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Outcome of Open Tibial Shaft Fractures Treated Using External Fixation As A Primary and Definitive Treatment in Tibebe Ghion Specialized Hospital, Bahirdar, Ethiopia

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DEPARTMENT OF Orthopedics and Traumatology

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A RESEARCH PROPOSAL TO BE SUBMITTED TO BAHIR DAR UNIVERSITY COLLEGE OF MEDICINE AND HEALTH SCIENCE, SCHOOL OF MEDICINE, DEPARTMENT OF ORTHOPEDICS AND TRAUMATOLOGY FOR PARTIAL FULFILMENT OF SPECIALITY IN OTHOPEDICS AND TRAUMATOLOGY

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OUTCOME OF OPEN TIBIAL SHAFT FRACTURES TREATED USING EXTERNAL FIXATION AS A PRIMARY AND DEFINITIVE TREATMENT IN TIBEBE GHION SPECIALIZED HOSPITAL BAHIRDAR, ETHIOPIA

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Declaration

I, the under signed, declared that this is my original work, has never been presented in this or any other university, and that all the resources and materials used for the research, have been fully acknowledged.

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Abstract

Background: Open fractures of the tibial diaphysis are caused by high energy trauma, most often from traffic accidents. It is also growing rapidly in developing countries. With rapidly increasing rates of motorization occurring in developing countries, knowing optimal treatment of open fractures of the tibial diaphysis is a global surgical priority. However, researches are limited in the field of orthopedic and traumatology in the study setting.

Objective: To assess the outcome of open tibial shaft fractures treated with external fixation as the primary and definitive method in Tibebe Ghion Specialized Hospital, Bahir Dar, Ethiopia, 2020.

Methods: A total of 53 patients (response rate of 88 %) with open tibial shaft fractures who were treated using external fixation at TGSH were retrospectively reviewed. Patients were interviewed and their charts were reviewed . Data was extracted, then entered and analyzed using SPSS, version 20. Descriptive analysis was used and summarized using frequency tables and charts. Binary logistic regression was also done to look for the association between independent factors and outcomes.

Results: The average age was 34 ± 14 years, with Thirty six (67.9%) male and seventeen (32.1 %) female. The leading cause of the injuries was road traffic accident 19 (35.8%) followed by bullet , 15 (28.3 %) patients. Out of 53 patients included in the study, 34 (64 %) of them were having infection. Malunion and nonunion were found in 8 (15.1 %) and 13 (24.5 %) patients respectively.

Conclusion: Open tibial shaft fractures are majorly caused by RTA. Using External fixation for treatment of such fractures as a definitive one in our setup has lots of complications. Infection , nonunion and malunion rates are higher than other studies with significant reoperation frequency. use of external fixation for definitive treatment of open tibial shaft fractures isn't reliable

Keywords: Open fracture , tibia , External fixation , outcome

Table of content

Contents

List of tables

List of figures

Acronyms/Abbreviations

ARHB Amhara Regional Health Bureau

BDU Bahir Dar University

EXFIX External fixation

GA Gustillo Anderson

IM Intramedullary

IRB Institutional Review Board

OR Operation Room

RTA Road Traffic Accident

TGSH Tibebe Ghion Specialized Hospital

1. INTRODUCTION

1.1. Background

Open fractures of the tibial diaphysis are caused by high energy trauma, most often from traffic accidents. Fractures of the tibial diaphysis constitute the most common open long-bone fracture, occurring in approximately two per 10,000 persons per year in the developed world. There is also a growing epidemic of open tibial fractures in populations in low- and middle-income countries. With rapidly increasing rates of motorization occurring in developing countries, identifying optimal treatment of fractures of the tibial diaphysis is a global surgical priority(1, 2).

Fractures of the tibia are relatively common and have been recognized as serious and debilitating injuries for centuries. Although most fractures are closed , open fractures of the tibia are more commonly seen than in many other bones because of its subcutaneous location(3). Open fractures comprise 23.5% of all tibial shaft fractures(4).

In Tanzania open lower-limb fractures are the second most common cause of death in the hospital's orthopedic department(5).

In Ethiopia , most fractures occurred in the femur (15.8%) followed by tibia (14.4%) and humerus (12.9%)(6).

Intramedullary (IM) nailing is considered the method of choice for treatment of closed diaphyseal fractures of the tibia. However, there is controversy in the literature regarding the best way of managing open tibial fractures, tibial shaft fractures with severe soft tissue injuries or compartment syndrome, and tibial fractures in multiply injured patients(7). External fixation is often used for more severe grade 3 fractures, where soft tissue injury may not allow for intramedullary fixation (8).

