done to assess alignment and reduction of fractures. Patients were placed in an arm sling primarily for comfort for two weeks. Gentle pendulum and active assisted shoulder and elbow range of motion were started at 2 weeks post-surgery followed by strengthening and passive range of motion exercises [4]. Patients were reviewed at 2, 6, 12 and 24 weeks. The primary outcomes measured were time to union, function and complications. Union was determined by radiographic evidence of cortical bone bridging at the fracture site, stable hardware position on radiographs, as well as absence of pain with manual palpation of the fracture site.

X-rays were taken immediately post operatively, at 6 weeks and at 6 months. Assessment for pain at the fracture site and evidence of union were checked at 6 weeks, while functional outcome using ASES and Mayo Elbow Performance scores were done at 6 months.

DATA COLLECTION AND STATISTICAL ANALYSIS

The researcher collected data from the patients. Predesigned data collection sheets were used. The data was analyzed using SPSS version 19 and descriptive statistics for sample variables presented in form of tables and graphs.

Repeated measures ANOVA were used to show any variations in the dependent variables while Pearson's correlation was used to check for any existing relationship in the variables. Data was considered significant at $p \leq 0.05$ and presented with 95% confidence interval. Data collected was analyzed and presented in the form of tables and charts.

RESULTS

45 patients with humeral shaft fractures were managed operatively by plating. The mean age was 34.6 years. Men accounted for 68.9% (31 out of 45) of the cases. Of these 38 were right hand dorminant while the rest were left handed.26 patients had right humeral shaft fractures while 19 had the left humerus affected. Sixteen patients experienced shoulder pains while 19 were on pain medications. The median shoulder functionality scores in the different age groups ranged from

80 to 85 out of 100. The oldest age group (45 years and above) had lower scores with median score of 80 and range 48.3 to 85.The duration of healing was about 6 months.

CONCLUSION AND RECOMMENDATIONS

The results of this study indicate operative management of humeral shaft fractures results in good functional outcomes with few complications.

Operative management by plating appears to be method of choice for internal fixation. All patients in this study were fixed by this method.

Studies should be done in future comparing functional outcomes of different operative modalities. Studies have been done in other countries which compare plating and nailing of humeral shaft fractures with reported good results.

In patients with indications for operative management of humeral shaft fractures, plating can be done because of good functional outcomes and healing potential. Special attention though has to be made to avoid damage to the radial nerve.

1.0 INTRODUCTION

Humeral shaft fractures account for approximately 3% of all orthopaedic injuries, and result in a significant burden to society from lost productivity and income. Majority of these fractures are managed conservatively. These humeral shaft fractures have traditionally been regarded as benign, with high percentage of primary healing with conservative methods. However loss of reduction in the plaster cast invariably leads to malunion. Surgery is however indicated in some of these patients for optimum outcome. With improved implant design and surgical technique, operative management of humeral shaft fractures has increasingly become accepted[2,3]. Plate and screw fixation remains the gold standard for surgical treatment[5.]

1.1 BACKGROUND OF THE STUDY

A study by World Health Organization in 2002 showed that fracture humerus accounted for 4.8% of non-fatal road traffic injuries. Fractures of the humeral shaft can have severe consequences to the individual and society as a whole.[1]

Fractures of humeral shaft are common and account for 1% of all fractures. They have traditionally been regarded benign, with high percentage of primary healing with conservative methods. However loss of reduction in the plaster cast invariably leads to malunion. The advantages of operative management are early mobilization and patient comfort. But operative management carries the risk of technical errors and post-operative complications infections, nerve injuries etc. Most of the studies have used fracture union as the major determinant of the outcome and very few studies have examined the functions at the shoulder and elbow [6,7,8.]

There are 2-3 frequency peaks [9,10]:

– During adolescence

– In the 3rd decade of life in men as a result of moderate to severe trauma

– In the 5th - 7th decades of life, especially in women after a simple fall.

Treatment modalities have greatly evolved since their first description in ancient Egypt (1600 BC); however, fundamental management principles have remained consistent throughout time[11].Non-operative, management continues as the mainstay for treatment of the majority of these injuries, with acceptable healing in more than 90% of patients. Surgical treatment is generally reserved for open fractures, polytrauma patients, ipsilateral humeral shaft and forearm fractures, and cases in where there is a failure to tolerate or maintain alignment in a functional brace[12].

Advances in internal fixation modalities have improved surgical outcomes. Operative treatment can be performed via external fixation, intramedullary nails, or plate-and-screw

constructs, with each method resulting in predictably high union rates[3,13]. Despite the numerous surgical techniques, plate fixation remains the gold standard for fixation of humeral shaft fractures. However, there is no consensus concerning which technique is to be used preferably for the different surgical indications[14,15].

Locally they occur mainly in the young socio-economically active age group; with the majority caused by automobile accidents[16]. With increasing high energy lifestyles and better roads, the incidence is projected to rise. Functional outcome of treatment of these injuries has however not been critically studied locally at Kenyatta National Hospital and PCEA Kikuyu Mission Hospital setup.

Fractures of the shaft of the humerus represent 1 to 3% of all fractures. They can occur at any age but there is an increasing incidence as of the fifth decade, up to almost 60 per 100 000 per year in the ninth decade[17].These are mostly caused by high energy trauma such as road traffic accidents, fall from a height or assault. The relative incidences of the proximal, diaphyseal and distal humeral fractures are approximately 40, 20 and 40%, respectively. Similar to proximal and distal humeral fractures, the management of diaphyseal (midshaft) humeral fractures has also been a lively topic of debate.

Closed humeral shaft fractures can be managed non-operatively by a hanging cast or brace with reported union rates as high as 94%.Although complete anatomical reduction is rarely achieved, there is usually a good functional outcome. When non-union does occur, it is likely to be related to the severity of the initial injury, the transverse pattern of the fracture, distraction of the fracture, soft tissue interposition or inadequate immobilization[18].

Sarmiento et al reported use of plastic sleeve with early introduction of functional activity. In a review of 51 fractures, there were no non-union among 49 non-pathological fractures and there was good restoration of joint motion. He also reported that non-operative treatment had the disadvantage of prolonged immobilization in cast or brace which may be required as long as 6 months resulting in huge morbidity[12,19].

Conservative treatment of segmental fractures is associated with increased risk of non-union[20] . Pathological fractures should be internally stabilized to maximize the patient's pain relief and upper extremity function and to ease nursing care.[15] Patients with ipsilateral humeral shaft and forearm fractures, and cases in which there is a failure to tolerate or maintain alignment in a functional brace requires operative management.

Appropriate operative treatment of patients with humeral shaft fractures, however, requires an understanding of humeral anatomy, the fracture pattern and the patient's activity level and expectations. The operative management of these fractures has become popular over the last two decades[14,15].

Knowledge of the basic anatomy of the humeral diaphysis is essential if one is to appreciate the diversities within the management of fractures to this area. The humeral shaft extends between the upper borders of the insertion of the pectoralis major muscle proximally to the supracondylar ridge distally [21]. The proximal portion of the humeral shaft assumes more of a cylindrical shape, but it develops into a triangular shape as you move distally.

The three main surfaces of the humeral diaphysis are: 1) the anterolateral surface, which contains the deltoid tuberosity, 2) the anteromedial surface, and 3) the posterior surface, the main feature of which is the spiral groove containing the radial nerve. These three surfaces serve as the attachment sites for many of the muscles of the upper limb including: pectoralis major, latissimus dorsi, teres major, triceps brachii, deltoid, coracobrachialis, brachialis, and brachioradialis.

The humeral shaft receives its main blood supply from branches of the brachial artery, with lesser contributions being made from the profunda brachii and posterior humeral circumflex arteries[21].

Operative treatment of these fractures is considered for specific situations including multiply injured patients, open fractures, patients with spinal cord injury (high quadriplegia) or brachial plexus injuries, fractures with associated neurovascular injuries, floating elbows and non-union[22,23,].

Generally, the anteromedial approach is avoided due to the vulnerable positioning of the brachial artery and median nerve with respect to the humeral shaft. The main advantage of compression plate fixation for humeral shaft fractures is that it is a very rigid stabilization technique. The rotation, length and angulation of the fracture site can all be strictly controlled using this method, and numerous studies have documented the effectiveness of this method in treating humeral shaft fractures[15,24,25,26.] One problem associated with this technique is that it requires a fairly wide surgical incision and thus increases the risk of infection. Pre-operative prophylactic antibiotics help reduce this risk.

