COMPARISON OF CLOSED FEMUR FRACTURE: SKELETAL TRACTION AND INTRAMEDULLARY NAILING COST-EFFECTIVENESS.

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DISSERTATION SUBMITTED IN PART FULFILLMENT FOR THE DEGREE M.MED ORTHOPAEDIC SURGERY AT THE UNIVERSITY OF NAIROBI.

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2013

DEDICATION

I would like to dedicate this dissertation to my lovely wife Evah and our two lovely daughters Nadia and Ella for being there through this journey offering me support in every step of the way.

I would also love to dedicate this dissertation to my Parents for the support they have given me and believing in me. I would not have achieved this without them.

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DECLARATION

Declaration by the candidate

This thesis is my original work and has not been presented for a degree in any other University. No part of this thesis may be reproduced without the prior written permission of the author and/or University of Nairobi.

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H58-71904- 08

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Date …….

APPROVAL

Declaration by the Supervisors

This thesis has been submitted for examination with our approval as university supervisors.

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CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr. David M. Kamau, MMed student, Registration number H58/71904/2008, Department of Orthopaedic Surgery, University of Nairobi.

This research was carried out at the Kenyatta National Hospital, Department of Orthopaedic Surgery.

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ABSTRACT

Background: *Fractures of the femur are common injuries affecting the productive age group. Skeletal traction is the mainstay of treatment in Kenya, hence comparison with operative management, to determine which is more cost-effective. No similar study has been done in Africa.* ***Objective:*** *To determine the cost-effectiveness of skeletal traction compared to intramedullary nailing.* ***Design:*** *Prospective conventional sampling analytical study.* ***Setting:*** *Hospital based study in a referral and teaching institution - Kenyatta National Hospital in the orthopaedic wards.* ***Study population:*** *Patients admitted at Kenyatta National Hospital with diaphyseal femur fracture between 18 – 50 years.* ***Duration of study:*** *October 2012 – May 2013.* ***Materials and methods:*** *A structured data collection sheet was used. It included the patient particulars, hospital stay and per diem cost, the type of injury, type of management and comparing the cost of each, x-ray findings during treatment and at 3 months to assess for union. Data was represented in form of tables, graphs and charts.* ***Results:*** *Males were more affected than females, with a mean age of* ***31.5 years****. The mean length of hospital stay was* ***11.48 days*** *for the operative group and* ***66.7 days*** *for the skeletal traction group. The average total hospital cost for the operative group was* ***54, 380.44 Kshs*** *compared to* ***67, 792Kshs*** *for the traction group. In the operative group* ***24*** *patients had union with one delayed union while the traction group* ***12*** *patients had union,* ***9*** *with mal union and* ***4*** *delayed union.* ***Conclusion:*** *Intramedullary nailing is more cost-effective than skeletal traction. It met the* ***dominant strategy****, because it was significantly less costly than skeletal traction, with a better outcome.*

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LIST OF TABLES, GRAPHS AND CHARTS

LIST OF ABBREVIATIONS

1. **RTA –** Road traffic accident.
2. **ST –** Skeletal traction.
3. **ORIF -** Open Reduction and Internal Fixation.
4. **CEA –** Cost-effectiveness analysis.
5. **TSSU –**Theatre Sterile Supplies Unit.
6. **DVT –** Deep venous thrombosis.
7. **SIGN –** Surgical Implant Generation Network.
8. **LOS –** Length of Stay.
9. **TEN –** Titanium Elastic Nail.
10. **KNH –** Kenyatta National Hospital.

DEFINITION OF TERMS

1. **COST – EFFECTIVENESS ANALYSIS** – Is the comparison of the outcomes of decisions in terms of their monetary value per natural unit of health outcome.
2. **DOMINANT STRATEGY –** Is when an intervention is less costly with an equal or better outcome, hence the preferred method of treatment.

BACKGROUND

Fractures of the femur are sustained following trauma, with the main cause being road traffic accidents.[1] In Kenya, conservative management is the mainstay of treatment[2], a pattern seen in most developing countries but obsolete in developed countries.

Skeletal traction leads to prolonged hospital stay and has more complication rates in comparison to operative management[3].The operative options for the management of closed femoral shaft fractures are; Intramedullary nails (K – nails, interlocking nails), plates and screws. The two treatment options result to eventual healing of the fracture. The question has been which one to adapt of the two treatment methods that will have better benefit to the patient and the hospital in terms of cost and outcome. Therefore, a cost-effectiveness analysis study is necessary to come up with the best way of management of femoral shaft fractures.

Cost-effectiveness analysis study is the most commonly utilized full economic health analysis. It has been used to compare different treatment modalities in the various medical and surgical fields. In this study, intramedullary nailing is more cost effective than skeletal traction or vice versa, if it meets the dominant strategy, if the outcome is worse with a less cost but the added benefit of the other mode of treatment is not worth the extra cost, or it is more costly with a better outcome and the added benefit is worth the extra cost [4, 5]. Little has been done on cost effectiveness of skeletal traction compared to open reduction and internal fixation of fractures of femoral shaft with majority of the work done in the pediatric age group [6, 7]. There is no documentation in Kenya and Africa showing the cost implications of skeletal traction compared to intramedullary nailing. The objective of the study is to determine which is more cost-effective between intramedullary nailing and skeletal traction.

LITERATURE REVIEW

Fractures of the femur shaft are very common injuries sustained following trauma [1, 2, 8]. The main cause of trauma in our country is road traffic accidents, which have been on the increment from 10,300 in 1990 to 17,400 in 2009, of the reported cases [9, 10].These injuries mainly affect people in the productive age group, between 20 – 40 years, with men more affected than women [1, 11].

Fractures of the femur take approximately 6-12 weeks to unite and 16-24 weeks to consolidate [3, 12]. In Kenya, conservative management, mainly skeletal traction remains the mainstay of treatment, a pattern seen in most developing countries [2].In developed countries this method has been obsolete for roughly the past forty years [13, 14].

Skeletal traction results in prolonged hospital stay, playing a major role in the crowded orthopaedic wards. This is due to high admission rates with an unequal discharge rate. There is a problem with theatre space, theatre equipment and time allocated to trauma surgeries. On the other hand operative management results in faster management of the patient, with quick mobilization and less complications [3, 12].

Complications related to non-operative treatment include; deep venous thrombosis (DVT), delayed union, non-union, mal union with limb shortening, pin tract infection, urinary tract infection, osteoporosis due to disuse and mechanical irritation of nearby nerves and vessels [3, 12]. In view of this, a cost analysis is required for better management at better costs for both the patient and hospital. The cost analysis that will be used in this study is a cost-effectiveness analysis.

Economic analyses in health care are very important and proving to be very useful in making decisions on the allocation of resources in an environment that requires consideration of costs [15].Various economic analyses are in use and applied depending on the study[16,17]. The economic analyses available are divided into partial and full. It is important to distinguish them because each will influence decision making in a different manner[18 – 23].The partial economic analyses are cost-of-illness analysis and cost-minimization analysis. The full economic analyses are cost-effectiveness analysis, cot-benefit analysis and cost-utility analysis[18 – 23].

Cost –effectiveness analysis is a fairly new concept in the medical field.[11]It has been found to be useful especially in formulation of policies. An intervention is said to be more cost effective if:-

1. It is less costly with an equal or better outcome, hence the preferred method of treatment [24, 25].
2. It is less costly with a worse outcome, but the added benefit of the alternative is not worth the extra cost [4, 26].
3. It is more costly with better outcomes, and the added benefit is worth the extra cost [4, 26].

There is minimal literature on the cost-effectiveness analysis of skeletal traction compared to open reduction and internal fixation for femur shaft fractures [27]. Much of it has been done on the pediatric age group and especially in the Western world. One of the main reasons that adult studies have not been done in the western world is that skeletal traction (conservative management) has been obsolete for over forty years [13, 14], hence the need for the studies. The reason Kenya and many parts of Africa might still be utilizing conservative management may be lack of resources, limited orthopaedic surgeons especially in the rural areas and also the assumption by the hospital management that conservative management is cheaper. This is considering the materials required for skeletal traction. Cost-effectiveness analysis has been utilized in other areas of orthopaedics, which acts as a benchmark for subsequent studies to be done, in policy making and in adoption of new technology.

Being a relatively new area in medicine, Tanner et al (2008) looked at how to conduct a good cost-effectiveness analysis [28].The analysis should provide a full economic comparison of healthcare strategies. It should consider all relevant patient groups, management options and possible outcomes [28, 29]. It should report results separately for patients who have different baseline risks [28, 30]. It should have a sufficiently wide viewpoint, like societal or third party payer viewpoint. It should establish clinical effectiveness; costs measured accurately including direct costs, indirect costs and working days lost [19, 29, 31]. Data on costs and outcomes should be appropriately integrated by calculating the incremental cost-effectiveness ratio (ICER). Appropriate allowances for uncertainties should be made by conducting sensitivity analysis. Timing of costs and consequences should be considered. The results should be applied to patient care, by assessing benefits versus the risks, settings in which similar costs and outcomes should be expected and resolution of the clinical scenario.

