

**"A SEVEN MONTH PROSPECTIVE STUDY OF PATIENTS
SEEN AT KENYATTA NATIONAL HOSPITAL WITH
DIAPHYSEAL FRACTURE OF THE HUMERUS"**

By

**DR. RUTURI, ALBERT J.M. M.B.Ch.B
UNIVERSITY OF NAIROBI**

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MASTERS OF MEDICINE (SURGERY)
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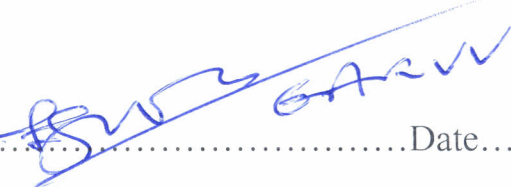
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DR. RUTURI, ALBERT J.M. M.B.Ch.B (UON)

SUPERVISOR:

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Signed..........Date.....1/12/04.....

PROF. L.N. GAKUU M.B.Ch.B , M.MED (Surgery) NAIROBI
Consultant Orthopaedic Surgeon/Head of Department of Orthopaedic Surgery, University of Nairobi.

DEDICATION

This dissertation is dedicated to the Ruturi family for their unwavering, unconditional love and support .

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ABBREVIATIONS

KNH	-	Kenyatta National Hospital
RTA	-	Road Traffic Accidents

SUMMARY

This was a prospective study over a period of seven months from February 2004 to August 2004 .The purpose of the study was to determine the pattern of diaphyseal fractures of the humerus in Kenyatta National Hospital .The study assessed the causes , sites and management of these fractures at the hospital .

A total of 78 patients were recruited into the study. Eleven patients were unavailable for follow up. Males were more affected in this injury (75.6%) than the females. There was a male to female ratio of 3:1. The mean age was 34 years with a range of 10 to 66 years.

Road traffic accidents were the leading cause of fracture of the shaft of humerus (52.6%). Other causes included falls, assault , gunshot injury , machine injury and pathological fractures.

Majority of these fractures involved the middle third of the shaft .Seventy seven of these fractures were initially managed by conservative means including U-slab, back slab and hanging cast. One patient had external fixators inserted.

Plating was the most commonly performed procedure (74%). Kirschner wiring was performed for 11.1% and Rush pin for 14.8%. Iatrogenic radial nerve palsy occurred in one patient (3.7%). Other complications documented during this period were Stiff elbow, stiff/ shoulder and deep infection.

Appropriate management and prognosis of radial nerve palsy complicating this fracture remains controversial.

Conservative management remains the mainstay of treatment of this fracture. However operative treatment can be carried out successfully when indicated.

INTRODUCTION

Humeral shaft fractures are common injuries accounting for approximately 3% of all fractures. ^(1,2,3,4) Most can be managed without surgery with anticipated good to excellent results. Appropriate non-operative and operative treatment of humeral fractures however, require an understanding of humeral anatomy, the fracture pattern and the patient's activity level and expectations.

The shaft of the humerus is defined as the part below the surgical neck and above the level of the epicondyles. It extends from the upper border of the insertion of the pectoralis major to the supracondylar ridge distally. The cylindrical proximal humerus assumes a more triangular shape in its distal third. The posterior surface contains the spiral groove for the radial nerve. The medial and lateral intermuscular septa divide the arm into anterior and posterior compartments. The blood supply to the humeral diaphysis arises from the branches of the brachial artery. ^(1,5)

The most common causes of injuries to the humeral shaft are falls, twisting injuries, industrial accidents, penetrating injuries, and motor vehicle accidents. Patients present with the cardinal signs of fracture such as pain, swelling, deformity, crepitation and loss of function. Soft tissue compartments of the arm and forearm should be examined to rule out compartment syndrome. The skin should be examined looking for abrasions, lacerations, and wounds to rule out open injury. A detailed motor and sensory

examination should be performed to document the history of the radial as well as median and ulnar nerves.

After healing of the fracture it has been noted that function of the upper limb is not affected significantly by as much as

- Anterior angulation of 20 degrees
- Varus angulation of 30 degrees
- Shaft shortening of 3 cm. ⁽⁶⁾

Non-operative treatment is recommended for most humeral-shaft fractures with excellent rates of union and restoration of function. This remains the preferred treatment for isolated fractures of the humeral shaft at this time. Non-union is an unusual occurrence following non-operative treatment, and when it does occur, it is usually associated with transverse fractures, distraction of the fracture and soft tissues interposition ⁽⁶⁾.

Despite the specific indications that have been advocated for operative intervention many surgeons are still reluctant to use internal fixation due to the problems that have been encountered. ^(7, 8, 9)

In his retrospective and prospective review of 45 patients who had open reduction and internal fixation (ORIF) *Rusagara* found that 38 patients (68.9%) had one or more complications. ⁽¹⁰⁾ His results compared well with the study done by *Stern et al* ⁽⁷⁾ who

found that 67% of the patients who had internal fixation of the humeral shaft fractures developed complications.

Samiento et al ^(11,12,13,14,15) in their series have demonstrated consistent and rapid healing of humeral shaft fractures treated with the use of prefabricated braces with resultant excellent alignment, early restoration of joint motion and minimal morbidity. Since then reports showing the consistent success of non operative treatment appeared, other authors strongly recommended closed treatment of humeral shaft fractures unless specific indications for operative intervention exist. ^(16,17,18)

More recent reports on the results of plate fixation in patients with multiple injuries showed a 97% rate of union and few complications. ^(19,20) However, other authors citing the higher complication rates of internal fixation, have recommended closed treatment, stating that stabilization of fractures in the lower extremities should allow upright positioning and permit the use of gravity-dependent methods of treatment for fractures of the humerus. ^(21,22)

The role of internal fixation in the treatment of acute fractures of the humeral shaft therefore remains controversial. One reason for this as noted above has been the higher rate of complications that have been reported after open reduction and internal fixation *than after non-operative treatment. However, such complications may not be entirely valid, since in many series a variety of methods of internal fixation (screws alone, plates and screws, cerclage wires or intramedullary rods) were used but results were evaluated collectively and were compared with the results obtained by non-operative methods.*

(23,24,25). In addition, it is the uncomplicated fracture that is often managed closed, while operative treatment is usually reserved for the so-called problem fracture.

Although as previously documented significant morbidity has been reported to follow operative treatment of the humeral shaft, the encouraging results that have been reported with advances in operative techniques and instrumentation have led to an expansion of the surgical indications for such fractures.

This study looked at the current management of these humeral shaft fractures at Kenyatta National Hospital (KNH).

LITERATURE REVIEW:

Non-operative treatment is recommended for most humeral shaft fractures with excellent results of union and restoration of function. This remained the preferred treatment for isolated fractures of the humeral shaft through much of the last century, despite reports of non union rates of 2% to 20% as well as problems with shoulder and elbow stiffness due to immobilization. ^(25,26,27)

The introduction of the concept of functional bracing by *Sarmiento* ^(11,12,13,14) was a great step forward in the non operative management of humeral shaft fractures and allowed many patients to achieve an appropriate outcome without surgery. In closed and Gustillo type 1 open diaphyseal humeral fractures treated with functional braces the non union rate is approximately 3%. ^(14,28,29) Functional bracing is predicted on the premise that motion at the fracture site encourages osteogenesis. ^(11,13) The method is therefore an unsatisfactory concept to those surgeons who feel that immobilization of the fractures is an important prerequisite for healing. ^(30,31,32) It is applicable to undisplaced or minimally displaced fractures or comminuted fractures with multiple parallel longitudinal fracture lines over the middle third. ⁽³³⁾ Relative contraindications include patients with bilateral humeral fractures and those fractures in poly traumatized patients unless they are able to stand erect early and ambulate with external support on the opposite side.