The treatment of non-union of a humeral shaft fracture was considered difficult by Watson-Jones and several operative options have been reported in recent decades, including dynamic compression plate (DCP) with cancellous bone grafting, intramedullary (IM) nailing, external fixation, vascularized bone graft, and on-lay bone-plate augmentation. Intramedullary nailing offers the advantages of biomechanical load sharing, closed insertion techniques, decreased soft tissue disruption and preservation of extramedullary blood supply but has been implicated in post- operative shoulder and elbow dysfunction[2].

Some authors advocate for the use of locked intramedullary nailing in non-union and acute humeral shaft fractures. It provides semi rigid fixation depending on the size, location and comminution of the fracture. Most recent studies report 94% to 100% success rate as long as proper technique and correct design nails are used[27,28,29].

However, Hems and Bhullar in a study of 50 fractures of the humeral shaft managed by locked intramedullary nail fixation found that 30% of the non-pathological fractures had failed to unite after eight months and that a similar percentage of their patients had poor or unsatisfactory function. In five patients (10%) comminution of the fracture occurred on insertion of the nail which required removal of the nail in three[30].

Plate and screw osteosynthesis is considered an appropriate choice with good final results reported by many authors in acute fractures and non-union. It allows anatomical reposition of most fractures with little risk of mechanical problems or failure of healing. In a multi-centre study Foster and Dixon reported a 100% union rate in 27 multiple injured patients and above 80% union rate in 10 patients with non-union. However there is a chance of injury to the radial nerve which should be exposed at the time of the primary surgery or elective removal of the plate after union[28].

Some studies done by Bell and Dabezeis on dynamic compression plate fixation report that the incidence of non-union ranges from 2-10%, infection 2-4% and iatrogenic palsy of the radial nerve from 2-5%. With a few exceptions patients regained a full range of pain free movement[24,25].Rommens did a retrospective study where he reviewed dynamic compression plate fixation of the humerus and then prospectively reviewed intra medullary nail fixation. They achieved better results with a retrograde nail than with an antegrade nail or plate; they recorded that 90%of their patients' regained excellent function in the shoulder and elbow, and found that only 5% required secondary surgery[31].

Siddharth M. Shah and Amit R. Ajgaonkar, 2012 did a comparative study of 47 humeral shaft fractures in 47 eligible patients; 23 fixed by intra-medullary nail and 24 by plate. They measured outcome based on clinical, radiological and functional parameter using the American Shoulder and Elbow Surgeons score (ASES) and found there was no significant difference in duration to union (13.9 week, nail v/s 15.3 weeks, plate)Functional outcomes assessed by ASES (81.5, IMN v/s 82.3, PLT; p=0.81) were comparable in the two groups[32].

Incidence of wound complications (two v/s none, p=0.49) and radial nerve palsies (one v/s none, p=1.00) were greater in the PLT group but not statistically significant. Incidence of shoulder pain was significantly greater (p= 0.0496) in the IMN group (four v/s none). Though not significant, more patients in the IMN group had restricted shoulder range of motion than in the PLT group (three v/s one, p=0.35) They also found that the short term functional and

radiological results of interlocked nailing and plating in patients with fractures of the shaft humerus were comparable[32].

Mc Cormark et al did a randomized prospective study of 44 patients with humeral shaft fractures managed operatively by an intramedullary nail (IMN) or a dynamic compression plate (DCP). Patients were followed up for a minimum of six months. There were no significant differences in the function of the shoulder and elbow, as determined by the American Shoulder and Elbow Surgeons' score, the visual analogue pain score, range of movement, or the time taken to return to normal activity. There was a single case of shoulder impingement in the plate group and six in the nail group. Of these six, five occurred after antegrade insertion of an intramedullary nail. In the plate group three patients developed complications compared with 13 in the nail group[33].

Heineman et al conducted a meta-analysis of 4 trials comparing treatment of humeral shaft fractures with different implants (plates and nails). After calculating the data of 4 trials (203 patients), they did not find any statistically significant differences between plates and nails regarding complications, nonunion, infection, nerve palsy, or reoperation[34].

Hee and Low et al did a study where 35 patients with humeral shaft fractures were managed by open reduction and internal fixation over a five year period. Bony union averaged 5.3 months radiographically. All cases of radial nerve palsy recovered eventually. Twenty-seven patients reported no pain. Twenty-six patients had full range of motion in the shoulder and elbow. Thirty-three patients had full muscle strength[35].

Measuring outcome of orthopedic procedures has changed remarkably over the last twenty to thirty years. Objective physician measurements in large part have given way to subjective patient reported outcome measures[36].The driving force for this was the inherent bias in the clinician assessment along with how this assessment method marginalized the patient's perception of their outcome[37,38]. Quality of life is the main outcome measure in orthopedics due to the simple fact that most orthopaedic interventions do not increase a patient's life span, so survival is not a realistic outcome measure.

Traditionally, outcome measures have been physician derived objective evaluations including range of motion and radiologic evaluations. However, these measures can marginalize a patient's perception of their disability or outcome. As a result of these limitations, patient self-reported outcomes measures have become popular over the last quarter century and are currently primary tools to evaluate outcomes of treatment. Patient reported outcomes measures can be general health related quality of life measures, health utility measures, region specific health related quality of life measures or condition specific measures[36,37,38.]

James D Wylie and James T Beckmann did a study in 2014 on functional outcome scores following upper limb surgery. They validated 18 scoring systems for shoulder and elbow dysfunction. They found that Disabilities of the arm, shoulder and hand (DASH) and American Shoulder and Elbow Surgeons (ASES) scores were most sensitive and specific. They favored the ASES score over DASH score because it had an 11 item questionnaire vs. 30 item questionnaire[39].

Umile Giuseppe Longo†, Francesco Franceschi did a study in Italy in 2008 rating the scoring systems for shoulder and elbow function. They found that ASES score and Mayo Elbow Performance Score were amongst the most sensitive and specific physician and patient based functional outcome scores[40].

The ASES score was created by the Society of the American Shoulder and Elbow Surgeons to facilitate standardization of outcome measures and to promote multicenter trials in shoulder and elbow surger[41]. The ASES score contains a physician-rated and patient-rated section; however, only the pain visual analog scale (VAS) and 10 functional questions are typically used to tabulate the reported ASES score. The total score - 100 maximum points – is weighted 50% for pain and 50% for function.

Calculation of the ASES score is somewhat more arduous that other shoulder outcome measures[42]. The final pain score (maximum 50 points) is calculated by subtracting the VAS from 10 and multiplying by five. For the functional portion, each of 10 separate questions is scored on an ordinal scale from 0-3 for a maximal raw functional score of 30 points. The raw score is multiplied by 5/3 to make the maximal functional score out of 50 possible points. The pain and functional portions are then summed to obtain the final ASES score

Psychometric properties of the ASES have been well established. The validity, reliability, and responsiveness have been assessed in a variety of shoulder problems including: rotator cuff disease, glenohumeral arthritis, shoulder instability, and shoulder arthroplasty. The ASES score has also been shown to be valid, reliable, and responsive to non-operative treatments[43,44.]

Although the ASES score has been rigorously evaluated, some inherent limitations are noteworthy. Weighting of the ASES score favors the domains of pain and patient-reported function. Unlike the Constant-Murleyscore, physician assessment is not included in the final score. This could be considered both a strength and weakness of the ASES, but it should be noted in interpreting results. The shoulder instability VAS of the ASES has been removed in some versions, although the scale has still been responsive to instability treatments without this portion of the survey[43,44,45].

The Mayo elbow performance Score[46] is one of the most commonly used physician-based elbow rating systems. This index consists of four parts: pain (with a maximum score of 45 points), elbow motion (20 points), stability (10 points) and the ability to perform five functional tasks (25 points). Pain is rated as none (45 points); mild (30 points) if there is no limitation of activity and occasional use of analgesics; moderate (15 points) if there is limitation of activity and regular use of analgesics; severe (0 points) if there is constant pain and regular use of analgesics.

The joint's stability is graded as stable, mildly unstable or unstable. The functional score is determined on the basis of the patient's ability to perform normal activities of daily living. The total score ranges from 5 to 100 points, with higher scores indicating better function. If the total score is included between 90 and 100 points, it can be considered excellent between 75 and 89 points, good; between 60 and 74 points, fair; less than 60 points, poor[47,48.]

Kingori and Sitati.F, 2009 did a 4 year retrospective study on the outcome of management of non-united humeral shaft fractures with a plate or plate and rush pin fixation. They found that the overall healing rate was 92.8 % (39/42 cases) at 6 months follow up. During final follow-up at 2 years, the American Shoulder and elbow score (Max 52) on average was 46 (Good); 6 patients had elbow stiffness which resolved 8 weeks after surgery following physiotherapy, while 2 patients had persistent extension deficit of more than 40° and one had elbow stuck at 90° flexion[29].