Bozic et al (2005) found that actual cost data is advantageous to charges or cost-to-charge ratios in cost effectiveness models [32-34].

Unfortunately, the studies done have found it hard to replicate the expected requirements. Some of the measures are also difficult to get accurate data like indirect costs and working days lost. There can also be a wide range of outcomes and complications. Some of the studies have utilized QALY (Quality Adjusted Life Years) as an outcome measure, which ideally is utilized in cost-utility analysis [35-37].

Brauer et al (2007) have looked at trends in cost effectiveness analyses in orthopaedic surgery[38]. They looked at orthopedic cost-effectiveness studies, reviewing critically methods used and examining the trends over time. The analyses were found to have a number of shortcomings such as inclusion of relatively few studies, inconsistent approaches to methodology and lack of transparency. Despite all this, cost-effectiveness analysis studies are important.

Cost-effectiveness analysis studies comparing conservative and operative management for fractures of the shaft of femur have been done more in the paediatric age group and very minimal in the adult which will be used as a benchmark for this study.

The study closest to the study question was done by Gosselin et al (2009). They did a cost-effectiveness analysis of replacing skeletal traction by interlocked intramedullary nailing for femoral shaft fractures in a provincial trauma hospital in Cambodia [4]. It was a retrospective study where they used specifically the Surgical Implant Generation Network (SIGN) nailing system, which is adapted for resource poor settings [39]. After exclusion, their data had a total of 87 patients, 50 in the skeletal traction group and 37 in the SIGN group with a follow up of 16 weeks. The length of stay was longer in the skeletal traction group with an average of 52.3 days compared to the 34.9 days for the SIGN group. There were better outcomes, earlier weight bearing and fewer complications in the SIGN group. The fixed costs were the same for the two groups, but variable costs were higher in the traction group, with per patient difference of $121.

In this study, the authors reviewed hospital records, x-rays and collected data on age, sex, type and time of fracture, time in traction and length of hospital stay. The outcome measures were weight bearing at discharge and healing. At discharge there were more patients on full weight bearing in the operative group.

There was a high percentage in healing in the operative group with fewer complications of non-union and mal-union compared to the traction group. The average length of hospital stay after traction was longer hence the total cost, which was highly attributable to the hospital per diem cost. Therefore surgery had less costs and better outcomes. The weakness is that the costs were not well reflected in the operative group because they was a mean of 20.7 days in traction and 14.2 days after nailing, in which the ideal would be to operate and discharge the patient within a week of admission thus adding the costs of the operative group. Surgery by different surgeons also affected the variable costs due to the learning curve. It was also harder to factor in wages lost due to lack of fixed income. The control group was retrospective and not matched, the two groups were not synchronous, and the follow up time was short.

Cost-effectiveness analysis studies have been done in the young age groups ranging from the ages of 3-17 years [6, 7, 40-42].They have looked at comparison of more than two different treatment methods of which internal fixation and traction were part of the management strategies [6, 42-46].One of the studies found the operative costs to be less compared to conservative treatment[43]; some found the same costs with operative having better outcomes[6, 44, 45] or operative being more costly [42, 46].The studies are as outlined below.

A retrospective study was done in the United States of America on 31 adolescents aged between 10-14 years with femoral shaft fractures, comparing hospitalization time, cost and time to mobilization between 20 patients who underwent closed reamed intramedullary nailing and 11 treated with casting and traction[43]. The time the operative group spent in hospital was shorter, and they mobilized faster compared to the traction group. The cost of the traction group was twice that of the operative. There was no malunion, limb length discrepancy or any evidence of arrest of the growth plate.

A comparison of effectiveness and cost of several treatment methods for isolated closed diaphyseal fractures of the femur in children aged between 4-16 years[6], showed skeletal traction had the longest hospital stay but with equal cost to external fixation and intramedullary nailing. Patients with intramedullary nails had the least complications. The weakness of the study was its retrospective nature, the sample size is small and the variables are many.

A prospective cohort study was done in the United States of America comparing titanium elastic nails with traction and Spica cast in the treatment of femoral fractures in 83 consecutive children aged between 6-16 years [44]. Treatment was not randomized, but depended on preference of treatment by the attending surgeon. Traction was applied for approximately three weeks. They analyzed the clinical and radiographic factors, complications, hospital charges and outcome factors, time to walking with aids till time to full activity. Forty eight children underwent surgery while 35 were treated by traction and spica casting. The operative group had short hospital stay, fewer complications, mobilized quicker but there were no differences in the total costs between the two groups.

Morbidity and costs of femoral shaft fracture treatment in 81 patients aged 6-16 years were evaluated [45]. The surgical costs were equivalent to traction followed by Spica casting. Early Spica casting was 3 times cheaper than surgery with low complications. Surgery resulted to quicker healing and return to full weight bearing, compared to external fixation which was found to have the highest complication rates.

A study on financial aspects of femoral shaft fracture treatment in children and adolescents analyzed the billing records of 58 children and adolescents with femoral shaft fractures [46]. The various treatments the patients underwent included spica casting, home traction, skeletal traction, skin traction and intramedullary rodding. They looked at both the hospital and orthopaedic surgeon, radiologist and anesthesiologists costs. The early spica group had the least cost of $5,494, compared to the skeletal traction ($21,093) and intramedullary rodding ($21,359).

A comparison on cost of treatment between compression plating and conservative management of paediatric femoral shaft fractures in 62 children between 5 – 16 years was done in four hospitals in Nigeria between January 1995 and December 2004 [42].
Half of the patients underwent traction and the other half dynamic compression plating. A cost analysis was done using direct costs and duration of hospitalization as economic indices. Direct costs implied, cost of admission, operations, drugs, dressings and radiographs. The mean hospital stay for the operative group was 3.9 weeks compared to 6.4 weeks for the traction group. The cost was N27, 844 for the operative group and N17, 315.60 for the traction group. The prolonged stay in the operative group was due to delay in the patients acquiring crutches for early mobilization and relative scarcity in the occupational therapist.

This reflected in the costs. They concluded the costs to be higher in the operative group due to cost of implants and antibiotics.

The above studies done have indicated some differences but have some short comings. The age range of the patients is fairly wide and there is an overlap in fracture healing characteristics comparing for example the healing time of a 5 year old compared to that of a 16 year old. The fractures of younger patients tend to unite faster [3, 12], hence a shorter time on traction resulting in reduced hospital per diem costs. Matching for age was not done which is important for reasons cited above. Cost of implants may also affect the total cost.
They compared a lot of variables which rather complicates the analysis.

Other confounding factors like scarcity of occupational therapists had an impact on costs as demonstrated by the study in Nigeria[42]. The sample sizes were also relatively small, probably due to the rarity of surgery amongst these groups. Follow up was also an issue. More importantly especially for the studies that found the cost to be higher, conclusions were made without calculating for the incremental cost-effectiveness ratio (ICER).

The studies are important especially when it comes to methodology for the study question. Flynn et al did not randomize the treatment method, an aspect that will be utilized in the study, to avoid bias or preference towards a cohort of patients when it comes to management.

Studies have also been done comparing external fixation and skeletal traction, which have been important in providing the variable cost items and also methodology applied providing a further benchmark for the study question [7, 40].

A cost analysis was done in Sweden on femoral shaft fractures in children between ages 3-15 years [7]. Costs included; hospital per diem, drugs, personnel costs, radiographs, laboratory costs, tutoring, physiotherapy, physician and surgeons' costs and theatre costs. The average total costs per patient were 10,000 EUR at hospital 1, 23,000 EUR at hospital 2 and 38,000 EUR at hospital 3. The main factor determining the costs was the number of days in hospital. They found that home traction can reduce the cost of treatment by about 40% compared to in patient traction but increased burden to the family, while the cost of external fixation group was half that of the home traction group.

The weakness of the study was its retrospective nature. The use of three different hospitals had an impact due to the varied costs of the hospitals. The extra costs outside hospital care were not really factored in especially for the home traction group, for instance time off work for the parent, or the cost of a care taker. The variable item costs were done quite well, hence most of the items catered for.