Sarmiento initially described the successful use of functional bracing in 50 of 51 patients.⁽¹¹⁾ The treatment protocol included the initial use of splints or a hanging cast followed by application of the functional brace (polypropylene sleeve) once the patient's acute pain and swelling has subsided. The most common residual deformity was varus angulation with 16% of patients demonstrating 10° to 20° of deformity. In a recent follow up study of 620 patients the incidence of non-union was 6% in open fractures and less than 2% in closed fractures. Fourteen percent of the patients exhibited less than 16° of varus angulation and shoulder motion was limited by more than 25° in 25% of cases.⁽¹⁵⁾ Prerequisites for successful functional bracing of humeral shaft fractures include patients who are ambulatory and who are able to perform active motion with their injured arm while undergoing treatment. Closed treatment is difficult in the patient who is bedridden, obese, multiply injured or unable to comply with or otherwise tolerate bracing.

Rusagara⁽¹⁰⁾ found that at KNH conservative management was the mainstay of treatment with the U-slab being the initial treatment in 91% of the patients. This U- slab of plaster may be applied after days in shoulder to wrist hanging cast with the elbow flexed to 90° and the forearm section suspended by a sling around the patient's neck. Caution however, should be taken in upper third fractures that tend to angulate at the proximal border of a short cast. The residual limitation of motion of the shoulder and elbow is very low. The cost of care is also reduced when compared with surgical treatments that require hospitalization. Non-union is an unusual occurrence following non operative treatment, and when it does occur is associated with transverse fractures, distraction of the fracture, soft tissue interposition, alcohol abuse and obesity.^(25,26)

Operative treatment of humeral shaft fractures is appropriate in patients who cannot tolerate closed management due for example to obesity or body habitus or in those who have multiple injuries and either cannot assume the upright position needed for non operative treatment or are better treated by fracture stabilization due to the presence of ipsilateral injuries.

Other indications include:

- Unacceptable alignment.
- Open fractures (Gustillo type II and greater)
- Bilateral humeral fractures
- Pathological fractures
- Non union
- Fractures with intraarticular extension.
- Progressive neurological deficit of recent onset after commencing non-

Operative treatment or brachial plexus injury or spinal cord injuries. ^(19,20,24,34)

Delayed union is considered to be when the fracture has not united in four months, while non union if the fracture has not united by eight months. ^(24,34,36,37) This may occur in transverse fractures of the humeral shaft especially if excessive traction has been applied (e.g. hanging cast), or if the patient has not actively exercised the elbow flexors and extensors. ⁽³⁸⁾ *Klenerman* (1966) ⁽⁶⁾ established that delayed union and non union following conservative management were more common in the middle third of the humeral shaft

than in other sites. Other recent studies however reveal that the areas at greatest risk are the proximal and the distal portions of the humerus. Transverse fracture pattern, fracture distraction, soft tissue interposition, inadequate immobilization and restricted limitation of shoulder motion are all associated with an increased risk for non-union. Other predisposing factors include old age, poor nutritional status, steroid use, anticoagulation, prior radiation therapy and fracture immediately adjacent to a burn. The rate of non-union associated with humeral fractures ranges from 0% to 15%. ^(38,39,40,41)

Radial nerve paralysis associated with fracture of the humerus is the most common peripheral nerve lesion complicating fractures. ^(35,42,43,44) Whether a radial nerve palsy is an indication for exploration and internal fixation remains controversial. In several studies, the incidence of actual nerve lacerations was low and there was a high rate of recovery of nerve function after closed treatment. In the absence therefore of other indications for open reduction and internal fixation this should be treated non-operatively. ^(43,44) *Holstein and Lewis* emphasize the danger of a spiral fracture involving the distal third of the humerus with radial angulation at the site – the radial nerve in such fractures was found caught between the bone ends. ⁽⁴⁵⁾

Open fractures require emergency debridement fracture stabilization after soft tissue cover which tremendously reduce the incidence of infection. ^(19,20,24,34) Fractures with concomitant vascular injury require stabilization to safe guard vessel healing and repair. Plate fixation of open humeral shaft fractures is considered the gold standard of care. ^(25,44,45,46)

When stabilization of the humerus is indicated, the choices are

- Open reduction and plating
- Intramedullary nailing
- External fixation including the Ilizarov circular external fixator

Rigid fixation and anatomic alignment are consistently achieved with good operative technique. A literature review by *Gregory and Sanders* ⁽⁴⁷⁾ found that non-union and hardware failure after humeral plating occurred in 3.6% of 302 cases reported by 6 different centers. The infection rate was 3.3% (10 of 302 cases) and the incidence of radial nerve palsy was 1.9% (6 of 302 cases).

Nevertheless, the risk of causing iatrogenic radial nerve palsy is of great concern to the treating surgeon. The reported rates of radial nerve injury associated with open reduction and internal fixation (ORIF) range from 0% to 5% with most of these palsies transient in nature.^(23,25,35,48) Since the incidence of radial nerve palsy does not appear to be influenced by the choice of approach, the choice of approach should be based on the pathoanatomy of the fracture and the preference of the treating surgeon. Popular approaches are the anterolateral and the posterior approaches.

The anterolateral approach is the most often used for ORIF. This approach provides access to the entire diaphysis of the humerus and can be extended both proximally and distally. The posterior approach provides exposure of the lower three fourths of the

humerus and is now often used for fractures of the distal third of the humerus .For these injuries the posterior surface of the humerus is relatively flat and therefore is ideal for placing a plate. The radial nerve is at some risk during posterior exposures and it must be identified and protected. ⁽⁴⁸⁾ Rarely, direct medial or lateral approaches to the humerus may be considered. Medial approaches are usually performed for exposure of open fractures with a medial wound, or when a vascular exposure is necessary. The lateral approach is an extensile approach that allows supine positioning and requires no muscle splitting. ^(48,49)

After open reduction of the fracture, osteosynthesis is most effectively performed with the standard AO/ASIF techniques.⁽⁵⁰⁾ This includes placement of a lag screw outside or preferably through the plate to achieve compression at the fracture site. The implant to be used must be selected based on the size and configuration of the fracture. For transverse or short oblique fractures a 4.5 mm AO compression plate can be used: fixation with a six or eight hole plate of this type usually is secure enough. Smaller, 3.5mm plates fit better more on more distal fractures. Fixation engaging eight cortices above and below comminuted fractures is recommended. For long and spiral fractures, transfixation lag screws can be used but some form of external support such as a humeral splint may be required .A bone graft may be helpful if comminution is excessive or fixation is less than ideal, such as in patients with osteopenia.

Newer plates and operative exposures have made it possible to use two plates in orthogonal planes. These include the modern low contact implants such as the limited

contact dynamic compression plate (LC-DCP), the PC fix and the so-called wave plate. With these techniques there is limited elevation of muscle from bone with minimal subperiosteal dissection and less surface area in contact with bone and it is likely that this techniques do not disrupt blood supply to the bone and do not limit the biological capacity of the bone to heal. It may therefore be possible to take advantage of orthogonal plates without compromising the biological aspects of bone healing.^(51,52,53,54,55)

In their recent prospective randomized, trial comparing plating and intramedullary nailing *McCormack et al*⁽⁵⁶⁾ noted that open reduction and internal fixation with a dynamic compression plate (DCP) remained the best treatment for unstable fractures of the shaft of the humerus. Fixation by intramedullary nail may be indicated for specific situations but is technically more demanding and has a higher rate of complication. Their findings compare well with earlier studies.^(57,58) However, *Chapman et al* in a similar prospective study found no difference between the two groups.⁽⁵⁹⁾

Intramedullary fixation of humeral fractures has gained popularity in recent years for several reasons including improved image intensification, the introduction of locking humeral nails, the relatively percutaneous insertion techniques that obviate the need for large incisions and the overall satisfaction with intramedullary nailing for fractures of other bones. The most important considerations in the decision to use an intramedullary device for a fracture of the humeral shaft include the type, location and anatomic

extension of the fracture and the canal diameter of the humerus, the situation where nailing is clearly indicated over plating include:

- Burns overlying a fracture
- Multiple injuries
- Pathological fractures
- Osteopenic bone
- Segmental fractures where closed methods have failed

The variety of implants that have been used for intramedullary nailing can be divided into two broad types: multiple flexible nails and simple rigid nails with interlocking capability.