2.0 JUSTIFICATION

Most fractures of the shaft humerus are managed conservatively with good results. However no local data exits on operative management and long term outcome of these fractures.

Most of the studies have used fracture union as the major determinant of the outcome and very few studies have examined the functions at the shoulder and elbow.

2.1 RESEARCH QUESTION

What are the functional outcomes of operative management of humeral shaft fractures at KNH and Kikuyu Hospital?

2.2 OBJECTIVES

2.2.1 Primary Objective

To study functional outcomes of operative management of humeral shaft fractures

2.2.2 Secondary Objective

1. To determine duration of healing
2. To determine method of fixation
3. To assess degree of pain
4. Evaluate function after surgery

2.3 MATERIALS AND METHODS

2.3.1 Study Population

Purposive recruitment of 45 patients will be done at Kenyatta National Hospital and PCEA Kikuyu Hospital wards and clinics.

2.3.2Study design

Prospective analytical study

2.3.3Setting

Kenyatta National Hospital and PCEA Kikuyu Hospital

2.3.4Study duration

1st April 2013 to 1st April 2014

2.4 INCLUSION CRITERIA

1. Acute diaphyseal fractures of humerus (within two weeks of injury)
2. Patients older than 18years

2.5 EXCLUSION CRITERIA

1. Patients with previous osteomyelitis of humerus
2. Patients who do not give consent.
3. Pathological fractures
4. Severe head injury with associated humeral shaft fractures
5. Conservatively managed humeral shaft fractures (older than 2 weeks)
6. Patients less than 18yrs age

7. Vascular/nerve injury/tendon injury

2.6 SAMPLE SIZE CALCULATION

Determination of sample size was based on an epidemiological study in the bone and joint journal, where humeral shaft fractures accounted for 3% of all fractures[17.s]

Using Fishers' formula

$$n = \frac{Z^2 PQ}{D^2}$$

Where

n is the estimated sample size.
Z^2 is the score of confidence interval at 95% and is 1.96^2.
P is the prevalence in this case at 3% and Q is 1 – P.
D^2 is the degree of error which is 0.05^2

Therefore

$$n = \frac{1.96^2 \times 0.03 (1 - 0.03)}{0.05^2}$$

n = **45 patients**

2.7 VARIABLES TO BE EVALUATED

Independent variables: patient demographic data:

1. Age
2. Gender

Dependent variables

1. Cause of traumas
2. Time of injury
3. Occupation of the patient
4. Associated injuries (e.g. neuro-vascular status, tendon injury)
5. Pain
6. Instability
7. Activities of daily living
8. Motion and Function

3.0 METHODOLOGY

Approval to perform the study was sought and obtained from the ethics, research and standards committee of Kenyatta National Hospital/University of Nairobi and PCEA Kikuyu Hospital.

Patients who met the criteria for surgery gave informed consent. Explanation of the study and its aims were done. All the data obtained was kept in the principal investigators possession at all times and subsequently entered into a password protected Microsoft Excel document after data coding. These patients with fracture shaft humerus as seen at casualty or in the ward had all the necessary clinical details recorded in a data collection sheet comprising of:

1. Age of the patient.
2. Mechanism of injury
3. Time of injury.
4. Occupation of the patient.
5. Associated injuries e.g. neuro-vascular status, tendon injury.
6. Medical history of the patient.

Then complete clinical examination comprising of local and systemic examination was recorded on trauma sheet itself.

1. Systemic Examination
2. Local Examination

a) Swelling and deformity of the shoulder or elbow
b) Check for circulatory status.
c) Sensation of the shoulder and arm.
d) Condition of the skin.

All the patients underwent operative management of humeral shaft fractures.

Blood investigations were taken and pre-operative review done by anaesthetist. Surgery was done under general anesthesia and prophylactic antibiotics were administered in all cases. Treatment consisted of a standard posterior triceps-splitting approach to the humerus. The radial nerve was identified and protected for the duration of the procedure. A dorsal 3.5mm or 4.5mm DCP plate was utilized. A minimum of eight cortices of fixation above and below the fracture site were obtained.

Patients were placed in an arm sling primarily for comfort for two weeks. Gentle pendulum and active assisted shoulder and elbow range of motion were started at 2 weeks post-surgery followed by strengthening and passive range of motion exercises.

Post operatively patients were followed up at 2weeks, 6weeks, 3 months and six months. X rays were done at 6weeks, 3 months and 6 months. At six months functional outcome was assessed using the American Shoulder and Elbow Surgeons Scoring System and Mayo Elbow Performance Score.

The American Shoulder and Elbow Surgeons Scoring System form has a patient self-evaluation section and a physician assessment section. The patient self-evaluation section of the form contains visual analog scales for pain and instability and activities of daily living questionnaire.

The patient can complete the self-evaluation portion of the questionnaire in the absence of a physician. The physician assessment section includes an area to collect demographic information and assesses range of motion, specific physical signs, strength, and stability but this has been modified in this study. Level of education was taken into consideration and whether patient has had post-operative physiotherapy or not.

3.1 PATIENT SELF-EVALUATION

The patient self-evaluation form is divided into three sections.

3.1.1Pain

The first section concerns pain.

The patients are asked to identify whether they are having pain in the shoulder and are asked to record the location of their pain on the pain diagram (Fig 1).

Patients are asked whether they have pain at night and whether they take pain medication. The next question identifies the use of a non-narcotic analgesic. Another question identifies the use of narcotic medication. The patient is asked to record the number of pills required each day. The severity of pain is graded on a 10 cm visual analog scale that ranges from 0 (no pain at all) to 10 (pain as bad as it can be).

3.1.2 Instability

The patient is asked to identify whether he or she experiences symptoms of instability (Fig 2). The sensation of instability experienced by the patient is assessed quantitatively according to a visual analog scale. A higher score is given, if the shoulder feels very unstable.

3.1.3 Activities of daily living

Ten activities of daily living are assessed on a four-point ordinal Scale (Fig 3). The patients are asked to circle 0, if they are unable to do the activity, 1, if they find it very difficult to do the activity, 2, if they find it somewhat difficult to do the activity, and 3, if they find no difficulty in performing the activity. Each shoulder is assessed separately. Because 10 questions are asked the maximum score is 30. The 10 questions include activities that are heavily dependent on a range of shoulder motion that is free from pain. The patients are also asked to identify their normal work and sporting activities. The cumulative activities of daily living score is derived by totaling the scores awarded for each of the individual activities.

3.2 SHOULDER SCORE INDEX

The information obtained from the patient self-evaluation form can be used to derive shoulder score. Equal weight is given to degree of pain experienced by the patient and the cumulative ADL score. The shoulder score is derived by the following formula:

(10 – Visual analog scale pain score) x 5 = • + (5/3) x Cumulative ADL score

For example, if the visual analog scale pain score is 6, and the cumulative

ADL score is 22, the shoulder function index is:

([10 - 6] x 5 = 20) + (5/3 x 22 = 37) = 57 (out of a possible 100).

Statistical analysis will be done using SPSS version 19.0. Summary descriptive statistics (mean, standard deviation, median, range and proportion will be determined and presented in the form of tables, line and bar graphs. The final outcome measure will be the shoulder score index.

Functional outcome will be graded as excellent, good, fair or poor. Excellent healing means that complete functional recovery is achieved. The outcome is rated as good if there is a suboptimal recovery without any impact on work and everyday activity. The functional outcome is rated as fair when patients experience functional impairment with daily activities and work. Poor recovery means that daily or work activities have to be abandoned because of functional impairment.

4.0 RESULTS

The study recruited a total of 45 adult patients admitted to KNH and PCEA Kikuyu Hospital orthopedic department with humeral fractures. The analysis of the patient characteristics and pain severity are presented in this chapter.

4.1 Sex distribution

As shown in figure 1, 31 (68.9%) male patients presenting with humeral fractures at KNH/PCEA Kikuyu Hospital were recruited in the study. The Male-to-Female ratio was approximately 2:1.