A retrospective clinical review was done over 2 years comparing hospital costs and charges between skeletal traction (90-90 traction and spica casting) and external fixation of pediatric femoral shaft fractures in the United States of America[40]. There were a total of 29 patients, children aged between 5-10 years.16 of them treated by external fixation and 13 by skeletal traction. Hospital billing data was looked at till cessation of treatment and fracture union was used as measure of outcome. The average charge of external fixation and spica casting was $32,094 compared to $21,439 of external fixation group while the average cost per patient was $22,396 and 11,520 respectively. The average stay in hospital was 22.7 days for the traction group and 4.7 days for the external fixation group. They concluded that external fixation of pediatric femoral shaft fractures resulted in decreased hospital costs and length of hospitalization and the difference in costs and hospital stay between the two methods was statistically significant. The weakness of the study was the sample size and retrospective nature of the study. They also did not dwell much on the complications and the effect on cost.

Some comparison studies have been done comparing operative management versus skeletal traction [41, 47-50]. They demonstrated shorter hospital stay and fewer complications for the operative group. The main weakness is that they are not cost-effectiveness analysis studies, because they look at one arm which is the outcome and not the cost, making it very difficult to change management protocols in resource poor setting. They are of importance where all facilities are available and cost is not a major factor.

Other studies done mostly in the pediatric age group have investigated the long term results of both traction and operative treatment and have reported favorable and comparable outcomes, therefore helping the practitioner in choosing a treatment method based on the economic outcomes [51-54].

From the studies done, the hospital per diem cost contributed greatest to the total cost. Traction has longer hospital stay and more complications compared to intramedullary nailing. The cost was more in conservative than operative, though more in some parts of the western world. Many studies have been done in the pediatric and adolescent group. Gosselin et al[4] and Timmerman and Rab[43] did studies which are closely related to the study question. The weakness of the majority of the studies is their retrospective nature. The sample sizes were fairly small with a wide range in the age especially in the paediatric studies. Some overlooked the cost and concentrated on the outcome, while some looked at cost without comparing to the outcome, therefore do not fit the description cost-effectiveness analysis studies. None of the studies achieved the ideals as described by Tanner et al [28].

Noted were also deficiencies in most of the studies. From the studies on methodology described, a lot of data is required to compute a proper cost-effectiveness analysis. Lubowitz and Appleby used QALY as a measure in cost-effectiveness analysis, which ideally is used as a measure in cost-utility analysis[35].

There is therefore need for cost-effectiveness study in Kenya and the region at large, considering that these injuries are responsible for majority of the hospitalizations in orthopaedic wards. There is need for fast management to enable the patient to get back to work soon enough, with less complications and an overall cheap cost for both the patient and the hospital. This study will also aid in policy making by the hospital, when it comes to resource planning for the management of these injuries.

OBJECTIVES

Broad objective

Determine the cost effectiveness of skeletal traction compared to intramedullary nailing in the management of closed femoral shaft fractures at Kenyatta National Hospital

Specific objectives

i. Determine the total cost incurred in the two modes of treatment.
ii. Determine the length of hospitalization in the two modes of treatment.
iii. Determine the outcome (delayed union) of the two treatment modes in 3 months.

NULL HYPOTHESIS

Skeletal traction is more cost effective compared to intramedullary nailing in the management of closed femoral shaft fractures.

METHODOLOGY

Study Design: -Prospective convenience sampling analytical study.
Study Setting: -Hospital based study in a referral and teaching institution - Kenyatta National Hospital in the three Orthopaedic wards.
Study Population: -Patients admitted at Kenyatta National Hospital Orthopaedic wards with closed femoral shaft fractures between 18-50 years of age.
Duration of Study: - October 2012 – May 2013.

SAMPLE SIZE

There is no specific formula for sample size calculation in cost-effectiveness analysis studies[55].Igo and Onche did a study on cost of treatment of femoral shaft fractures in paediatrics comparing compression plating versus conservative treatment [42]. The mean hospital stay for the two groups when calculated is 4.9(±2.7) SD weeks, and the mean difference in hospital stay for the two groups is 2.5 weeks. The statistician advised therefore to use the formula in The Fundamentals of Clinical Trials Second Edition Page 96.

$$2N = \frac{4(Z\alpha+Z\beta)^2\,\sigma^2}{\delta^2}$$

Where:-

2N = Total sample size (sum of both arms).

$Z\alpha = 1.96$ Statistic for the level of confidence of 95%, 1.96.

$Z\beta = 1.282$ at Power 90%.

σ = overall standard deviation of length of hospitalization for the two groups = 2.7

δ = mean difference in hospital stay for the two groups (2.5 weeks)

Substituting in the formula:

$$2N = \frac{4(1.96+1.282)^2\ 2.7^2}{2.5^2}$$

$2N = 49.03$, therefore $n = 49.03/2 = 24.5 \sim 25$.

Each arm of the study had 25 patients with a total of 50 patients.

Cost-effectiveness in this case looked at the financial (monetary) implications of skeletal traction compared to Intramedullary nailing to both the patient and the hospital for closed femoral shaft fractures. That is in terms of the amount of money paid at time of discharge following treatment. A follow up was done on the patients for up to 3 months to assess for union of the fractures as an outcome measure. This was done by booking the patients in the clinics and taking their phone numbers to schedule follow up dates. The number of admitted patients with femoral shaft fractures per week was looked at; comparing those put on skeletal traction and those on ORIF. The operative methods which were documented are those readily available in the hospital. That is models like K-nails, sign nails and Treu nails.

RECRUITMENT OF STUDY SUBJECTS

Convenience sampling was used to assess patient data. Patients were recruited depending on the default management to avoid bias. Patients already on traction were followed up to 3 months and patients who were operated within one week were included in the operative group. Radiological examination in this case the x-rays were taken, that is of the affected limb:

1. On admission
2. At 2 weeks, for patients on skeletal traction to ascertain whether reduction was proper and maintained.
3. Skeletal traction also at 8 and 12 weeks to observe for adequate radiological evidence of fracture healing and at 3 months.
4. Surgery patients, post operatively to assess for success of operation and at 3 months.

INCLUSION CRITERIA

Patients admitted to the KNH orthopaedic wards from the age of 18-50 years with closed fractures of the femur.

EXCLUSION CRITERIA

1. Patients with multiple fractures, that is more than one fracture requiring surgery or will affect hospital stay.
2. Co-morbid conditions that may prolong patient stay in hospital or healing.
3. Mentally disturbed.
4. Pregnancy.
5. Patients on traction who end up in theatre for ORIF before the 3 months follow up period have elapsed.
6. Pathological fractures.

DATA COLLECTION

A structured data collection sheet was used. This included the patient particulars, hospital stay and per diem cost which were inclusive of bed charges, meals, nursing care and doctor visits. The type of injury, type of management and comparing the cost of each, x-ray findings during treatment and at 3 months to assess for union. Data was represented in forms of graphs and charts.

DATA ANALYSIS

Data collected was analyzed using SPSS 17.0. The independent variables are the interventions, that is, skeletal traction and intramedullary nailing, while the dependent variables are the total cost incurred and union as an outcome measure. Patients were not matched for age because they have the same healing characteristics hence the same expected outcome measure. The means generated from the study were compared using the student t-test. A p value of 0.05 was used.

ETHICAL CONSIDERATIONS

Ethical approval and permission was sought from the Kenyatta National Hospital Ethical and Research Committee. The purpose, procedure, rights and benefits of the study were explained to the patient by the investigators and research assistants. Written consent to participate in the study was obtained from the patients. Denial of consent did not interfere with the treatment of the patient in any way whatsoever. Confidentiality of patient data was upheld and no names were put on any of the data collection sheets. At the end of the study, these data sheets were shredded by the investigators to ensure complete destruction. The study was considered to be completed when the results had been disseminated.

LIMITATIONS

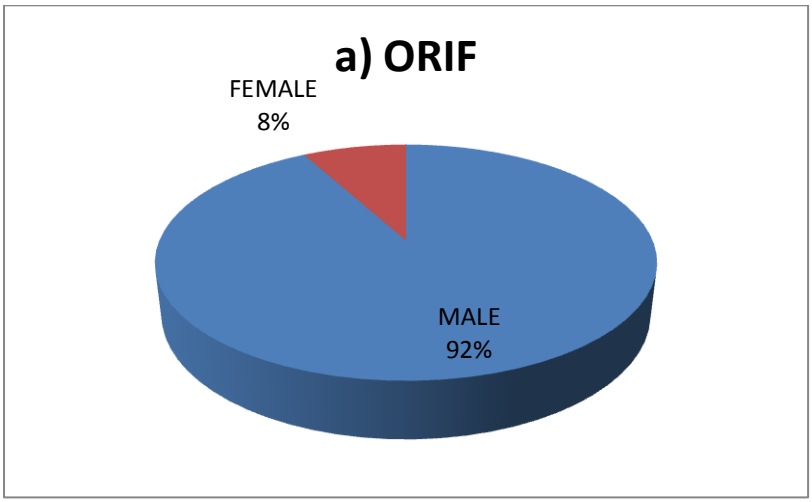
- Loss to follow up.
- Some patients on traction underwent surgery before the follow up time was over.
- Management of patients and co morbidities.
- Different surgeons hence outcomes.
- Costs were lumped up, so difficult to attain specific costs like nursing costs and doctor costs which were all included in per diem cost.