Flexible nails maybe inserted antegrade through the greater tuberosity or retrograde through the humeral epicondyles. The goals of treatment are to fill the humeral canal with multiple nails and to achieve interference fit creating both rotational and bending stability. The use of flexible implants for intramedullary nailing is often associated with nail migration. However, good results have been reported after the use of Enders nails, Hackethal nails, Rush rods and Kirschner wires, with union rates of more than 90% demonstrated.⁽⁶⁰⁾ While nails can be locked at the end with wire or 3.5mm cortical screws to prevent migration, shortening and/or angulation may still occur in spiral comminuted fractures because static locking is not possible. At present most surgeons use them in fractures with a transverse or short oblique pattern.

The development of locked nails is an attempt to overcome the stability problems associated with flexible nails, while maintaining the ability to use closed technique of fracture fixation. Intramedullary nailing is a well established technique with documented union rates of 95% and a low risk of problems such as malunion, delayed or non-union, infection or radial nerve injury. However, many series document a definite incidence of shoulder pain of 10% to 30% of patients.^(61,62) Most cases of pain appear to be mild and self-limited. The pain is thought to be due to the damage to the subdeltoid bursa, subacromial bursa and/or the rotator cuff. Some degree of shoulder pain is also seen in patients with humeral fractures that are treated with means other than antegrade nailing. It appears that the approach to the rotator cuff has a significant effect on the incidence and the severity of shoulder pain after antegrade humeral nailing. The surgical approach initially recommended and still used by many surgeons is a lateral deltoid splitting approach. *Reimer et al*⁽⁶³⁾ and *Lin and coworkers*⁽⁶⁴⁾ noted that the use of an anterior subacromial approach was associated with a lower incidence of postoperative shoulder dysfunction. To avoid the complication of shoulder pain associated with antegrade nailing several traumatologists began to use retrograde insertion of humeral nails. When inserted from the distal end, the nail must be long enough to engage the cancellous part of the head of the humerus because the wide medullary part of the proximal part of the shaft does not give the nail enough stability. For retrograde nailing, a large portal in or just above the olecranon fossa is necessary and due to the amount of bone that must be removed, the distal humerus is weakened and may be prone to fracture at the nail entry site. In addition, there are clinical reports that describe iatrogenic fractures occurring at

the entry site of nail insertion. It is also easy to inadvertently ream the anterior cortex of the distal humerus as the entry portal is being created which further weakens the distal humerus. (65,66)

Reaming the intramedullary canal has not been shown to increase the union rates reported for humeral nailing. Concerns about damage to the radial nerve and thermal necrosis due to reaming have led to development of implants that are small enough to be inserted without reaming. (67,68,69)

Retrograde insertion is contraindicated for fractures of the distal third of the humerus, fractures in osteoporotic bone or when the intramedullary canal is less than 10 mm in diameter. In comminuted fractures care must be taken not to lengthen the humerus while locking proximally or distally.

Advantages of intramedullary nailing include reduced blood loss, increased speed of procedure and maintenance of soft tissue envelope and blood supply to the fracture site. Intramedullary fixation has been used frequently for pathological fractures secondary to malignant tumors: in these stability and comfort are more important than eventual union.

The relative benefits of plating compared with locked nailing are controversial. Advocates of intramedullary nailing claim that this method provides for closed fracture treatment and reduces the risk of radial nerve injury and infection that is associated with the surgical exposure required for open reduction and plate fixation. By contrast the advocates of plate fixation cite the higher union rates and less shoulder pain compared with antegrade nailing of humeral fractures. *McCormack's* and *Chapman's* papers

document that the major difference between compression plating and intramedullary nailing is the type of complications that are encountered. Nailing when performed antegrade, is associated with a higher incidence of shoulder pain and dysfunction whereas plating is associated with more elbow stiffness and pain.

Generally, solitary fractures of the humerus in children are treated with closed reduction and immobilization with a cast but this can cause problems for some patients with multiple injuries .consideration should be given to operative treatment of all displaced fractures in the multiply injured child . However, wounds and fractures heal more quickly in young children than they do in adults .In addition, children who have multiple injuries were typically active and healthy before the trauma. Substantial angulation and displacement can be accepted because the bone remodels excellently after this fracture even in teenagers. Nonetheless there are some relatively frequent clinical situations in which it is best to treat the fractures either by external or internal fixation . These situations include a displaced and shortened fracture in a comatose child , an open or closed fracture associated with a large wound or loss of skin , vascular injury , compartment syndrome and ipsilateral fracture of the forearm . The techniques used for internal fixation of fractures in children differ in some ways from those used in adults. The main types of internal fixation in children are kirschner wires and AO plates . The primary purposes of internal fixation in children are to align the fracture fragments enough to allow healing, to facilitate the care of other injured organ systems and to prevent complications that may be associated with immobilization of the extremity. Since non-union of fractures is unusual in children, the fixation does not have to be as rigid as it

needs to be for adults. In addition, intramedullary fixation with reaming should be avoided in order to prevent iatrogenic injury to the open growth plates.

External fixator devices appliances are useful in open fractures of the humerus in which the insertion of internal fixation may lead to infection or other complications. The Ilizarov circular external fixator has been used successfully to manage non-union of the humerus. (70)

The key to successful management of a humeral fracture is determining the most appropriate non operative or operative approach for each patient. The benefits and risks of each procedure must be evaluated and care must be taken to avoid potential complications as much as possible. Adequate preoperative planning to reduce operative time, prophylactic antibiotics, and meticulous soft tissue techniques will reduce the incidence of infections and complications.

OBJECTIVES OF STUDY

Main objective

To determine the pattern of patients presenting with humeral shaft fractures, managed by both non-operative and operative methods at Kenyatta National Hospital.

Specific objectives

- To determine the number patients with humeral shaft fractures seen at Kenyatta National Hospital.
- Find out age and sex distribution of patients with humeral shaft fractures.
- Determine causes of these injuries
- Determine the types of associated injuries.
- Determine the site and pattern of humeral shaft fractures
- Identify indications of conservative management of these fractures.
- Identify indications for operative treatment
- Documents methods of internal fixation.
- Establish the complications following conservative management.
- Establish the immediate complications following internal fixation of the humeral shaft.

RATIONALE OF STUDY

Non-operative treatment has been the preferred treatment for fractures of the humeral shaft. The role of operative treatment of the fractures remains controversial however; a review of recent literature reveals a shift towards operative treatment than earlier advocated.

A previous study at KNH revealed a higher morbidity for those humeral shaft fractures managed operatively and recommended a higher emphasis on conservative management (*Rusagara M.Med. Dissertation 1991*).

This study documented the presentation and current management of these injuries at K.N.H.

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MATERIALS AND METHODS

This was a prospective descriptive study over a period of seven months between February 2004 and August 2004.

Study setting

KNH serves as a referral hospital to all government, provincial and district hospitals. It is the main trauma center serving the city of Nairobi. Currently it is also the University of Nairobi teaching hospital.

Study plan.

All patients with diaphyseal fractures of the humerus were recruited from the KNH accident and emergency department, the orthopedic wards and the orthopedic clinics. The age, sex and cause of injury were noted .Any other associated injuries as well as other fractures were recorded .Radiographs taken at admission were reviewed to determine the site and pattern of fracture. Indications, methods and dates of internal fixation were also noted .Post-operative radiographs were reviewed .Follow up consisted of reviews at the fracture clinic , where examination and appropriate investigations were conducted to determine clinical and radiological evidence of bone union and to establish development of complication. Any additional surgical procedures for complications were recorded. A proforma questionnaire was used to record all the required information.