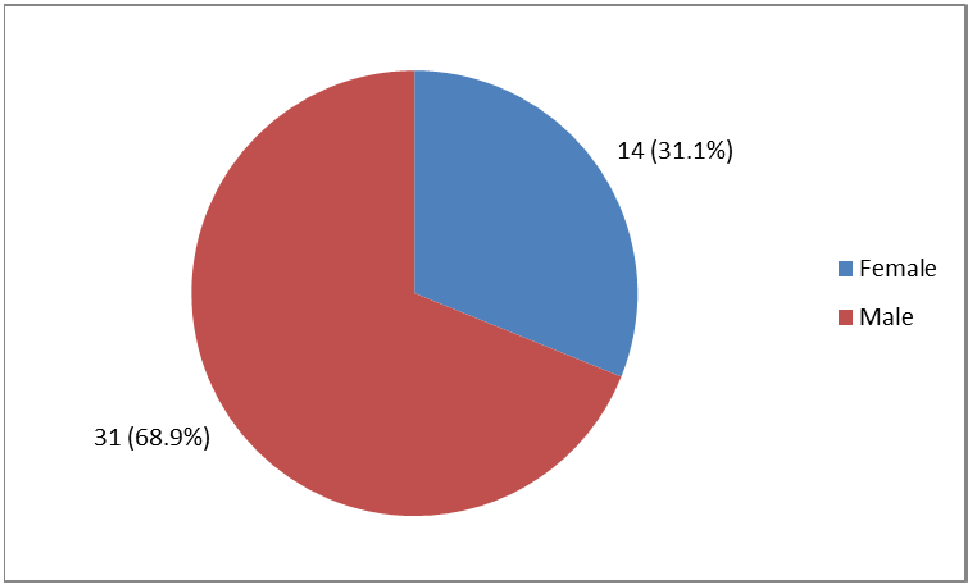


Figure 1: Sex distribution of patients with humeral fractures at KNH/PCEA Kikuyu Hospital

Patient age

The mean age of patients presenting with humeral fractures in KNH was 34.6 years (SD 10.3) with a range between 18 and 57 years. The modal age group was 35-44 years with 17 (37.8%) patients in this age category (figure 2). The second most common patient age group was 25-34 years accounting for 14 (31.1%) patients.

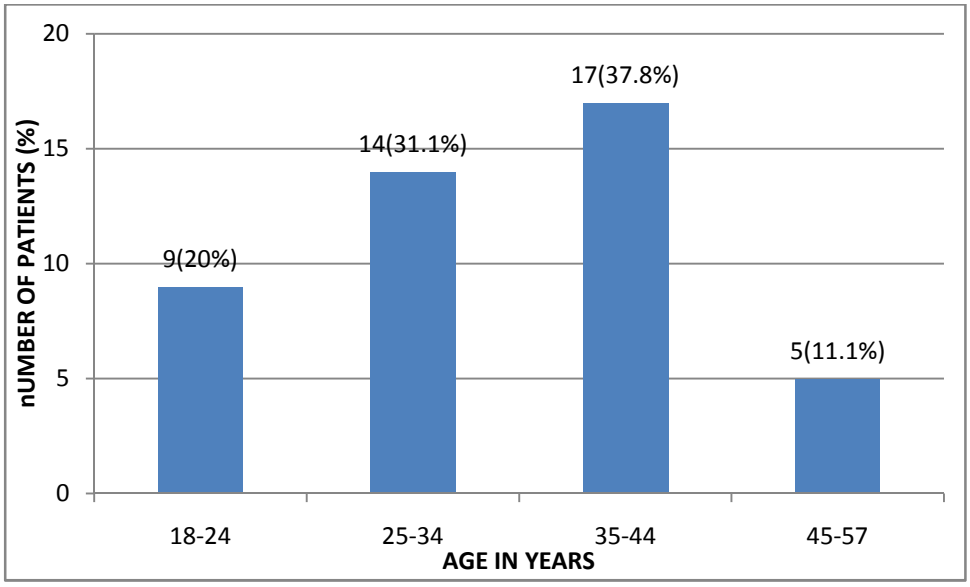


Figure 2: Age distribution of patients with humeral fractures at KNH/PCEA Kikuyu Hospital

Table 1: Indications for Operative management

Indications	No. of patients	Percentage (%)
Humeral shaft fractures with multiple injuries	25	55
Open fractures (gustillo 1)	5	11
Fractures with unacceptable reduction	7	16
Humeral shaft with ipsilateral forearm fractures	4	9
Bilateral humeral shaft fractures(one limb operated)	4	9

Table 2: Complications

	No. of patients	Percentage
Radial nerve injury	4	8.9%
Infection	0	0

4.2 Humeral fractures

Out of the 45 patients, 38 (84.4%) had the right dominant hand and the remaining 7 (15.6%) patients had left hand dominant. No patients had the ability to use both left and right hands competently either on physical examination or self-report. Table 1 shows the distribution of fractures according to affected limb and hand dominance. Overall, 26 (57.8%) fractures affected the right limb and 19 (42.2%) the left limb. Hand dominance did not show an association with the body side affected by fracture, p = 0.38 (table 1).

Table 3: Humeral fractures according to hand dominance and body side affected by fracture

	Side of fracture			
Dominant hand	**Right**	**Left**	**Total**	**Chi; P value**
Right	23 (60.5%)	15 (39.5%)	38 (84.8%)	**0.76; 0.38**
Left	3 (42.9%)	4 (57.1%)	7 (15.6%)	
Total	26 (57.8%)	19 (42.2%)	45 (100%)	

4.3 Pain characteristics and pain management

Sixteen (35.6%) patients with humeral fractures reported shoulder pains associated with the fracture (table 2). Nineteen (42.2%) patients had pain medications administered and of these patients on pain medications, 6 had stronger pain medications administered (narcotic pain medications e.g. codeine). Of the patients who received pain medications, 5 received a single pill, 8 two pills and the remaining 6 received between three and six pills (table 2). Two (4.6%) patients reported having had an unstable feeling in the shoulder joint.

Table 4: Characteristics of pain and pain management in patients with humeral fractures

at KNH/PCEA Kikuyu Hospital

	Frequency (n)	Percent (%)
Shoulder pain	16	35.6
Patients on pain medication	19	42.2
Strong pain medication administered	6	13.3
Number of pills		
None	26	57.8
1	5	11.1
2	8	17.8
3	4	8.9
4	1	2.3
6	1	2.3
Unstable feeling	2	4.6

4.4 Method of fixation

All patients were managedby plating.

4.5 Degree of pain and functioning after surgery

Patient self-evaluation of pain severity

Based on a visual analogue scale ranging from 1 to 10 for severity of pain, 22 (48.9%) patients rated pain severity associated with humeral fracture at 0 and 14 (31.1%) rated pain at 1 (figure 3).

The maximum pain severity reported was 6 out of 10, rated by one patient.

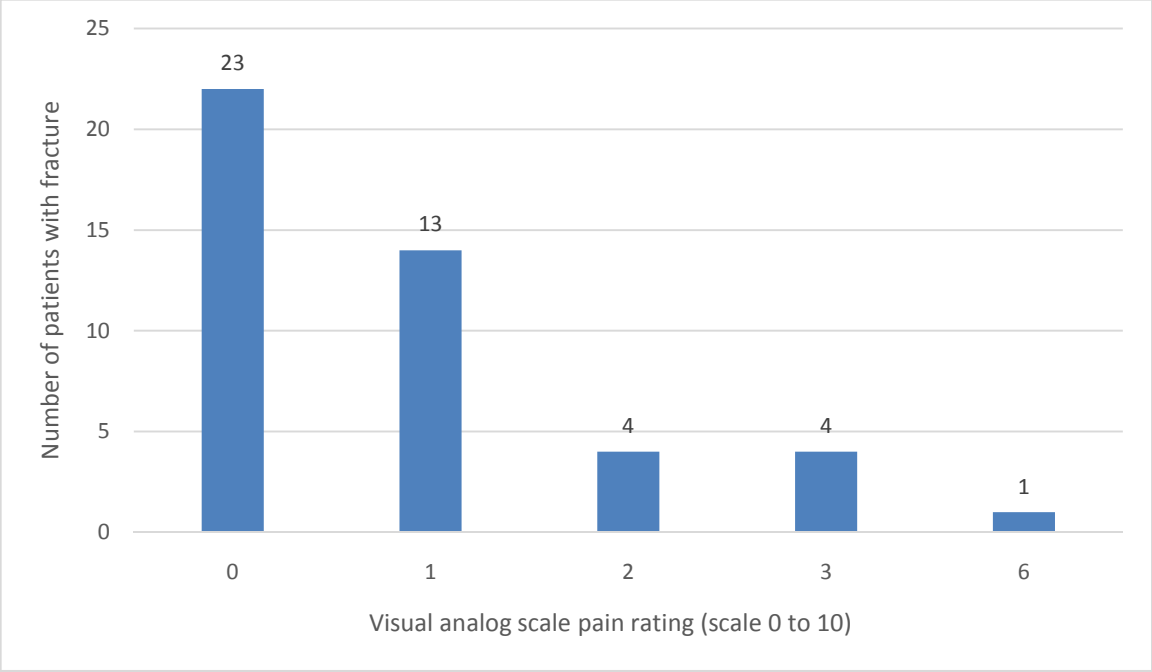


Figure 3: Visual analog scale rating of pain severity in patients with humeral fractures at KNH/PCEA Kikuyu Hospital

Physician assessment

The findings of the physical assessment of patients with humeral fractures conducted by a physician are presented in table 3. In common with patient self-reports, physicians established that 23 (51.1%) patients were not in pain. Of the remaining 22 patients, 21 patients had a visual analog pain scale ranging from 1-3.One patient had a visual analog pain scale of 6. The range of motion in 42 (93.3%) patients was characterized by an arc of motion > 100 degrees and 41 (91.1%) patients had shoulder joint stability. Functional ability was retained for mostactivities of daily living: combing hair (100%); bathing (93.3%); self-feeding and dressing (86.7%).