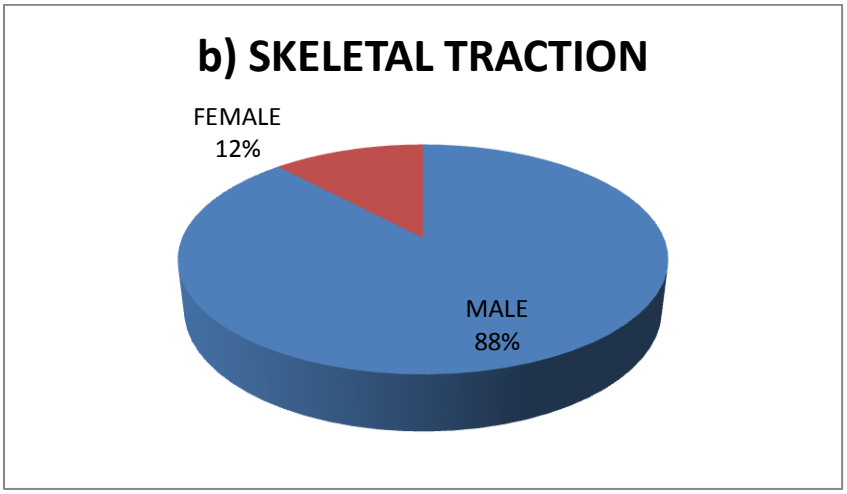
DELIMITATIONS

- Patient data on cost was easy to obtain.
- Cheap to carry out the study.
- Cases were easy to obtain.

RESULTS

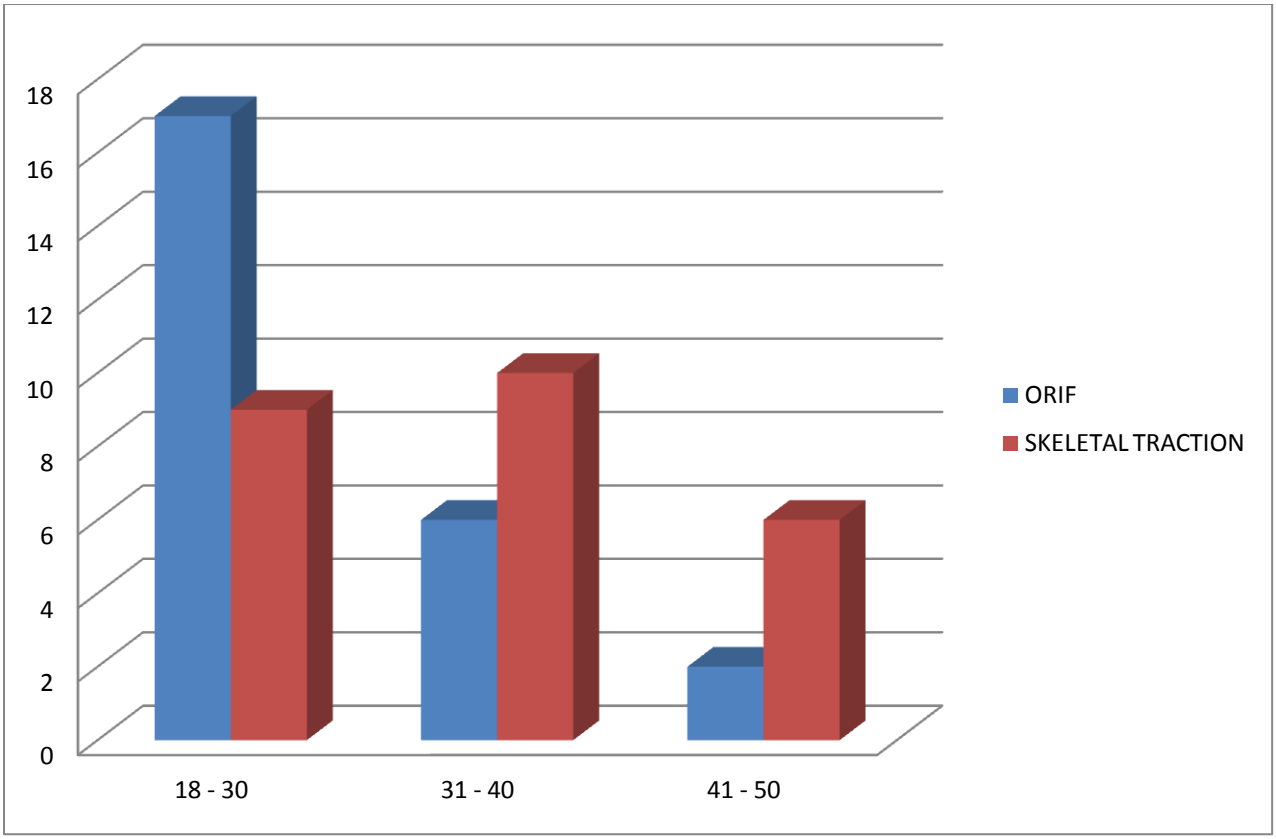
Data was collected for 50 patients, 25 for the skeletal traction group and 25 patients who underwent surgery (Intramedullary nailing). Follow up was done for upto 3 months. There was no loss to follow up. Males were more affected than females, with 45 males affected compared to 5 females, as demonstrated in the pie charts below.





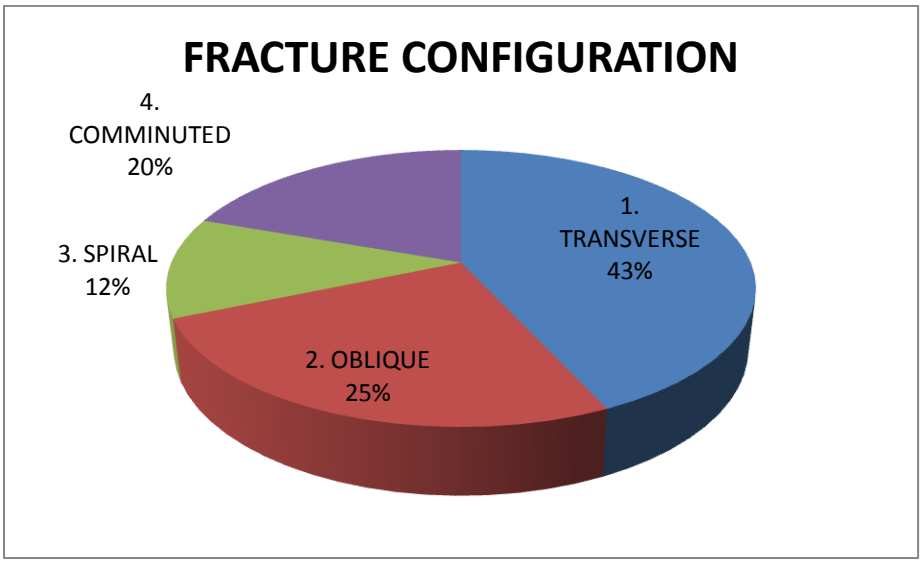
I. **Pie chart 1: -** Percentage of male patients compared to female patients in **a)** Open reduction and internal fixation (ORIF) **b)** Skeletal traction.

The mean age was 31.5 years in both groups with majority of the patients (26 patients) between the ages of 18 – 30 years and the least affected between the ages 41 – 50 years. As demonstrated below in bar graph 1.



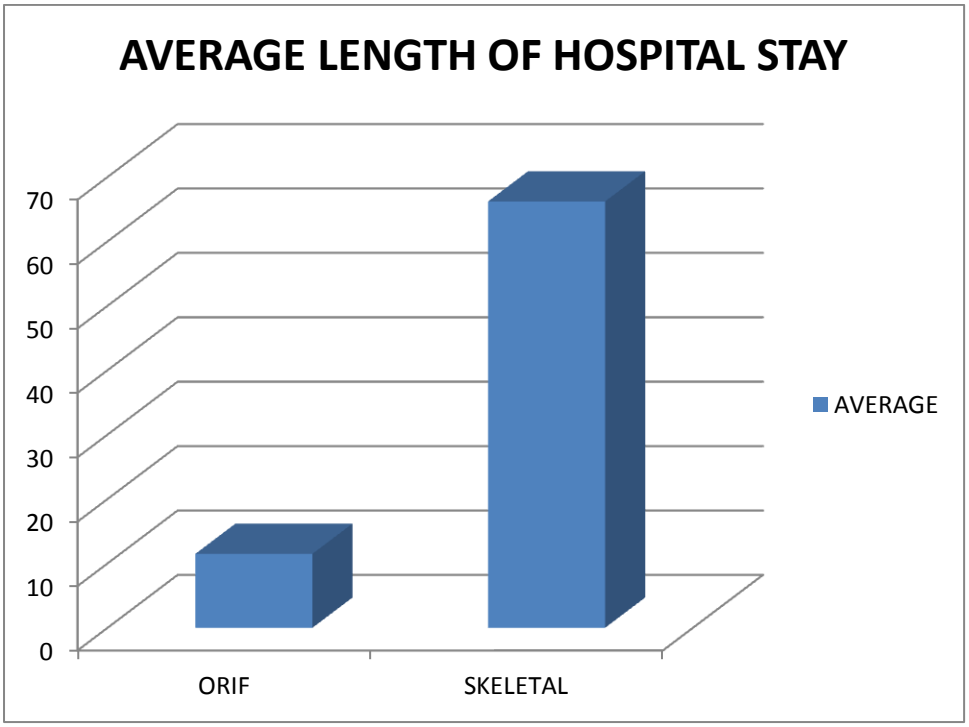
II. Bar graph 1: The number of patients between three age groups for both groups. On the x-axis is the number of patients and on the y-axis the age groups of the patients in years.