Inclusion criteria

All cases of fractures of the humeral shaft presenting at the KNH accident and emergency department, those admitted in the orthopedic wards and managed at this hospital either operatively or non-operatively and those on follow up at the fracture clinics during this period.

Exclusion criteria

All patients refusing consent to participate in the study.

Study Population

All patients with diaphyseal fractures of the humerus and managed at KNH either conservatively or operatively.

ETHICAL ASPECTS

An application was made to the ethical and research committee of KNH to permit the study to be conducted in the institution. All patients' records were handled confidentially. Patient's names and personal numbers do not appear in the final text. The information obtained will not be used for any other purpose. The data collection started only when the ethical committee gave consent for the study to proceed.

Data Presentation

This is in the form of tables, bar charts, graphs and pie charts.

Data Analysis

The information was collected in the data collection sheet. This data was analysed using the SPSS/PC+ software for Windows Version 10 was used for data entry and analysis. Descriptive statistics like means and standard deviation for continuous data and frequency distribution for categorical data was generated.

STUDY LIMITATION

1. The study was limited to the Kenyatta National Hospital and may therefore not be wholly representative of the country.
2. Some patients were lost to follow up.

SAMPLE SIZE

The sample size was estimated using the formula provided for by Lwanga and Lemeshow.⁽⁸⁸⁾

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

Where:

Z is standard normal variant corresponding to the 95%

Confidence interval, and is 1.96

p is expected prevalence of patients with diaphyseal

humeral fractures . A value of 3% was used (estimated

prevalence of diaphyseal fractures).

d is the required precision of the estimate (0.05)

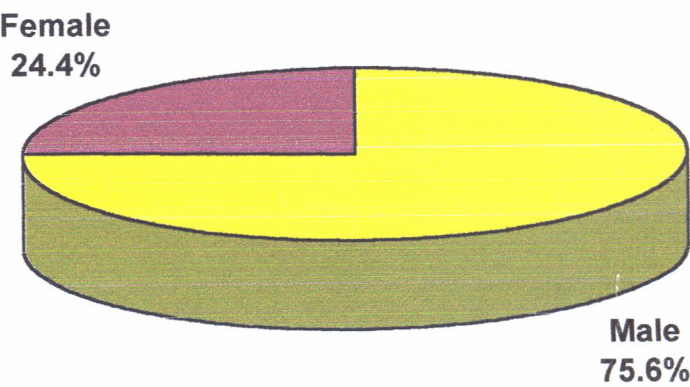
q is (100 -p)%

and therefore :

$$n = \frac{1.96^2 \times 0.03 (1 - 0.03)}{(0.05)^2} = 44.7$$

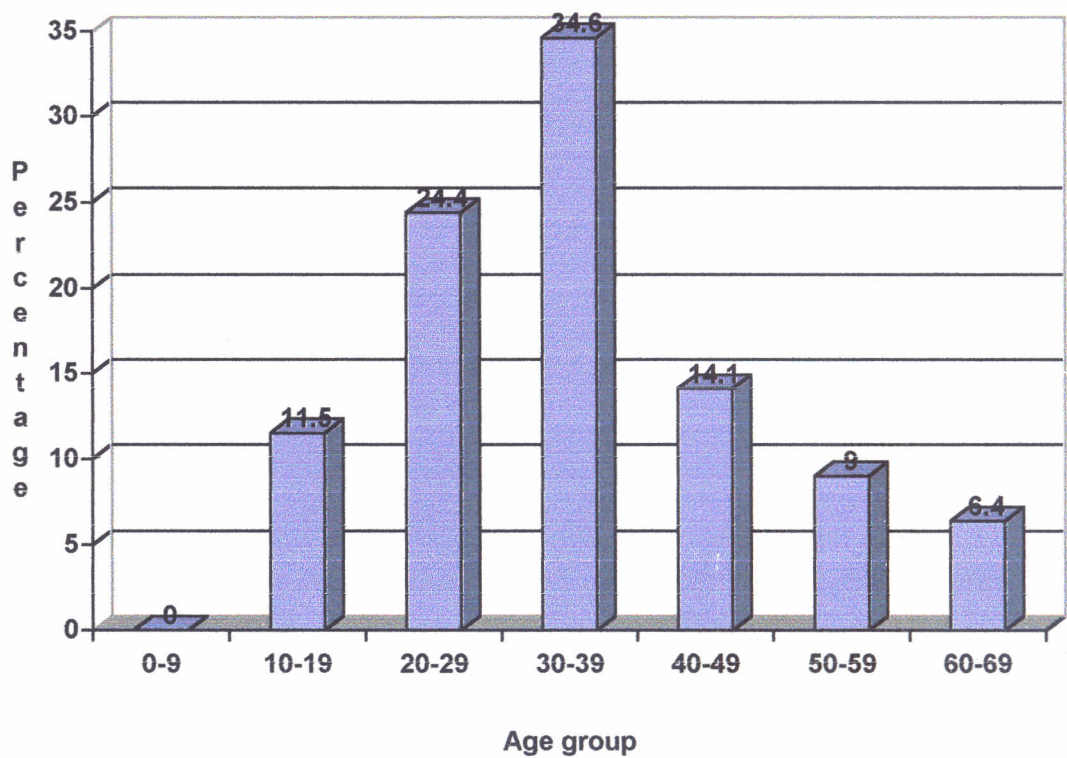
RESULTS

Figure 1: **Sex Distribution**



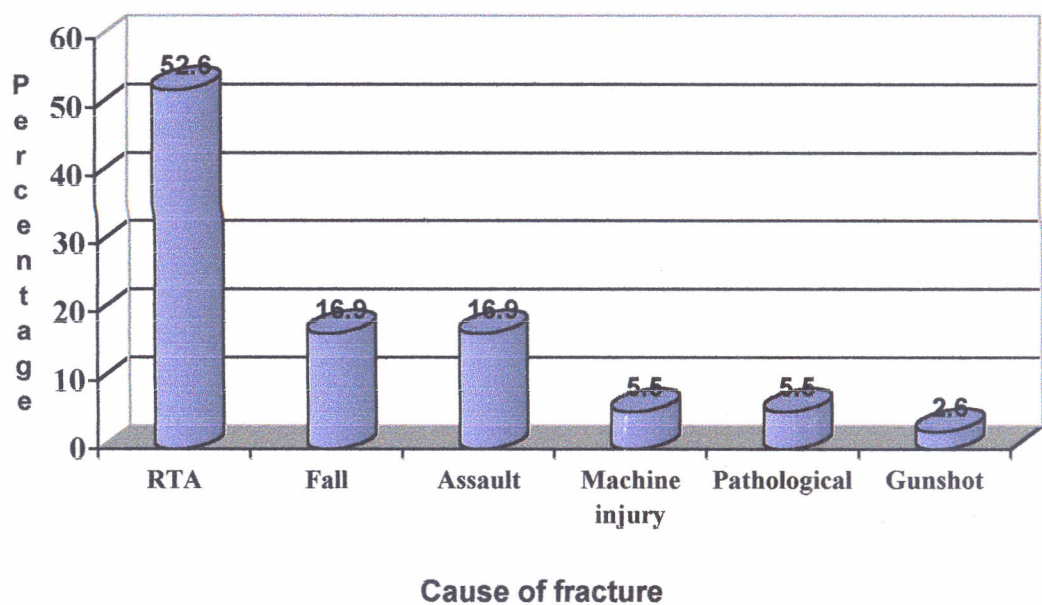
Males were more than females , with a male to female ratio of 3:1

Figure 2: Age distribution



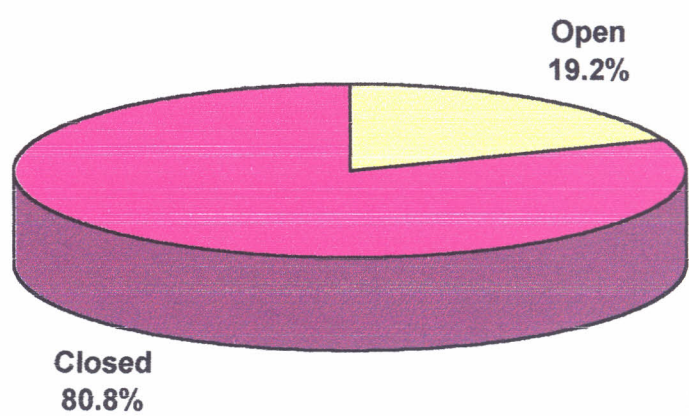
The mean age was 34 years . The most common age group in this study was 30 -39 which accounted for 34.6%

Figure 3: Causes of fracture (humeral diaphysis)



The commonest cause of the fracture was road traffic accidents which constituted 52.6%. Falls and Assault each accounted for 16.9 % of the patients.