Table 5: Physician assessment of pain, stability, motion and functional ability in humeral fracture patients at KNH/PCEA Kikuyu Hospital

	Frequency (n)	Percent (%)
Pain intensity		
None	23	51.1
Mild	20	44.4
Moderate	2	4.4
Range of motion		
Arc of motion > 100 degrees	42	93.3
Arc of motion 50-100 degrees	3	6.7
Stability		
Stable	41	91.1
Moderately unstable	4	8.9
Functional ability		
Can comb hair	45	100.0
Can feed themselves	39	86.7
Can bath	42	93.3
Can wear shirt/blouse	39	86.7
Can wear shoes	42	93.3

4.6 Functional Outcome after surgery

Functional Outcome was assessed using ASES score for shoulder function derived from patient self-reported visual analog score (50%) rating of pain and cumulative activities of daily living scores (50%), yielding a maximum score of 100. On average shoulder functioning following surgery was good with a mean ASES score of 81.1 (SD 10.6) and range 46.7 to 91.7.

The shoulder index score had a negative correlation with patient age (Pearson's correlation, r = -0.236). Figure 4 shows that shoulder functionality declined by 0.26 points for each unit increase in age (in years) but the decline was not statistically significant (p = 0.101).

Figure 4: ASES shoulder index score and age of patients with humeral fractures at KNH/PCEA Kikuyu Hospital

The median shoulder functionality scores in the different age groups ranged from 80 to 85 out of 100. The oldest age group (45 years and above) had lower scores with median score of 80 and range 48.3 to 85.

Table 6: ASES shoulder functionality scores according to patient age groups

	ASES shoulder index		
	Median	**Minimum**	**Maximum**
Age group			
18-24 years	83.3	71.7	90.0
25-34 years	85.0	66.7	90.0
35-44 years	83.3	46.7	91.7
45 years +	80.0	48.3	85.0

Patient sex was not significantly associated with shoulder functionality. Table 5 shows the scores for male and female patients. Female patients had a lower median score (83.3 versus 85.0) but the differences in shoulder index scores was not statistically significant (Kruskal Wallis $p = 0.842$).

Table 7: Patient gender and shoulder functionality following surgery for humeral fractures

	ASES shoulder index		
	Median	**Minimum**	**Maximum**
Sex			
Female	83.3	66.7	90.0
Male	85.0	46.7	91.7

The shoulder functionality score was associated with presence of shoulder pain in patients (figure 5). The median ASES index score for patients with no shoulder pain (median = 88.3, IQR 83.3-90) was significantly higher than the index for patients without shoulder pain (median = 73.3, IQR 69.2-82.5), Kruskal Wallis $p < 0.001$.

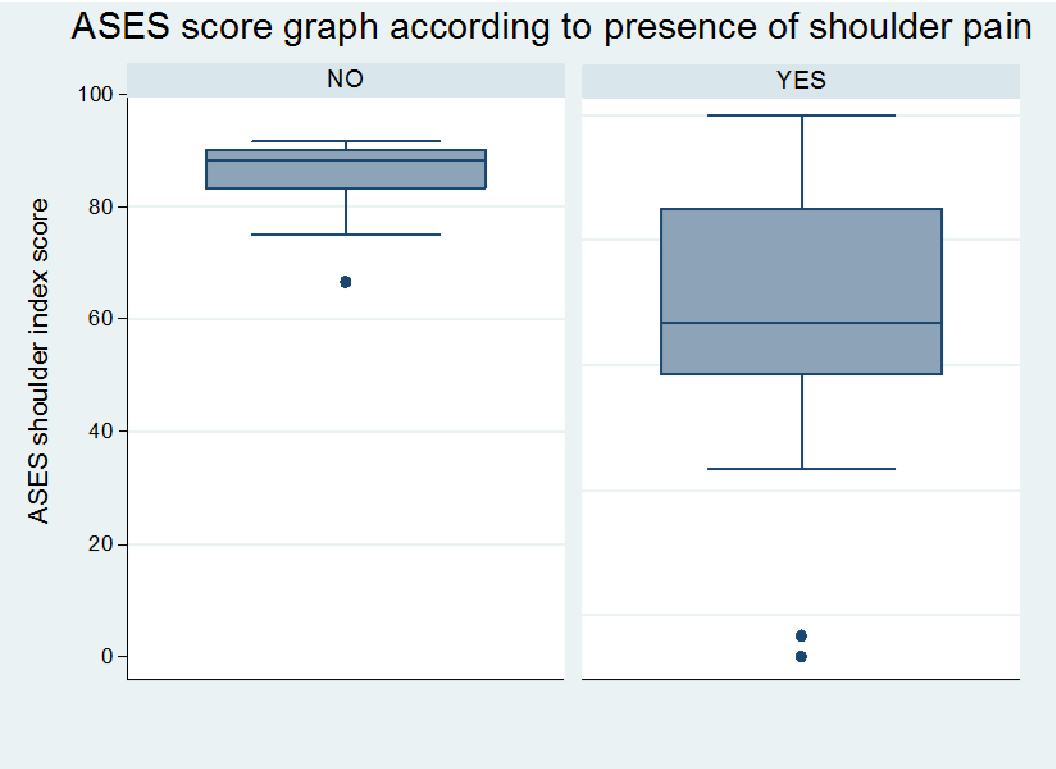


Figure 5: ASES shoulder index scores in patients with humeral fractures in KNH/PCEA Kikuyu Hospital according to presence of shoulder pain

Similarly as shown in Table 6, patient report of night pain was associated with the shoulder functionality score. Among the patients reporting no night pain the median ASES score was 90 (IQR 83.3 – 90) and this score was significantly higher than the median score in patients with night pain (median = 75, IQR 71.7 - 85.0), Kruskal Wallis $p < 0.001$. Shoulder functionality was also lower in patients on pain medication ($p < 0.001$), patients on stronger pain medication ($p < 0.001$) and patients with unstable feeling in the shoulder joint ($p = 0.02$), table 6.

Table 8: Pain characteristics and shoulder functionality in humeral fracture patients in KNH/PCEA KIKUYU HOSPITAL