The most common fractures were the transverse fractures, in 21 patients, oblique fractures in 13 patients, comminuted fractures in 10 patients and spiral fractures in 6 patients, as demonstrated in pie chart 2 below.



III. Pie chart 2: Type of fractures represented as percentages.

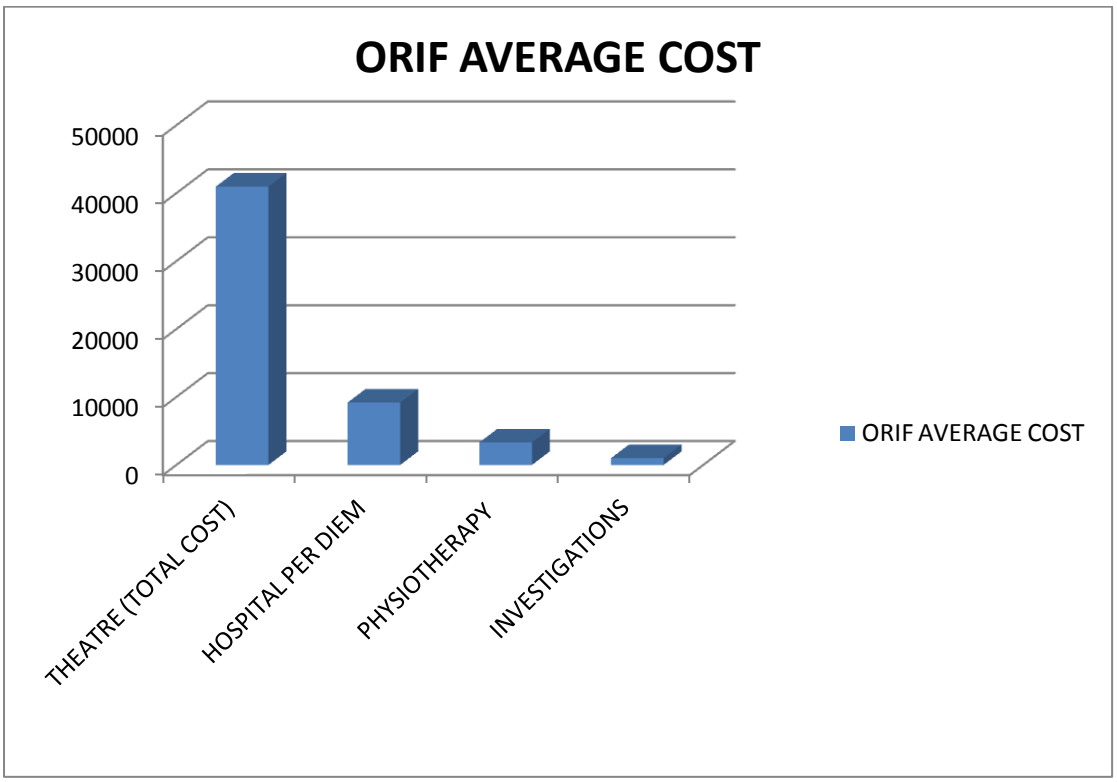
The mean length of hospital stay for the operative group was **11.48** days ranging from 4 – 19 days. The mean time to surgery from the day of admission was 4 days. The mean length of hospital stay for the skeletal traction group was **66.2** days ranging from 44 – 119 days. The results are as demonstrated in bar graph 2 below.



IV. Bar graph 2: The average lengths of hospital stay for the two groups of patients.

The average total hospital costs for the operative group was **54, 380.44 Kshs**, ranging from **45, 080 – 62, 378Kshs**. This was inclusive of the total theatre cost which contributed **75.3%** of total cost for the operative group. This included the operation fees which contributed around **50%** of total theatre fees, anaesthetic fees, theatre time charges, oxygen time charges, consumables fees, pharmacy fees and TSSU fees. Apart from the operation and anaesthetic fees which were constant for all the patients, the other charges differed depending on the length of surgery; drugs used and blood loss, though the difference amongst all the patients was not significant. The hospital per diem costs contributed to **16.8%** of the total cost. This was inclusive of the consultation, meals and bed, nursing care, doctor and medication administered. The physiotherapy costs and investigations contributed to the last **7.9%** of the total costs. The physiotherapy costs were inclusive of the sessions by the physiotherapist which were two to three sessions per week.

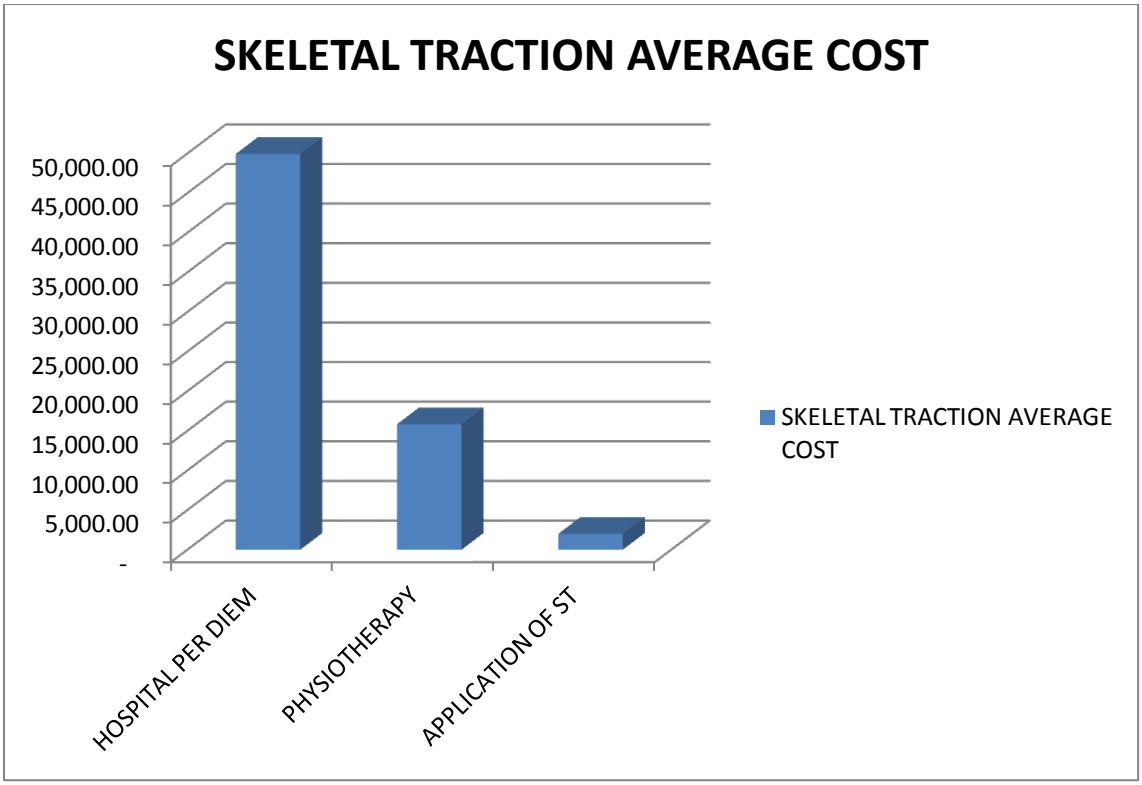
The investigations were the x-rays done and the blood works in preparation for surgery, which are the full blood count and urea/electrolytes/creatinine. The findings are demonstrated in bar graph 3 below.



V. **Bar graph 3:** The average total theatre cost, hospital per diem, physiotherapy and investigations contributing to the average total cost for the operative group.