Figure 4: Type of fracture



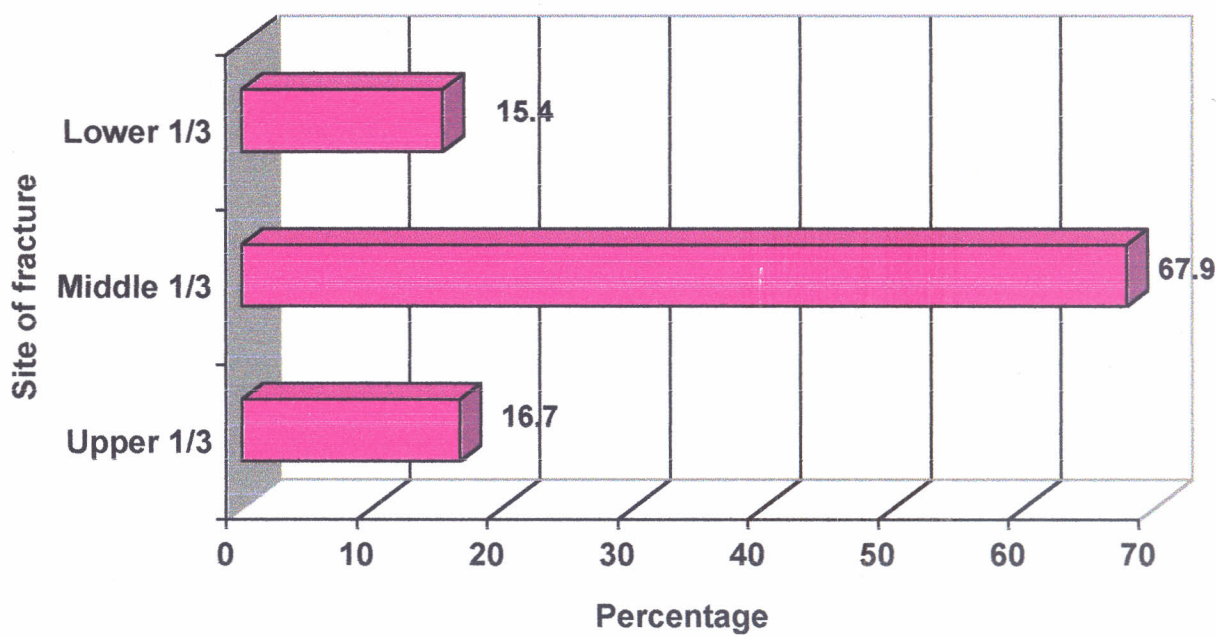
Majority of the patients seen during this study with diaphyseal fracture of the humerus had closed fractures with 80.8%.

Table 1: **Fracture pattern**

Fracture pattern	Number	Percent
Transverse	29	37.2
Oblique	24	30.8
Spiral	16	20.5
Segmental	5	6.4
Comminuted	4	5.1
Total	78	100

Transverse fractures predominated with 37.2%.

Figure 5: Site of Fracture



The middle third of the shaft was the most frequent fracture site (67.9%)

Table 3: Indications for internal fixation

Indication	Number	Percent
Non union	11	40.7
Multiple injuries	8	29.6
Pathological fractures	1	3.7
Neurovascular injury.	5	18.5
Malunion	2	7.4

The leading indication for internal fixation was non union (40.7%) followed by multiple injury (29.6%).

Table 4: Types of internal fixation

Type of internal fixation	Number	Percentage
Plating	20	25.6
K-wiring	3	3.8
Rush pin	4	5.1

Plating was the commonest performed procedure for internal fixation of diaphyseal fractures of the humerus in this study.

Table 5: Complications following internal fixation

Complication	Number	Percentage
Radial nerve palsy	1	3.7
Stiff elbow	2	7.4
Stiff/painful shoulder	1	3.7
Deep infection	1	3.7
Non union	1	3.7

Immediate complications following internal fixation in this fracture noted during this study included iatrogenic radial nerve palsy which occurred in one patient (3.7%) , deep infection , stiff elbow , stiff painful shoulder and deep infection . Only one patient was noted to have developed non union in this study as the follow up period was short.

DISCUSSION

Over the seven month period from February to August 2004 a total of 78 patients with diaphyseal fracture of the humerus were recruited into this study.

Of these, seventy seven had initial management by conservative means. These included U-slab, hanging cast and back slab. One patient with a compound fracture with extensive soft tissue loss had an external fixator inserted following emergent surgical toilet.

Twenty seven patients had internal fixation performed for various indications during the period of the study.

Eleven patients (14.1%) were unavailable for follow up for various reasons. These included five patients (three of whom were street people) that did not present themselves for follow up at the clinic after initial management and six patients that were advised to proceed to their respective wards to book for surgery, have not had surgery and have not been back to the clinic. It is probable that some patients may not have understood the need for follow up once the pain had settled and they were able to use their limbs, others may not have had the necessary funds to attend the clinic and others to obtain operative treatment.

The age of the patients ranged from 10 to 66 years. The mean age was 34 years. The age group most affected was the 30-39 age group accounting for 34.6% of the patients

studied. There were no patients below 10 years of age. A diaphyseal injury in a child with an inconsistent injury mechanism should raise the suspicion for abuse.

Fifty nine patients (75.6%) were male while nineteen patients (24.4 %) were females.

Sarmiento et al ⁽¹⁴⁾ found the average age patients with diaphyseal fractures of the humerus to be 36 years (range 16 to 83 years) at the time of injury with 63 % of their patients being males.

The most frequent cause of fracture in the study was road traffic accidents which accounted for 41 patients (52.6%). Falls accounted for 16.7 % with 13 patients, assault 13 patients while machine injury and pathological fractures represented 5.1% of the fractures each. There were two patients (2.6%) who sustained a fracture of the shaft of humerus following gun shot injury.

Rusangara in his study found that road traffic accidents accounted for 71.1% of the fractures followed by falls which accounted for 20 %.⁽¹⁰⁾

Sarmiento et al ⁽¹⁴⁾ found that the majority of the injuries were sustained as a result of motor vehicle accidents (34 %), followed by fractures sustained as a result of a fall (31 %), and 19% of the fractures were sustained from gunshot injuries . Various other casues included bicycle accidents, direct blow to the arm or a twisting force (16 %).

Fractures that occur spontaneously without apparent injury suggest pathologic fracture. Causes include cancer metastatic to the bone, paget's disease, multiple myeloma and bone cyst.⁽⁸³⁾

Fracture of the humeral diaphysis is rarely a sporting injury .None was found in the present study. However, it has been described as an unusual sequelae of the overhead throwing motion.This injury has been sustained by professional and nonprofessional athletes throwing several different types of objects. The fracture is postulated to be the result of torsional stress concentrated in the middle and distal humeral diaphysis.^(85,87)

Sixty three of the patients (80.8%) had closed fractures while 15 patients (19.2 %) had open fractures. Four patients (26.7%) sustained open fractures due to road traffic accidents. Assault caused open fractures in 7 patients (46.7%) with two being caused by gunshots. Assault is becoming a major cause of trauma in our setting with insecurity becoming a major issue in our country.