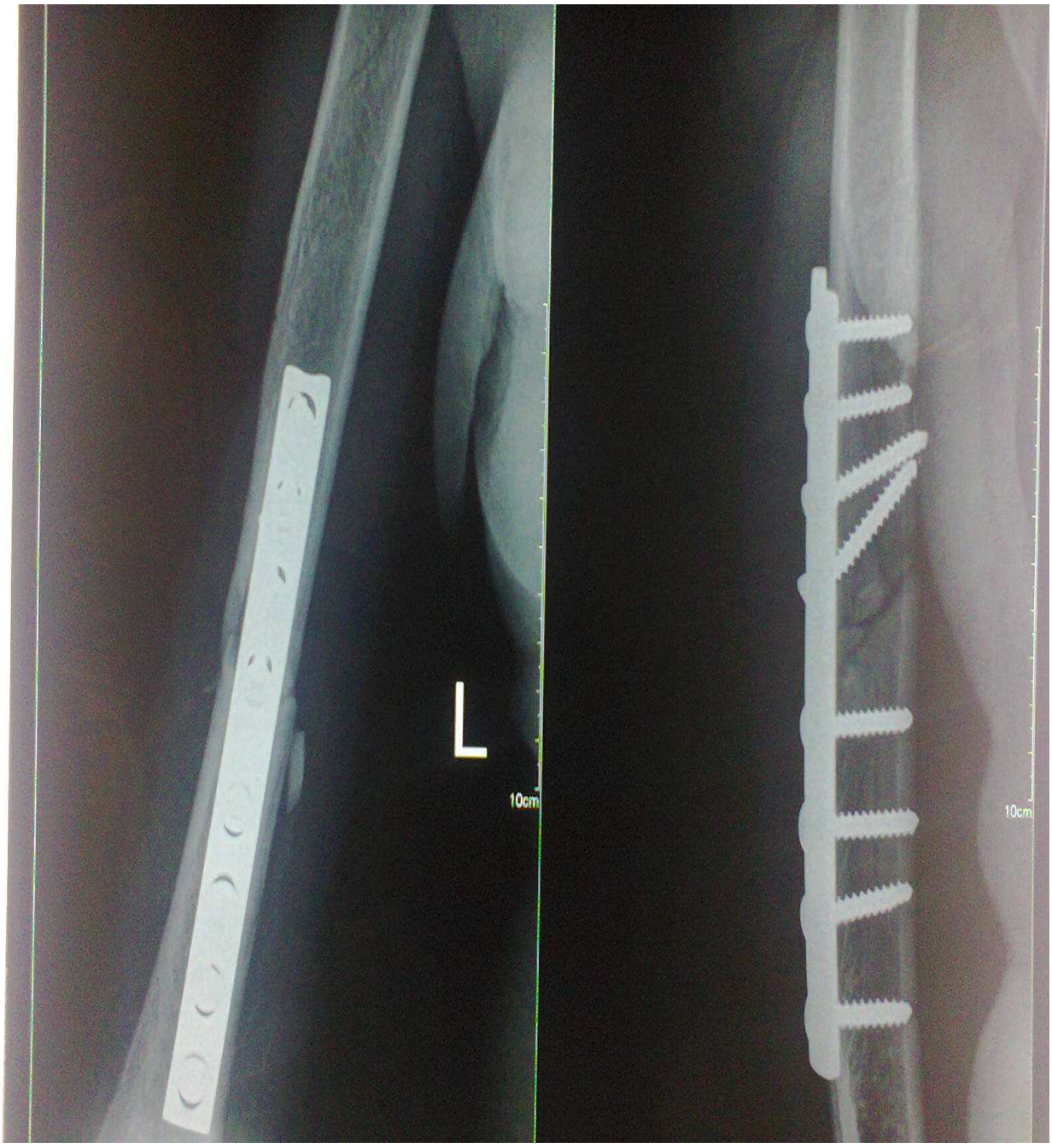
	Characteristic present	Characteristic absent	
	Median ASES (IQR)	**Median ASES (IQR)**	**Kruskal Wallis P**
Night pain	75(71.7-85)	90(83.3-90)	<0.001
Pain medication	73.3(66.7-81.7)	90(83.3-90)	<0.001
Stronger medication	64.2(48.3-73.3)	85(80-90)	0.0003
Unstable feeling	47.5(range 46.6-48.3)	85(76.7-90)	0.02

4.7 Duration of healing

On average duration of healing was around 4.5 months based on clinical and radiological evidence.

Study	Mean Healing Time (Plating)
Amit Putti[36]	16 weeks
Munene	17.4 weeks

a) Check x-ray immediately post op



b) Check x-ray at 6 weeks post op

c) Check x-ray at 6months post op

5.0 DISCUSSION

In the one year study period, 45 patients with midshaft humerus fractures were admitted both at Kenyatta National Hospital and PCEA Kikuyu Hospital. This is under one patient on average per week.

The indications for open reduction and internal fixation of acute fractures of the humeral shaft have been described as: fractures in patients with multiple injuries, open fractures, fractures associated with vascular or neural injuries or with lesions of the shoulder, elbow or forearm in the same limb; bilateral upper extremity injuries, fractures for which closed methods of treatment have failed and pathological fractures[25]. In several reported series, the presence of associated multiple injuries was the most frequent indication for internal fixation of the humeral shaft. In my study failed closed reduction and associated injuries were the most common indications.

The mean age of patients presenting with humeral fractures in KNH and Kikuyu Hospital was 34.6 years with a range between 18 and 57 years. The modal age group was 35-44 years with 17 patients in this age category. The second most common patient age group was 25-34 years accounting for 14 patients.Studies by Ekholm R and Adami J,found that incidence of these fractures increased from the 5th decade onwards[22].This is because the studies included elderly population, in whom osteoporosis is common particularly women after the 5th decade[49,50.]

A retrospective study by Gichuhi in 2007studied and analyzed the pattern of injuries among non-fatal road traffic accident victims[16]. He found that 69% of patients presented with factures. The 15-44 age groupswere the most affected. However,Tytherleigh-Strong and G.Wallsfound there was a peak in the third decade for these fractures with a mean age of 40.3 years[49].

Most of these humeral shaft fractures occurred in the male population with a ratio of 2:1 (68%).This is in keeping with previous publications[18,49].

Of the 45 patients operated on, 38 were right hand dominant while the remaining were left handed. Of the 38 patients with right hand dominance 23 sustained right humeral shaft fractures while 15 sustained left humerus fractures. Seven patients had left hand dominance and of these 3 had right humerus fractures while 4 had left. In summary, 26 out of 45 patients sustained right humeral shaft fractures accounting for 57.8% while the rest were left. This is in contrast with previous studies which show humeral shaft fractures affecting the left arm[49,50].

The humeral shaft extends between the upper borders of the insertion of the pectoralis major muscle proximally to the supracondylar ridge distally[21]. The proximal portion of the humeral

shaft assumes more of a cylindrical shape, but it develops into a triangular shape as you move distally. A study done in Malawi found 48.8% of the fractures occurred at the lower end of the humerus while 41.1% occurred at the humeral shaft, with only 10.1% of the fractures occurring at the upper end[50].

Adifferent study by Ekholmfound that these fractures were through the middle (43.2%) or proximal (40.8%) part of the shaft[22]. This differs somewhat from the findings of Tytherleigh-Strong who used the AO classification and reported an incidence of fractures of the mid-shaft of 64% and of the proximal part in 25%[49.]His study looked at osteoporotic and fragility humeral shaft fractures in the elderly.This may be explained by the different methods of classifying fractures of the proximal shaft and by the fact that pathological fractures were included in the Tytherleigh-Strong study[49].

Sixteen (35.6%) patients with humeral fractures reported that they experienced shoulder pains at 6 months review. Nineteen (42.2%) patients had pain medications administered and of these patients on pain medications, 6 had stronger pain medications administered.

Of the patients who received pain medications, 6 received a single pill, 8 two pills and the remaining 6 received between three and six pills. Two (4.6%) patients reported having had an unstable feeling in the shoulder joint.

All 45 patients were managed operatively by plating. This could be due to surgeon's preference/experience and good previous results with this mode of fixation

.

In a study carried out by Amit Putti [36] he reported a mean time of healing of 16 weeks in patients with DCP plating and 18 weeks in patients treated with nailing. In our study we achieved a mean healing time of 17.4 weeks in patients treated with DCP plating. In previous reports the incidence of non-union after plating has ranged from 2% to 4%[52.] In this study no cases of non-union occurred.

The incidence of post-operative radial nerve palsy with fracture shaft humerus varies from 6% to 15%[53.] In our seriesfour patients developed iatrogenic radial nerve injury and they were all sent to the physiotherapist.Dabezies EJ et al in his study found that in the DCP group incidence of post-operative radial nerve palsy is 2% to5%[34.]Previous studies have shown excellent results with plating[24,33,25],though most compare plating and intramedullary nailing with no significant difference in functional outcomes[32,33,34,35].

Based on a visual analogue scale ranging from 1 to 10 for severity of pain, 22 (48.9%) patients rated pain severity associated with humeral fracture at 0 meaning they had no pain and 14 (31.1%) mild pain rated at 1. The maximum pain severity reported was 6 out of 10, rated by one patient. This pain was on activity.

The findings of the physical assessment of patients with humeral fractures conducted by a physician were similar to patient self-reports, physicians established that 23 (51.1%) patients were not in pain. Of the remaining 22 patients, 20 had mild pain.

The range of motion in 42 (93.3%) patients was characterized by an arc of motion > 100 degrees and 41 (91.1%) patients had shoulder joint stability. Functional ability was retained for most activities of daily living: combing hair (100%); bathing (93.3%); self-feeding and dressing (86.7%). Kingori and Sitati.Fdid a similar study though retrospective and found good range of motion post operatively[26].