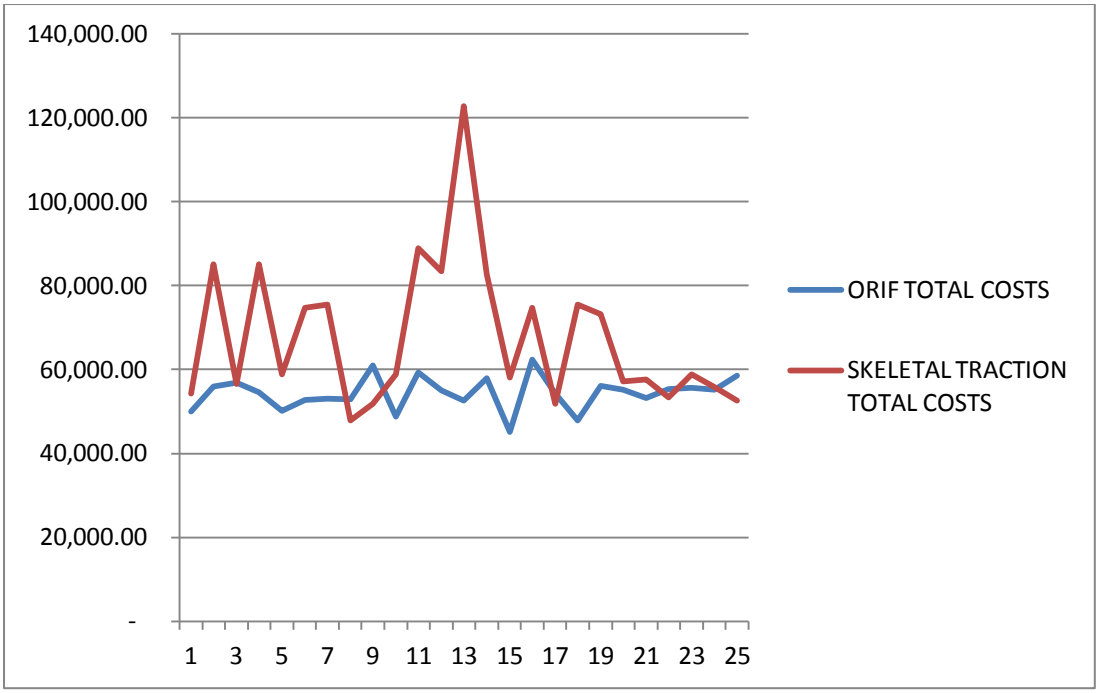
The average total hospital costs for the traction group was **67, 792 Kshs** ranging from **47, 900 – 122, 800Kshs**. The hospital per diem costs were the main contributing factor to the total costs, averaging **73.7%** of the total costs. This was inclusive of the consultation, nursing care, meals and bed which were higher than the operative group due to the number of days in hospital. The cost of drugs was less than the operative group, because they needed analgesics for the first few days and didn't require antibiotics. Physiotherapy and investigations done contributed **23.4%** of the total costs. The investigations were x-rays, there were no blood works done, thus slightly cheaper than the operative group.

The cost of x-rays was similar to that of the operative group. The physiotherapy costs were higher for the traction group compared to the operative group due to the number of days in hospital hence the sessions were more. Application of the skeletal traction which included the local anaethesia, application costs and the components of the traction contributed to **2.9%** of the total costs. These findings are demonstrated in bar graph 4 below.

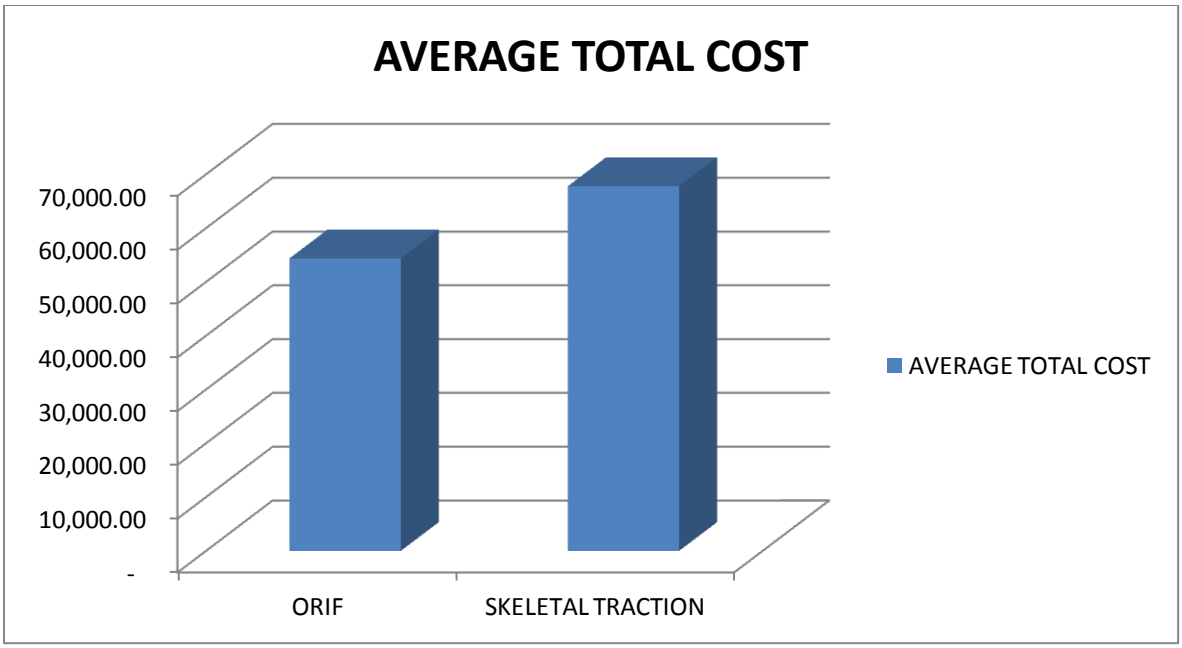


VI. **Bar graph 4:** The average hospital per diem, physiotherapy and investigations, and application of skeletal traction cost, contributing to the average total cost.

The average total costs for the operative group was compared to that of skeletal traction using the Student's T-test, with a p-value of **0.05**. There was a very significant difference in cost with a p-value of **0.04**. The total costs incurred by the 50 patients are demonstrated in line graph 1 below and the average costs for the 2 groups are demonstrated in bar graph 5.



VII. **Line graph 1**: The total costs for the patients on the x-axis, against the number of patients on the y-axis. Demonstrates the cost incurred by each patient.



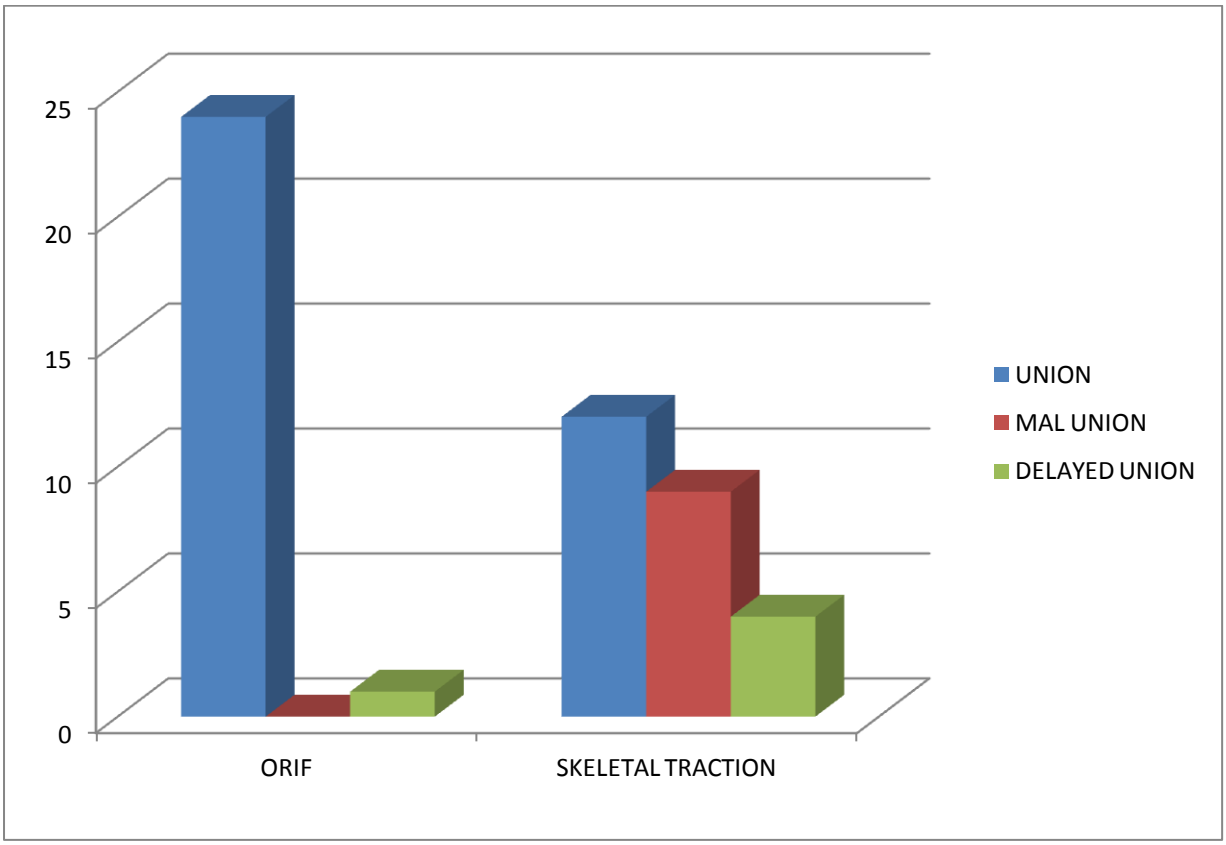
VIII. **Bar graph 5:** The average total cost comparing the operative group and skeletal traction group.