All the patients had surgical toilet performed within forty eight hours. Only one patient had antibiotics while awaiting surgical toilet. No antibiotics were given in the accident and emergency department. All patients with open injuries received anti tetanus toxoid on arrival at the accident and emergency department. One patient had external fixation performed following surgical toilet while the rest had a backslab applied after surgical toilet to facilitate dressing of the wounds.11 patients had surgical toilet performed for soft tissue injuries unrelated to the fractures.

Open humeral fractures are not common. They most often present in patients with multiple injuries and carry a high risk of radial nerve palsy. Low grade open fractures can be managed non-operatively after surgical toilet. However, in the presence of radial nerve palsy consensus holds that operative exploration is required. For those with severe soft tissue injuries external fixators are indicated.

In what is considered the largest reported series in the literature of open humeral shaft fractures and probably the first reported series of immediate fixation of such fractures *Nair et al*⁽⁴⁶⁾ reported a retrospective study of 53 patients with open humeral shaft fractures treated at a level one trauma centre . Immediate irrigation and debridement as well as open reduction and internal fixation were conducted for all patients. Reduction and internal fixation were achieved in the majority of patients within 8 hours of hospital admission. No iatrogenic nerve injuries or infections occurred .The authors concluded that immediate irrigation , debridement , and immediate osteosynthesis of open humeral fractures leads to excellent results. By following AO principles with a desired fixation of eight cortices above and below the fracture site, they achieved a 100% union rate.

Forty five patients had fractures on the left and thirty three had fractures on the right humerus. There were no patients with bilateral humeral fractures noted in this study.

Fifty three patients (67.9%) presented with fractures in the middle third, 12 patients (15.4%) had fractures in the lower third while in the upper third 13 patients (16.7%).

Transverse fractures occurred in 29 (37.2%) of the patients Oblique fractures were the second most common occurring with 24 patients (30.8%), 16 patients (20.5%) had spiral fractures and 4 (5.1%) had comminuted fractures.

Griend et al ⁽²⁰⁾ found the left humerus fractured at the diaphysis in 21 patients and the right in 15. They also reported that the fracture was located in the proximal third in 3 patients (8.3%), middle third in 23 (63.8 %) and distal third in 10 patients (27.3 %).

Majority of the patients (64 %) had U slab and arm sling as the method of conservative management. This is applied particularly for fractures involving the upper and middle thirds. 33% had hanging cast and arm sling applied. This is mostly applied for fractures involving the lower third.

The average period to achievement of satisfactory union was 8 weeks (range 4 to 16 weeks). This was determined radiologically by the presence of bridging callus in two views and clinically by the absence of pain and bony tenderness. ^(14,15)

Non operative management still remains the treatment of choice for most fractures of the humeral diaphysis. High rates of union and satisfactory functional results have given

credence to this method. *Osterman et al*⁽⁷¹⁾ reported non union of four (2%) of 191 fractures. *Zagorski et al*⁽¹⁸⁾ reported that three (2%) of 170 patients had a non union.

It is not known by what mechanism motion encourages fracture healing but it is postulated that the pain and subsequent irritation created by motion between the two fragments results in a cascade of favourable events such as increased vascularity, piezoelectric potentials and local chemical and thermal changes

Sarmiento et al⁽¹⁴⁾ recently reported on the management of diaphyseal fractures of the humerus with a prefabricated brace that permits full motion of all joints and progressive use of the injured extremity. In their report where they were able to follow up 620 patients between 1978 and 1990, they conclude that treatment of the humeral diaphysis with functional bracing is associated with a high rate of union, particularly when used for closed fractures. They found that the residual angular deformities are usually functionally and aesthetically acceptable. In this study *Sarmiento*⁽¹⁴⁾ and his colleagues found a rate of non union of less than 2% in 465 patients who had closed fractures and 6% in the 155 patients who had open fractures. The brace consists of two plastic sleeves that encircle the arm and are held together by two adjustable Velcro straps.

None of the patients in this study were managed by a prefabricated brace.

A total of 27 patients had internal fixation performed for fractures of humeral shaft during the period of the study. Plating was the most commonly performed procedure

accounting for 20(25.5 %) of the patient).Of these, the majority (70%)were performed through the anterolateral approach .Seven patients(9 %) had intramedullary fixation performed with 3 patients having kirschner wires(k wires) inserted and rush pins inserted in 4 patients .Of these, two patients had the intramedullary fixation performed by the retrograde method while five by the antegrade method.

The goal of internal fixation is stable fixation of fracture fragments with maintenance of anatomic alignment and load transference across the fracture site to induce osseous union.⁽⁴⁾ Controversy remains, however, concerning the ideal method of internal fixation of fracture of the humeral diaphysis. Numerous studies comparing internal fixation with plate osteosynthesis versus intramedullary nail fixation have cited advantages of each method. Recently, in a randomized prospective evaluation comparing intramedullary nailing versus plate fixation of humeral shaft fractures, *Chapman et al* ⁽⁵⁹⁾ reported comparable rates of union using either method with a higher incidence of shoulder pain and stiffness in the intramedullary nail group and a higher incidence of elbow stiffness in the plate fixation group.

Plate fixation has been demonstrated to achieve high rates of union with early active shoulder and elbow range of motion but may require extensive exposure and periosteal stripping although technical advances have introduced methods with less disruption of the soft tissue envelope. ^(14,72,77) Most humeral fractures may be exposed successfully by using either an anterolateral approach or a posterior approach .Both approaches require measures to protect the radial nerve. The anterolateral approach is the most often used

for internal fixation. This approach provides access to the entire diaphysis of the humerus and can be extended both proximally and distally. In general the posterior approach is used for patients with fractures of the distal one third of the humerus. For these injuries the posterior surface of the humerus is relatively flat and therefore ideal for placing a plate.⁽⁷²⁾

Intramedullary rod fixation offers the advantages of biomechanical load sharing, closed insertion techniques with decreased soft tissue disruption, and preservation of the extramedullary vascular supply, but has been implicated in post operative shoulder and elbow dysfunction.⁽²⁸⁾

The most common indication for operative management in this study was non union with 9 patients (36%). Multiple injuries followed with 32%. This differs with other studies elsewhere that have multiple injuries as the leading indication.^(22,37) *Foster et al*⁽³⁷⁾ found that multiple injuries was the most common indication for internal fixation accounting for 43.8%. However this reveals a trend towards a change with a rise in multiple injuries as an indication for internal fixation at K.N.H. when compared to what *Rusagara* found in 1991.⁽¹⁰⁾

Fracture healing requires a good vascular supply and bone apposition. Non unions occur when the blood supply is insufficient, when there is excess motion or when there is soft tissue interposition or a bony gap. When a fracture of the humerus that has been treated non operatively fails to heal, it is usually due to excess motion.⁽⁷³⁾ Other factors that may

contribute to humeral shaft non union include obesity, transverse fractures, infection, alcoholism and poor patient compliance ⁽⁴¹⁾

Significant difficulty occurs in treatment of humeral non unions in patients who have sustained bone loss from gunshot injuries and from severe osteoporosis due to immobilization. Non union is best treated by compression plating .Surgical objectives include creation of osseous stability, elimination of the non union gap , maintenance or restoration of bone vascularity and elimination of infection. Two recent studies have reported excellent results for treatment of humeral non union with compression plating combined with cancellous bone grafting. *Rosen et al* ⁽⁷³⁾ reported a 97% union rate in 32 humeral non unions treated with plates and screws. *Baguet* and co workers ⁽⁷⁴⁾ reported successful union in 24 of 25 (96%) non unions of the humerus .