Functional Outcome was assessed using ASES score for shoulder function derived from patient self-reported visual analog score (50%) rating of pain and cumulative activities of daily living scores (50%), yielding a maximum score of 100. On average shoulder functioning following surgery was good with a mean ASES score of 81.1 (SD 10.6) and range 46.7 to 91.7. This was similar to a previous study by Kingori and Sitati.F whose ASES score on average was 46[26.]

The shoulder index score had a negative correlation with patient age (Pearson's correlation,

r = -0.236). This implies that as one gets older ASES score becomes poorer.

Female patients had a lower median score (83.3 versus 85.0) but the differences in shoulder index scores was not statistically significant (Kruskal Wallis p = 0.842).The shoulder functionality score was associated with presence of shoulder pain in patients. The median ASES index score for patients with no shoulder pain (median = 88.3,

IQR 83.3-90) was significantly higher than the index for patients without shoulder pain (median = 73.3, IQR 69.2-82.5), Kruskal Wallis $p < 0.001$.

Patients reporting no night pain had a median ASES score of 90 (IQR 83.3 – 90) and this score was significantly higher than the median score in patients with night pain (median = 75, IQR 71.7 - 85.0), Kruskal Wallis $p < 0.001$.

Shoulder functionality was also lower in patients on pain medication ($p < 0.001$), patients on stronger pain medication ($p < 0.001$) and patients with unstable feeling in the shoulder joint ($p = 0.02$)

6.0 CONCLUSION

Fractures of the shaft humerus are one of the common fractures affecting present generation and treatment modality has to be decided carefully. I am of the opinion that the operative

treatment of the humerus fractures should be done in patients with poly trauma and in patients with failed conservative treatment.

The results of this study indicate operative management of humeral shaft fractures results in good functional outcomes with few complications.

Operative management by plating was the only method used for internal fixation. All patients in this study were fixed by this method.

Studies should be done in future comparing functional outcomes of different operative modalities.

For patients with indications for operative management of humeral shaft fractures, plating can be done because of good functional outcomes and healing potential. The limitations of the study are that the sample size is small and no patients were managed operatively by nailing.

7.0 RECOMMENDATIONS

From this study, we can deduce that fracture humerus is a common orthopaedic injury. These fractures are managed conservatively with varying degrees of success. My study shows that patients who undergo operation tend to have good functional outcomes.

Another study should be done comparing conservative vs operative management. Other studies should also be done to comparing different modes of operative management. Some studies have compared interlocking nail vs plating with different functional outcomes.

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APPENDICES

Appendix I

SHOULDER ASSESSMENT FORM AMERICAN SHOULDER AND ELBOW SURGEONS			
Study Number:			Date:
Age:	Hand dominance: R L Ambi		Sex: M F
Diagnosis:			Initial Assess? Y N
Procedure/Date:			Follow-up: M Y

Fig 1: Pain

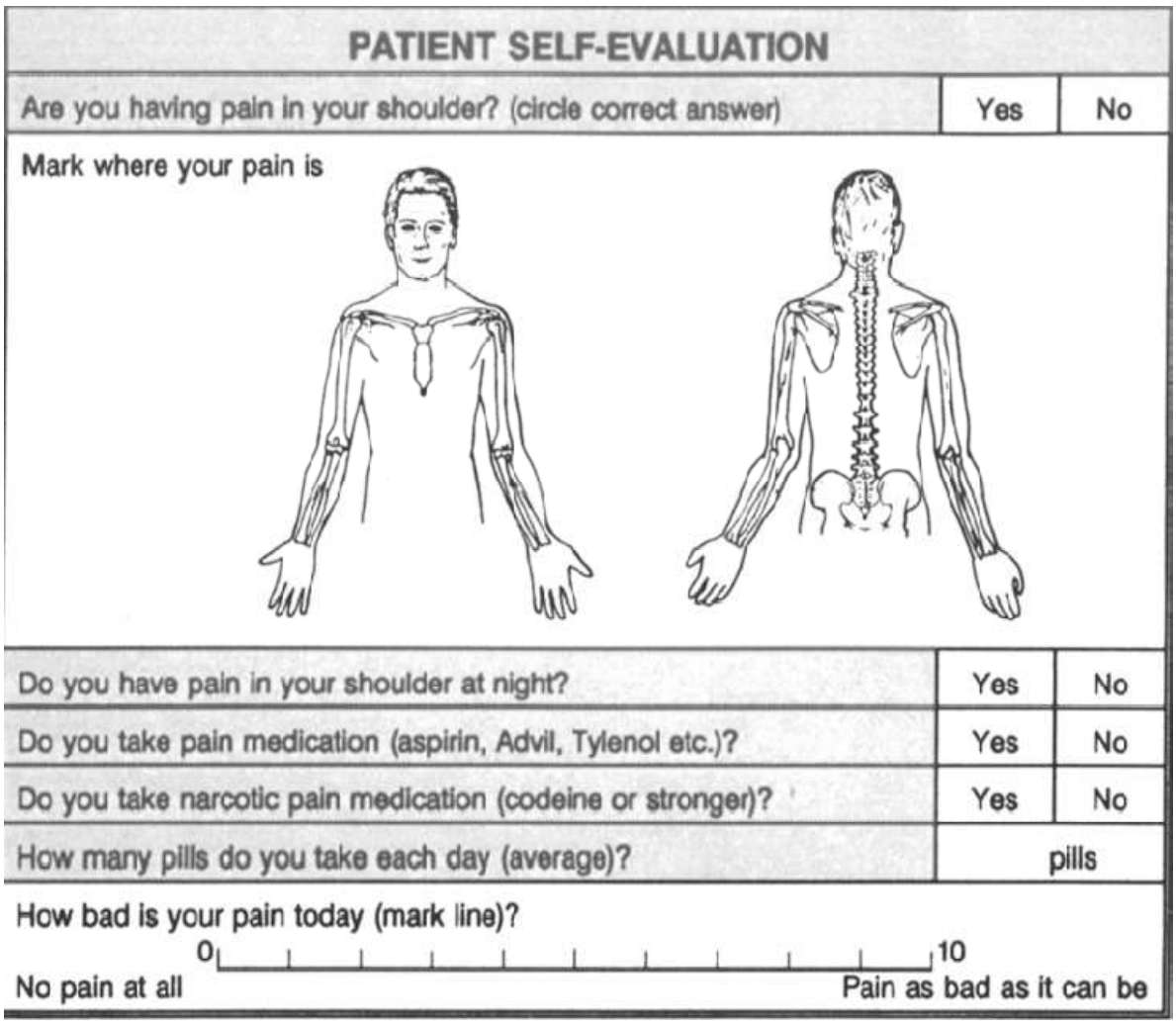

Fig 2: Instability

Does your shoulder feel unstable (as if it is going to dislocate?)	Yes	No
How unstable is your shoulder (mark line)? 0 ——— 10 Very stable — Very unstable		

Fig 3: Activities of daily living

Circle the number in the box that indicates your ability to do the following activities: 0 = **Unable** to do; 1 = **Very** difficult to do; 2 = **Somewhat** difficult; 3 = **Not** difficult			
ACTIVITY		**RIGHT ARM**	**LEFT ARM**
1. Put on a coat		0 1 2 3	0 1 2 3
2. Sleep on your painful or affected side		0 1 2 3	0 1 2 3
3. Wash back/do up bra in back		0 1 2 3	0 1 2 3
4. Manage toiletting		0 1 2 3	0 1 2 3
5. Comb hair		0 1 2 3	0 1 2 3
6. Reach a high shelf		0 1 2 3	0 1 2 3
7. Lift 10 lbs. above shoulder		0 1 2 3	0 1 2 3
8. Throw a ball overhand		0 1 2 3	0 1 2 3
9. Do usual work - List:		0 1 2 3	0 1 2 3
10. Do usual sport - List:		0 1 2 3	0 1 2 3

Fig 4: Mayo Elbow Performance Score

Section 1 - Pain Intensity	
None	
Mild	
Moderate	
Severe	

Section 2 – Motion	
Arc of motion > 100 degrees	
Arc of motion 50-100 degrees	
Arc of motion < 50 degrees	

Section 3 – Stability	
Stable	
Moderately unstable	
Grossly unstable	

Section 4 - Function (Tick as many as able)	
Can comb hair	
Can feed themselves	
Can bath	
Can wear shirt/blouse	
Can wear shoes	

Appendix II
INFORMED CONSENT LETTER

Title of the study: Functional outcome of operative management of humeral shaft fractures

I am Dr.Peter Munene Gichunge, a post graduate student at University of Nairobi Department of Orthopaedic Surgery (H58/64206/2010). I am carrying out a study on the functional outcome of operative management of humeral shaft fractures at Kenyatta National Hospital and PCEA Kikuyu Hospital. My research assistant will be a clinical officer.