Follow up was done at 3 months. In the operative group, fractures of **24 (96%)** of the patients had radiological evidence of union. There was no mal union, but in one patient there were no signs of union. For the skeletal traction group, **12(48%)** patients had both clinical and radiological evidence of union. Nine patients **(36%)** had mal union while **4 (16%)** of the

patients had no signs of union of the fracture. The Student's T-test was used with a p-value of 0.05 to compare union as an outcome measure between the two groups. The p-value was **0.03** which is very significant between the two groups. The findings are demonstrated in table 2 and bar graph 6 for the outcome.

TREATMENT	UNION	MAL UNION	DELAYED UNION
ORIF	24	0	1
SKELETAL TRACTION	12	9	4

IX. **Table 1:** Shows the number of patients with union, mal union and delayed union in the operative and the skeletal traction group.



X. **Bar graph 6:** demonstrates the outcome in the two groups, the number of patients is on the x-axis.

DISCUSSION

Fractures of the femur shaft are responsible for morbidity of majority of the patients in the orthopaedic wards with the mainstay of treatment being skeletal traction in our setup[2]. These fractures can either be managed conservatively, that is skeletal traction that results in prolonged hospital stay for at least 6 weeks, with higher complication rates[3, 4, 12]. The other option is operative management either using plates and screws or intramedullary nails, which has an advantage of faster management of the patient with quicker mobilization and has fewer complications.

Being in an economic constrained environment, this study set out to establish the best way to manage these fractures and at a cheaper cost for both the patient and the hospital, which would also help decongest the wards. A cost-effectiveness analysis was adapted, a sample of 50 patients analyzed, 25 in each group. The patient demographics were taken (sex and age), the type of fracture and the length of hospital stay. The main aspects of the study; the cost for each mode of treatment and outcome, in this case union were analyzed and comparisons were done.

Majority of the patients were male (90%) while the remaining 10% were female. The average age affected was 31.5 years, with the most affected age group between 18 -30 years. Fractures of the femur have been shown to be more common in the reproductive age group, between 20 – 40 years, with men more affected than women[1, 11]. This is because most of the fractures are due to RTA's[9, 10]. This is probably due to the risky and high speed driving by the younger age groups especially men, and also this is the age group constantly on the road travelling to and from work places as opposed to the older age groups. The most common fracture configuration was the transverse fracture, with the least common the spiral fracture. This is likely because of the mechanism of injury, and since K-nailing was the most utilized fixation method and the indications are limited.

The mean length of hospital stay for the operative group was 11.48 days, ranging from 4-19 days. The mean time to surgery from admission was 4 days. The skeletal traction group had an average length of hospital stay of 66.2 days ranging from 44 – 119 days. The only adult study done in Cambodia comparing skeletal traction to SIGN nailing, found the mean length of hospital stay for the traction group to be 52.3 days while that for the operative group to be 34.9 days[4].

The pitfall was that for the operative group the mean length in traction before surgery was 20.7 days, therefore the actual mean LOS was 14.2 days[4]. CEA studies done in the adolescents also demonstrated longer LOS for the traction group compared to the operative group, despite the period in skeletal traction being approximately 3weeks, half that of the adults[6, 43-45]. In the operative group the least number of days in hospital was 4 days. The patient was operated on arrival and discharged 4 days later. This was not the case for majority of the patients who had to wait at least 4 days due to difficulty in availability of theatre space. In the ideal situation where patients are operated on arrival or one day later at latest, with aggressive rehabilitation the length of hospital stay would have been reduced to one week or less. Two patients took 16 and 19 days in hospital, this was due to delayed payment following discharge from hospital affecting the number of days. The patient who took the least time was 42 days on traction, rehabilitated in 2 days on crutches and discharged taking a total of 44 days. Two of the patients took roughly 116 and 119 days (4 months), this was due to the time taken to clear the hospital bills. The fractures of both patients had not united at 4 months.

The average total costs for the operative group was 53, 380.44 Kshs. The difference in cost was due to length of hospital stay, in that the ones who paid higher had a comparatively longer stay. The theatre costs contributed 75.3%. Half of this was the operation fees, that is the cost of implant and the surgeons' fee. The hospital per diem costs contributed to less than a quarter of the total fees. The physiotherapy costs were also low because, there were no complications like knee stiffness to deal with, but how to use crutches. The average costs of the traction group was 67, 792 Kshs ranging from 47, 900 – 122,800 Kshs. The hospital per diem costs were responsible for 73.7 % of the total cost. The cost of physiotherapy was also higher comparing to the operative group. The difference in costs within the traction group was dependent on length of hospital stay. There was a significant difference in terms of cost between the two groups with a p-value of 0.04. Skeletal traction was therefore shown to be more costly in the management of femoral shaft fractures in comparison to intramedullary nailing. The findings were similar to the study done in Cambodia, where they found that skeletal traction was more costly compared to the operative group with a difference of $ 121 per patient[13]. The operative group had an average hospital stay of 34.9 days, of which 20 days were on traction[13]. This means the difference in cost would even have been higher comparing the two groups.

Other studies on costs were done in the paediatric age group and adolescents. The study done by Igo and Onche comparing compression plating to skeletal traction showed operative treatment to be more costly[42]. The shortcoming was that the difference in length of stay was around 2.4 weeks and the implant costs contributed largely to the costs. Despite 3 week hospital stay for the traction group in the study done by Timmerman and Rab, the cost of traction was 2 times that of the operative group[43]. Two studies showed similar costs in both groups[6, 44]. In the study done by Flynn et al (2004)[44], the type of nails used (TEN's) are generally very expensive nails, hence contributing to the costs. Comparison with these studies is fairly difficult because in majority, the length of hospital stay in the pediatrics for the traction group is about half that of the adults (3weeks comparing to 6 weeks). Otherwise, the studies showing similar costs[6, 44], done in adults, the traction costs would have been higher. On the overall the hospital per diem costs are shown to be the main contributor of the difference in costs between the two groups [4, 6, 7, 40 - 44]. The total cost of treatment for fractures of the femur shaft is largely dependent on the length of hospital stay.

The outcome measure in the study was union. In the operative group, 96% united and 4% had not united. For the skeletal traction group, 48% of the fractures united, 36% mal united and 16% had not united. The difference between the two groups was very significant with a p-value of 0.03. Skeletal traction has higher complication and worse outcomes than intramedullary nailing for fractures of the shaft of the femur. This was similar to the study done by Gosselin et al (2009)[4]. They did a follow up for 16 weeks. The operative group had early weight bearing, 92% of the fractures united, there was no malunion and 8% of the fractures did not unite. In the traction group 74% united, 4% went into malunion and 22% into non union. Flynn et al (2004) showed a high complication rate in the traction group of 34%, with the main complications being limb length discrepancy, angulation, loss of reduction, knee stiffness and pressure ulcers[44]. The study done by Webb, Gristina and fowler showed traction had higher complication rates and union took a longer time, 34 weeks for the traction group compared to 18 weeks for the operative group[50].

Studies done in the pediatrics also showed higher complication rates in the traction group compared to the operative group [6, 43, 45, 49].

CONCLUSION

Intramedullary nailing is more cost-effective than skeletal traction. It met the dominant strategy, because the cost was significantly low compared to skeletal traction and the outcome was better compared to skeletal traction. The length of hospital stay was shorter for the operative group compared to the traction group, and this had a direct impact to the total cost. Therefore from this study, the best way to manage closed fractures of the femur shaft is intramedullary nailing, and should be done as soon as possible if there are no other co-morbidities. This will help reduce the cost to the patient, help decongest the wards and reduce the complication rates. Thus other orthopaedic conditions can be managed due to available ward beds and in the overall increase the productivity in the country, by aiding people to get back to work sooner.