Eight patients had internal fixation performed due to multiple injuries. All were involved in road traffic accidents. These included one patient with an ipsilateral fracture femur, one patient with a contralateral fracture of the ulna and two patients with ipsilateral fractures of the distal radius. Five patients sustained vascular injuries with successful primary anastomosis . No patient had an ipsilateral fracture of both radial and ulna shafts (floating elbow). No patients sustained bilateral fracture of the humerus and there were no patients with concurrent burns.

Fractures that have concomitant vascular injury require stabilization to safeguard vessel healing and repair. Ipsilateral fractures of the humerus and both radius and ulna (floating elbow) are best managed with internal fixation followed by early range of motion.⁽⁹⁾ Ipsilateral fracture of the lower limb is an indication for surgery as a stable arm is required to use crutches. Bilateral fracture of the humerus requires operative stabilization to facilitate patient self care. This indication has been mentioned by others but not encountered in this study ^(9,11,14). Patients with polytrauma may be unable to sustain the semisitting posture recommended for effective fracture reduction; furthermore, operative stabilization supports the general rehabilitation of these patients.

In one patient Plating was performed and chemotherapy initiated after a diagnosis of multiple myeloma was made. Another had a backslab applied and was referred to the oncology clinic for follow up after biopsy revealed a plasmacytoma. No other findings support the diagnosis of multiple myeloma as she has a normal serum electrophoretic pattern, urine is negative for bence –jones proteins and radiographs of the skull and pelvis are normal. She however had not had a bone marrow aspirate performed at the conclusion of the study.

Oburu (M.Med dissertation 2003) noted that most malignant pathological fractures were in the spine. A malignant pathological fracture is less likely to occur in the upper limb than in the pelvis and the lower limbs. ⁽⁸³⁾

Many authors have advised closed intramedullary nailing for pathological fractures which avoids opening the fracture site, while biopsy can be performed at the same time using intramedullary biopsy forceps. In patients with diffuse disease such as multiple myeloma good bone stock is not always available. Bone cement can provide the necessary support in many circumstances.

Radial nerve palsy was observed at admission in seven patients. Two patients that sustained compound fractures in the middle third of the shaft following machine and gunshot injury with neurovascular involvement underwent plate fixation with repair of the vessels successfully. One patient had plate fixation for a compound fracture with radial nerve involvement. One patient was explored and plating performed after there was noted to be no improvement in nerve function on conservative management. All the patients presenting with radial nerve palsy had fractures in the middle third.

Radial nerve paralysis associated with fracture of the humerus is the most common peripheral nerve lesion complicating fractures. Approximately 12% of fractures of the shaft of the humerus are complicated by immediate radial nerve paralysis.^(32,33) The relationship between the level of the fracture and the likelihood of radial nerve injury is established⁽³²⁾. In fractures involving the lower third of the humerus the nerve may be caught up in between the fragments as in the so called *Holstein –Lewis* fracture.⁽⁴⁵⁾ Whether a radial nerve palsy is an indication for exploration and internal fixation remains controversial^(42,45). In several series, the incidence of actual nerve lacerations was low and there was a high rate of recovery of nerve function after closed treatment.⁽³⁴⁾

However, exploration and internal fixation should be considered for any patient in whom radial nerve palsy develops after manipulation, because nerve entrapment at the fracture site is a frequent cause of this complication. *Holstein and Lewis* ⁽⁴⁵⁾ emphasize the danger of a spiral fracture involving the distal third of the shaft of the humerus with radial angulation at the fracture site. The radial nerve was found caught between the bone ends. If suspected open reduction should be performed. At this point the radial nerve has least mobility as it pierces the lateral intermuscular septum. At the middle third the nerve is in direct contact with the bone in the lower part of the spiral groove. ⁽⁸⁶⁾

Five patients (18.5%) developed immediate complications following internal fixation. These included one patient (3.7%) who developed a deep infection, one that developed a stiff painful shoulder following antegrade insertion of rush pin and two patients that developed stiff elbow following plate fixation. Radial nerve palsy was noted in one patient following plate fixation. Sensation in this patient is intact and his motor function is recovering well on occupational therapy. Non union was not documented following internal fixation as the period of follow up was short.

Because of the close proximity of the radial nerve to the humeral shaft and the necessity to dissect the radial nerve, plating is associated with a potential risk of radial nerve injury ⁽¹⁷⁾. Using plate osteosynthesis, difficulties with shoulder and elbow function that are described after antegrade or retrograde nailing of the humerus can be avoided. However, due to the risk of iatrogenic radial nerve palsies, open reduction and compression plating is technically demanding. Rates of radial nerve lesions of 5% to 8 % are reported ^(18, 19)

Gregory and Sanders ⁽²⁰⁾ in their review article report that the more common complications after plating procedures were infection and iatrogenic nerve palsy. Infection rates ranged from 0 % to 6 % with the majority of cases being associated with open fractures. Iatrogenic nerve palsy occurred in 0% to 5 % of cases and was usually a transient problem that did not require further intervention. They concluded that compression plate fixation of humeral shaft fractures was an effective and predictable procedure that restores skeletal anatomy and with a minimum of complications and functional problems. They found that the range of motion of the elbow and shoulder of the involved extremity returned to well after the plate fixation. Many surgeons advise that the plates should not be removed due to the risk of intraoperative radial nerve injury.

Intramedullary fixation of humeral shaft fractures avoids some of these disadvantages but the nails are not without complications. Unlocked nails have fallen out of favour because of failure to provide rotational stability and frequent slipping causing irritation to the joint. However locked nails provide good rotational stability but a potential risk of radial nerve injury remains because of the distal locking screws. Studies that have compared the results of plate fixation versus closed intramedullary nailing, report similar rates of union in both groups with fewer complications in the nail group ^(21, 22, 23).

Qidwai in his study of twenty nine patients treated by closed intramedullary kirschner wires (k wires) found a union rate of 93 % which is close to that reported in the literature on intramedullary stabilization of humeral fractures ^(24,25,26). There were no

problems of shoulder impingement and adhesive capsulitis in this series because the soft tissues of the shoulder remained untouched.

Stern et al ⁽²⁶⁾ found that adhesive capsulitis was a significant problem in their series of 70 humeral fractures treated with open intramedullary nailing. This is because most of the nails were inserted antegradely through a small incision in the rotator cuff.

CONCLUSIONS

On the basis of the data collected and analysed in this study and the review of current literature certain conclusions can be made.

- Conservative treatment remains the mainstay of treatment of this fracture. However, operative treatment can currently be performed successfully with minimum complications when indicated. This contrasts with *Rusagara* ⁽¹⁰⁾ who found an unacceptable morbidity following internal fixation especially with respect to iatrogenic radial nerve palsy. The cost of care of fractures of the humeral diaphysis by conservative means is nevertheless, lower than that of operative treatment, since hospitalization is not required, the rate of non union is low and recovery occurs within a short period .These are important factors to be considered in view of the high cost of health care .
- The indication for internal fixation is mainly non union with few patients having surgery for other indications. This is similar to what *Rusagara* found in 1991. the follow up period for this study was short. However, it is clear that there more procedures being performed currently for this fracture at K.N.H. as shown by the fact that there were twenty seven internal fixations performed in the six months of this study as compared to 45 procedures recorded by *Rusagara* in his five year retrospective study. A review of literature reveals that this finding mirrors that in other settings.

- Plate fixation remains the most commonly performed procedure in internal fixation of this fracture at K.N.H. Unless otherwise indicated plate removal should not be performed due to the risk of iatrogenic radial nerve palsy. Intramedullary nailing is only occasionally performed at K.N.H. for this fracture. However a review of current literature reveals that intramedullary fixation is now being used increasingly for the upper limb fractures. Insertion of K wires has been found to be a safe, simple and minimally invasive with minimal blood loss during surgery, satisfactory axial and rotational stability, low cost with minimal complications and easy removal of implants⁽²⁴⁾.
- Road traffic accidents (RTA) remain a major cause of this injury. However, anecdotal evidence reveals that recent measures introduced in the transport sector including controlled motor vehicle speeds and the wearing of seatbelts to have reduced the incidence of accidents. It is therefore anticipated that the contribution of RTAs will decline.
- Antibiotics are not routinely given to patients presenting with open fractures at the K.N.H. accident and emergency department.