Study number:…….

Hospital number:……..

PART A

Introduction

Fractures of the humeral shaft can have severe consequences to the individual and society as a whole. Most of these fractures are managed conservatively, thus functional outcome of patients with humeral shaft fractures managed operatively remains incomprehensively studied. This study seeks to fill in that gap

You are invited to participate in this study, which will look at the functional outcome of patients with humeral shaft fractures who are operated on. Kindly read this form and understand it well before agreeing to the study. Any questions you have will be answered.

Purpose of the study
The findings obtained from this study will provide information on what is the functional outcome of patients with humeral shaft fractures managed operatively. This would help in the development of policies on the management of such patients requiring orthopaedic implant surgery.

Lastly information obtained will be used for purposes of obtaining a Master degree in Orthopedic Surgery for the principal investigator.

Study procedure

If you agree to participate in this study, your particulars will be recorded in the data collection sheet. Patients who meet criteria for surgery will have blood samples taken and pre-operative anaesthetic review done after admission. Surgery will be carried out by a qualified orthopaedic surgeon. Post-operatively patients will be followed up in the ward and clinics and x-rays will be done serially at 6 weeks, 3 months and 6 months. At 6 months functional outcome will be determined using Mayo Elbow Performance Score and American Shoulder and Elbow Score.

Risks and benefits of study participation

There is no harm or risk anticipated in participating in this study. There is no added radiation risk associated with taking of x-rays. Participation in this study will result in better management of patients with fractures of the humeral shaft.

Study costs

If you accept to take part in this study, there will be no payment expected from you or to you.

No added investigations will be required and x-rays done will be as per routine post-operative management and follow up of these fractures.

Confidentiality

The data collection sheet is strictly confidential. Your name will not appear in it and your telephone number is strictly for follow up purposes. If you so wish you will be given a copy of this consent form.

Participant information

Your participation in this study is voluntary and failure to participate or withdrawal from the study will not affect your management in any way at any stage.

Contacts and Questions

The researcher conducting this study is Dr. Peter Munene Gichunge. You may ask any questions you have now or if you have any questions later, you are encouraged to contact him through mobile number: 0724 571240, or email pmneshi@yahoo.com

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the following:

The Director,

KNH/University of Nairobi – Ethical Review Committee

Telephone: 726300 – 9 or (254 - 020) 2726300 Ext 44102

PART B

Participant consent form

I have understood the above information which has been fully explained to me by the investigator and I voluntarily consent to participate.

Signature……..

Or participants thumb print.

Date……

Witness signature……..

KIBALI CHA RUHUSA YA KUHUSIKA

Utafiti cheo – Matokeo ya wagonjwa waliovunjika mkono na kufanyiwa upasuaji

SEHEMU A

Jina langu ni Daktari Peter Munene Gichunge, ninasomea shahada ya upasuaji wa mifupa (orthopaedic surgery) katika Chuo Kikuu cha Nairobi (H58/64206/2010). Ninafanya utafiti kuhusu wagonjwa waliofanyiwa upasuaji na kuwekwa chuma baada ya kuvunjika mkono. Msaidizi wangu katika utafiti huu ni afisa wa hospitali (clinical officer). Tafadhali soma fomu hii na kuielewa vizuri kabla ya kukubali utafiti. Maswali yoyote utakayo kuwa nayo yatajibiwa.

- Nambari ya utafiti
- Nambari ya hospitali

Sababu ya utafiti

Lengo nikupata taarifa juu ya matokeo ya wagonjwa waliovunjika mifupa ya mkono. Huu utafiti utasaidia pia katika mabadiliko ya usimamizi wa sera ya majeraha hayo katika hospitali na nchi kwa ujumla. Taarifa itakayopatikana ni muhimu pia kwa kufikia shahada ya uzamili katika upasuaji wa mifupa (orthopaedic surgery) kwa mpelelezi mkuu.

Utaratibu wa utafiti

Habari kuu inayo hitajika kutoka kwako ni maelezo yako kama katika karatasi ukusanyaji.Wagonjwa wanaohitaji upasuaji watalazwa hospitalini na kufanyiwa operesheni na daktari wa mifupa aliye hitimu. Picha ambazo zitapigwa kama maendelezo ya matibabu yako zitafanywa baada ya wiki sita, miezi tatu na miezi sita. Utafuatiliwa kwa muda wa miezi sita na baadaye matibabu yako yata endelea kama kawaida.

Hatari na manufaa

Hakuna hatari zozote zinaweza kutokea kwa kushiriki katika utafiti huu. Hakuna hatari zaidi itatokana na kupigwa picha ya mkono na pia hakuna gharama zaidi zitatozwa kwa kushiriki katika utafiti huu.

Usiri

Ukusanyaji wa karatasi takwimu ni madhubuti ya siri. Jina lako haliita andikwa na nambari yako ya simu ni madhubuti kwa ajili ya kufuatilia makusudi. Kama unataka utapewa nakala ya fomu hii ya ridhaa.

Habari kwa mshiriki

Ushiriki wako katika utafiti huu ni wa hiari yako na kushindwa kushiriki au kujiondoa kutoka utafiti huu, hauta adhiri usimamizi wako na matibabu yako katakana njia yoyote katika hatua yoyote.

Mawasiliano na Maswali.

Mtafiti anaye fanya utafiti huu ni Dkt. Peter Munene Gichunge. Unaweza kuuliza maswali yoyote sasa au ukiwa na maswali yoyote baadaye, unahimizwa kuwasiliana naye kupitia nambari ya simu 0724 571240, au barua pepe: pmneshi@yahoo.com

Kama una maswali yoyote au wasiwasi kuhusu utafiti huu na ungependa kuzungumza na mtu mwingine badala ya mtafiti(s), unahimizwa kuwasiliana na

Mkurugenzi,

KNH / Chuo Kikuu cha Nairobi – Maadili Kamati ya Uchunguzi

Simu:- 726300 – 9 or (254 - 020) 2726300 Ext 44102.

SEHEMU B

Fomu ya mshiriki wa ridhaa.

Mimi……..……nimeshaelewa maelezo niliyo ambiwa kikamilifu na mpelelezi na nitashiriki kwa hiari yangu kwa kutia sahihi kwa ridhaa.

Sahihi ..... Au kidolegumba cha mshiriki.

Tarehe .....

Sahihi ya shahidi .....

Appendix III

DATA COLLECTION TOOL FOR A STUDY ON FUNCTIONAL OUTCOME OF OPERATIVE MANAGEMENT OF HUMERAL SHAFT FRACTURES

A) Patient details

Study number _____ OP/IP number _____

Date of Birth ……./…../….. Sex _____

Formal Education Level a) None b) Primary _____ c) Secondary _____

d) Post-Secondary Training _____ e) University _____

Occupation a) Unskilled b) Semiskilled c) Professional _____ d) Student

e) Housewife f) Other

Employer a) Self Employed b) Small Business c) Factory d) Unemployed

B) Injury Details

a) i) Date of injury ……./..../….. ii) Time of injury…….

b) i) Date of Presentation to Hospital ……./…../…. ii) Time …….

Type of injury (tick all that apply)

a) Fracture (Specify Site)…….……..

b) Other Injuries (Specify Site) …….……

Cause

1. Motor Vehicle accident 1.Yes….2.No……

If Yes; a) Driver (Restrained/Unrestrained)

b) Passenger (Restrained/Unrestrained)

c) Pedestrian

2. Motor cycle accident.1. Yes……2.No…….

If Yes a) Rider b) Passenger, c) Pedestrian,

3. Bicycle accident 1.Yes…..2.No……

If Yes a) Rider b) passenger c) Pedestrian,

4. Fall 5.Assaults 6. Machine accidents 7. Sports injuries

8. Gunshot/bomb blast 9. Others, specify ……

C) Accompanying Injuries

i) Are any other injuries present - a) Yes b) No

ii) Where are these other injuries?

a) Ipsilateral Upper limb b) Contralateral Upper Limb

D) Radiological Evaluation

i) Has patient had any radiographs taken? - a) Yes b) No

ii) X-ray Views taken a) AP view

b) Lateral view

E) Local and Systemic Examination

1) Local Examination

a) Swelling and deformity of the shoulder or elbow

b) Check for circulatory status.

c) Sensation of the shoulder and arm.

d) Condition of the skin.

2) Systemic Examination