RECOMMENDATIONS

1. Fractures of the femur should be managed as an emergency or urgent procedure of fixation.
2. Skeletal traction should be abandoned, and used only in patients with fractures of femur and are not fit for surgery.

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APPENDIXES

APPENDIX ONE:

Informed Consent Letter

Study title: - Comparison of closed femur fracture: Skeletal traction and intramedullary nailing cost effectiveness.

PART A

Introduction

My name is Dr. Kamau David, a masters student at the University of Nairobi school of medicine, department of Orthopaedic Surgery. I am conducting a study on cost-effectiveness of skeletal traction compared to Intramedullary nailing of fractures of the femur shaft. My research assistant for this study is a clinical officer.

Fractures of the femur are common injuries following trauma affecting the reproductive age group. Skeletal traction is the mainstay of treatment in Kenya, which results in prolonged hospital stay for at least 6 – 12 weeks. Therefore, the purpose of the study is to compare whether this is cost effective compared to operative management which has shorter hospital stay and less complications.

You are invited to participate in this study, which will look at the total hospital costs you have incurred, during your course of treatment whether operative or conservative. 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 purpose is to obtain information on the best way of managing fractures of the femur shaft, with less cost and better outcomes or even if more costly the outcome will supersede the cost treatment, to both you the patient and the hospital. This will also help in changing of management policy of these injuries in the hospital and the country at large. The information obtained is also important for the attainment of a Masters degree in Orthopaedic surgery for the principal investigator.

Study procedure

The main information required from you is your particulars as in the data collection sheet. Much of the information will be obtained from the total charges accrued from admission till discharge and x-rays which are taken as part of your management. Follow up will be done for upto 3 months. Thereafter further management and rehabilitation will continue as usual.

Risks and benefits to the participant

No risks are directly related to the study because management is as usual. The benefits will be participation in a study that will result in better management in a cost effective manner of fractures of the femur shaft.

Study costs

If you accept to take part in this study, there will be no payment from you and to you. No added investigations will be required and x-rays done will be as the usual done as part management of these injuries.

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. David Kamau. You may ask any questions you have now or if you have any questions later, you are encouraged to contact him through mobile number: 0721 884079, or email daveymush@gmail.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……..

KIAMBATISHO 1:

Yamenyesheje barua ya idhini.

Utafiti cheo - Ulinganisho wa funge traction femur fracture ya kiunzi na Intramedullary nailing gharama nafuu.

SEHEMU A

Utangulizi.

Jina langu ni Dr Kamau Daudi, mwanafunzi mabwana katika Chuo Kikuu cha Nairobi shule ya dawa, idara ya upasuaji Orthopaedic. Mimi ninafanya utafiti juu ya ufanisi wa gharama ya uvutaji mifupa ikilinganishwa na Intramedullary nailing ya kuvunjika kwa kati ya mfupa wa paja. Msaidizi wangu katika utafiti huu ni afisa wa hospitali (clinical officer).

Kuvunjika kwa mifupa ya paja ni majeruhi ya kawaida kiwewe, yanayoathiri kikundi cha umri wa uzazi au vijana. Uvutaji wa miguu ndio matibabu ya msingi nchini Kenya, ambayo husababisha kukaa muda mrefu hospitalini kwa angalau 6-12 wiki. Kwa hiyo, lengo la somo hili ni kulinganisha kama hii ni ya gharama nafuu ikilinganishwa na oparesheni ambayo mtu hukaa hospitalini kwa muda mfupi, na pia ina matatizo machache.

Wewe ni baadhi ya walioalikwa kushiriki katika utafiti huu, ambayo itakuwa inaangalia jumla ya gharama hospitalini ya matibabu utakayopata, iwe oparesheni au kuvutwa kwa mguu. Tafadhali soma fomu hii na kuielewa vizuri kabla ya kukubali utafiti. Maswali yoyote utakayokuwa nayo yatajibiwa.

Madhumuni ya utafiti.

Lengo ni kupata taarifa juu ya njia bora ya kutibu kuvunjika kwa mifupa ya paja, kwa gharama ya chini na matokeo bora zaidi au hata kama gharama kubwa zaidi lakini matokeo yanapita gharama ya matibabu, kwako mgonjwa na hospitali. Hii itasaidia 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 Orthopaedic kwa mpelelezi mkuu.

Utaratibu wa utafiti.

Habari kuu inayohitajika kutoka kwako ni maelezo yako kama katika karatasi ukusanyaji. Mengi ya taarifa kupatikana kutoka mashtaka jumla kutoka kiingilio hadi mwisho wa matibabu yako na picha ambazo zitapigwa kama mandelezo ya matibabu yako. Utafuatiliwa kwa muda wa miezi mitatu na baadaye matibabu yako yataendelea kama kawaida.

Hatari na faida kwa mshiriki.

Hakuna hatari inayotoka moja kwa moja kuhusiana na utafiti huu kwa sababu usimamizi ni kama kawaida. Faida itakuwa kushiriki katika utafiti amabao utaimarisha usimamizi bora kwa njia ya gharama nafuu ya kuvunjika kwa mifupa hii.

Gharama ya utafiti.

Kukubali kushiriki katika utafiti huu hakuna gharama yoyote kwako na pia hutopata malipo yoyote. Uchunguzi wa picha utakazofanya ni kama kawaida ya matibabu utakayopata, hakuna tofauti na ambaye hashiriki utafiti huu.

Usiri.

Ukusanyaji wa karatasi takwimu ni madhubuti ya siri. Jina lako hatilitaandikwa 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 hiari yako na kushindwa kushiriki au kujiondoa kutoka utafiti huu, hautaadhiri usimamizi wako katika njia yoyote katika hatua yoyote.

Mawasiliano na Maswali.

Mtafiti anayefanya utafiti huu ni Dkt. David Kamau. Unaweza kuuliza maswali yoyote sasa au ikiwa na maswali yoyote baadaye, unahimizwa kuwasiliana naye kupitia nambari ya simu 0721 884079, au barua pepe daveymush@gmail.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 nimeyoambiwa kikamilifu na mpelelezi na nitashiriki kwa hiari yangu kwa kutia sahihi kwa ridhaa.

Sahihi .....

Au kidole gumba cha mshiriki.

Tarehe .....

Sahihi ya shahidi .....

APPENDIX TWO

DATA COLLECTION SHEET

PARTICULARS

Age.....Sex……Address…… District …

Occupation …….

Date of admission……

Date of discharge……

Hospital stay ……days.

Type of Fracture:- 1. Transverse fracture.

2. Oblique fracture.

3. Spiral fracture.

4. Comminuted fracture.

MANAGEMENT

1.Skeletal traction

2. ORIF

Skeletal traction

- Time and date of application…….
- Type of analgesia……..
- X-ray findings:-
    a) Rotation – 2/52……..1/12…….3/12……
    b) Varus/valgus angulation(>5^0) – 2/52…..1/12…..3/12….
    c) Anterior/posterior angulation(>10^0) – 2/52……..1/12……3/12……...
    d) Shortening (>1cm) – 2/52……1/12……3/12……..
- At 3 months 1) union 2) malunion 3) non union.

Open reduction and internal fixation.

- Time and date of surgery…….
- Type of surgery- (1) Interlocking nail (2) K-nail.
- Type of anesthesia – (1) general (2) spinal.
- X-ray findings post-operatively-
    a) Rotation
    b) varus/valgus angulation (>5^0)
    c) anterior/posterior angulation (>10^0)
    d) shortening (>1cm)
- Revision of surgery/ re-operation – 1) Yes 2) No.
    - Reason……
- 3 months after surgery 1) Union 2) Malunion 3) Non union

DIRECT COSTS (KNH RATES 2012)

1. Admission:-Kshs per day ***** no. of days in hospital……
2. Medication…….
3. Investigations…….
4. Wound dressing…….
5. Crutches/wheel chair…….

Skeletal Traction

Personnel	**Number**	**Time/hr**	***Cost***
Medical officer			
Plaster technician			
Nurse			

Supplies:

a) Analgesia……

b) Sedation…….

c) Local anesthetic……..

d) Antiseptic solution……..

e) Dressing materials……

ORIF

Personnel	**Number**	**Time/hr**	**Cost**
Consultant			
Registrar (S.H.O)			
Consultant Anesthetist			
Registrar Anesthetist			
Scrub nurse			
Assistant nurse			

Supplies:

a) Anesthetics……

b) Infusions……...

c) Latex gloves……..

d) Scalpels…….

e) Theatre set…….

f) Sutures……..

g) Antiseptic solution…….

h) Dressing materials &gauzes…….

i) Implant:

1) K-nail ……..

2) Interlocking nail……..