- Immediate exploration of closed injuries presenting with radial nerve palsy remains controversial. Spontaneous recovery is expected to occur in virtually all instances if the fracture is closed. It is however, indicated in patients presenting with open fractures and neurovascular injuries.

RECOMMENDATIONS

- Functional prefabricated brace with collar and cuff sling is recommended .It is light weight, adjustable and well tolerated. Low grade open fractures may also be treated with this method after surgical toilet. This should be considered at K.N.H.
- The indications for internal fixation at K.N.H. should be expanded to include more of those patients with multiple injuries.
- Anterolateral approach with identification of the radial nerve in plate fixation is recommended.
- A protocol for the acute management of open fractures should be introduced at the K.N.H. accident and emergency department and enforced. This would include immediate, anti-tetanus toxoid, antibiotics, urgent surgical toilet and ideally urgent internal fixation if indicated. Preparation for surgery should therefore be done at the accident and emergency department and the patients admitted to the ward only after emergent surgical toilet has been performed
- Further local studies in the management of humeral shaft fractures should be considered. This may include a long term randomised prospective study comparing the various methods of management of this fracture.

- Measures should be taken to ensure that enforcement of the recently introduced traffic rules are sustained to reduce the impact of RTA in trauma.
- With a large number of patients being lost to follow up, the present study illustrates the difficulties encountered in carrying out follow up of patients in our set up with many of our patients unable to afford the services available and the long waiting lists for surgery. A sustainable solution should be sought.

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APPENDIX 1

MANAGEMENT OF FRACTURE OF THE SHAFT OF THE HUMERUS IN KNH

QUESTIONNAIRE

FILE NO.

1. AGE in Years

2.SEX 1= Male 2= Female

3. DATE OF INJURY

4. CAUSE OF INJURY

1. Fall
2. Road traffic accident
3. Machine injury
4. Pathological
5. Others _____ specify _____

5. Other history

6. Smoking 1= Yes 2= No

7. Alcohol 1= Yes 2= No

8. Chronic illness eg. Diabetes Mellitus 1= Yes 2= No, Hypertension 1= Yes 2= No

3. Others.....

5. Other immobilization techniques Specify

12 Indications for Internal Fixation

1. Non union
2. Multiple injuries
3. Pathological fractures
4. Other (specify)

13 Date and Method of Internal Fixation

a Date

b Plating 1= Yes 2= No

Approach: 1= Anterolateral

2= Posterior

3= Others

c Intramedullary Nailing

1 Approach: 1= Retrograde

2= Anterograde

2 Type: 1= K-wiring

2= Rush pin

3= Others

d External Fixators 1= Yes 2= No

14 Complications after Internal Fixation

- 1 Delayed union
- 2 Non union
- 3 Deep infection

- 4 Stiff shoulder / painful shoulder
- 5 Stiff elbow
- 6 Refracture of plate
- 7Other (specify)

15.Additional Surgical Procedures Performed:

- | | |
|--------------------------------------|------------|
| 1.Removal of implant | Date:..... |
| 2 Incision and Drainage | Date:..... |
| 3Replating | Date:..... |
| 4 Manipulation of the shoulder joint | Date:..... |
| 5 Manipulation of the elbow joint | Date:..... |
| 6 Other (specify) | |

16 Duration of Union

APPENDIX 2

CONSENT EXPLANATION

A SEVEN MONTH PROSPECTIVE STUDY OF PATIENTS SEEN AT KENYATTA NATIONAL HOSPITAL WITH DIAPHYSEAL FRACTURE OF THE HUMERUS

My name is Dr. Albert Ruturi from the department of surgery , University of Nairobi . I am carrying out a study of patients with diaphyseal fracture of the humerus at Kenyatta National Hospital . I have obtained approval from the Kenyatta National Hospital Ethics and Research Committee to carry out this study. This study will determine the magnitude of the problem at this hospital, the causes of injury, the sex and ages of those involved and the management of their injuries.

All patients who present at the hospital with this injury during the period of the study will be invited to participate. If you accept to participate in the study it will be on a voluntary basis and you can withdraw your consent at any time. This will not affect your treatment in any way.

The information you provide will be treated with utmost confidentiality and your name will not be included in the final draft.

If you accept to participate in the study, please sign the consent. Should you have any questions in the course of your treatment, please do not hesitate to contact me.

DR. A. RUTURI
P.O. BOX 180 -00202,
K.N.H.

TELEPHONE : 0722-717355.

APPENDIX 3

CONSENT BY THE PATIENT:

I have understood the explanation given to me by Dr.Ruturi who is carrying out a study on fracture of the humerus and hereby consent to participate in the study .I agree to participate of my own free will and also to do the following :

1. Be interviewed and examined physically on the nature of my illness.
2. To be followed up on the subsequent management of my illness.
3. To have these details recorded by Dr.Ruturi.

KIBALI CHA MGONJWA

Nimeelewa maelezo yote aliyonipa Dr.Ruturi ambaye anafanya utafiti/uchunguzi juu ya uvunjikaji wa mfupa wa sehemu ya juu wa mkono na ninatoa kibali cha kuhusika kwa huu utafiti. Ninakubali kuhusikakwa hiari kwa huu utafiti .Ninakubali kuhusika kwa hiari na pia kuhitimisha maagizo yafuatayo-

1. *Kuhojiwa na kuchungunzwa kimwili juu ya maradhi yangu*
2. *Kufanyiwa uchunguzi zaidi kufuatia matibabu ya badaye*
3. *Kuidhinisha na kunukiliwa na Dr. Ruturi*

I have understood that my participation is completely voluntary and that I can withdraw my consent at any time during the study and that this will not affect my treatment in any way .

Nimeelewa kuwa kuhusishwa kwangu ni kwa hiari na nina uhuru wa kujiondoa kwa hu utafiti wakati wowote , bila kuadhiri matibabu yangu kwa njia ye yote .

That the information that I give will be treated with confidence and that my name will not be included in the final draft .

Na kuwa habari yote nitakayo toa ni siri na jina langu halitonakiliwa kamwe katika nakala ya mwisho.

Dr A RUTURI

Signed.....

Daktari

Sahihi.....

Participant

/Guardian.....Signed.....

Mhusika

Sahihi.....

Witness.....

Signed.....

Shahidi

Sahihi.....



KENYATTA NATIONAL HOSPITAL

Hospital Rd. along, Ngong Rd.
P.O. Box 20723, Nairobi.

Tel: 726300-9

Fax: 725272

Telegrams: "MEDSUP", Nairobi.

Email: KNHplan@Ken.Healthnet.org

Ref: KNH-ERC/01/2163

Date: 27 February 2004

Dr. Ruturi Albert J M
Dept. of Surgery
Faculty of Medicine
University of Nairobi

Dear Dr. Ruturi,

RESEARCH PROPOSAL "A SIX MONTH PROSPECTIVE STUDY OF PATIENTS SEEN AT
KENYATTA NATIONAL HOSPITAL WITH DIAPHYSEAL FRACTURE OF THE HUMERUS"
(P100/9/2003)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and **approved** the revised version of your above cited research proposal for the period 27 February 2004 – 26 February 2005. You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely,

PROF. A N GUANTAI
SECRETARY, KNH-ERC

Cc Prof. K Bhatt, Chairperson, KNH-ERC
The Deputy Director (C/S), KNH
The Dean, Faculty of Medicine, UON
The Chairman, Dept. of Surgery, UON
CMRO
Supervisor: Prof. L N Gakuu, Dept. of Surgery, UON