1.2. Statement of the problem

Although it is known that the first and crucial step in the management of open tibial fractures is emergency irrigation and debridement, there is no consensus on the best method of obtaining and maintaining alignment and stability of the tibia. There are a lot of options such as intramedullary nails (IM), external fixation, external fixation followed by IM nailing, and plates which at times will end up with less optimal result(7, 9, 10).

The main and gold standard way of treatment for close diaphyseal & Gustilo Anderson (GA) type I, II & most of IIIA open fractures of tibia is considered to be interlocking intramedullary nailing. But there is no agreement in the literature for open GA type IIIB fractures. The available options for such fractures are primary intramedullary nailing , external fixation followed by intramedullary nailing& primary external fixation as a definitive treatment(11).

External fixation may have uneven results and a high rate of complications though(12). It is associated with a higher incidence of nonunion, malunion, and reoperations comparing to IM nailing. Literatures comparing external fixators and unreamed IM nails have shown no significant difference between the two ways of treatment in terms of union, delayed union, deep infection and chronic osteomyelitis. But malunion and reoperation rate was more significantly associated with external fixation(13).

Generally many consider about the association of external fixation with increased rate of nonunion and infection. 25% superficial and 10% deep infection were observed in the literature following unilateral external fixation (8, 14, 15).

Another idea is temporary external fixation of the fracture until the soft tissue healing and infection control which will be subsequently changed to IM nailing after a few weeks. Shorter external fixation time which can decrease bacterial colonization of the pin sites in this sequential protocol has better outcome and lower infection rate (11).

External fixation can be entirely satisfactory and safe form of definitive treatment for tibial diaphyseal fractures keeping in mind that better care is needed both during operation and afterwards (16).

As our trauma burden is high in our setting, we are treating many tibial fractures. External fixators are used for open tibial fractures mainly as a primary and definitive way of treatment in

our hospital. There is no study on the outcome of external fixation for such fractures in our country and hospital in particular to our search. In clinical experience we noticed complications following this procedure such as pin site infection, mal-union and nonunion.

The aim of this study is to assess outcome of open tibial shaft fractures treated using external fixation as a primary and definitive treatment in Tibebe Ghion Specialized Hospital, Bahirdar, Ethiopia.

1.3.Significance of the study

This study will be important to know the result of open tibial shaft fracture external fixation which will guide an evidence-based clinical practice, to establish better treatment and prevention of complications in resource-limited settings. It will also aid to develop protocols, know the magnitude of the problem, and probably change our trend of management. Furthermore, interventional studies can be done following this research paper.

2. LITERATURE REVIEW

A prospective study was done in St Paul, Minnesota (1978 – 1981) to examine the hypothesis that safe and effective external fixation in the leg depends upon three basic principles for optimal use of these devices. They confirmed the proposed basic principles of external fixation are safe and effective which are avoid damage to vital anatomical structures, allow access to the injured area and achieve mechanical demands of the patient and the injury. Excellent functional results and low complication rate have been reported in this series which didn't depend on specific frame type(12).

External Fixation of High-Energy Tibia Fractures were also retrospectively studied by Stuart H. Myers and et al. in Children's Hospital of Philadelphia (2007). Thirty-one children were included in this series, and the mean follow-up was 15 months. Union time was 4.8 months on average. Minor malunion was seen in 26% (8/31) of cases and major malunion in 10% (3/31). Leg length discrepancy (LLD) was observed in 10% (3/31) of patients. The injured tibia was longer than uninjured one in all cases. 13% (4/30) developed delayed union and nonunion observed in 6% (2/31). Twenty-nine percent (9/31) developed a pin track infection which were treated with antibiotics well. From six patients who had delayed or nonunion, three developed a pin track infection (50%). Of the 25 patients who did not have a delayed or nonunion, six developed a pin track infection (24%)(17).

A Network Meta-analysis by Clary J. and et al. done in Ontario, Canada (2015) to assess which surgical treatment for open tibial shaft fractures has low reoperation rate. Moderate confidence evidence showed that unreamed nailing may reduce the likelihood of reoperation compared with external fixation (network odds ratio [OR], 0.38; 95% CI, 0.23–0.62), although not necessarily compared with reamed nailing (direct OR, 0.74; 95% CI, 0.45–1.24). Only low-quality evidence showed primary outcome for other treatment comparisons, like I plate fixation, Ilizarov external fixation, and Ender nailing. Ranking based on reoperation data showed that unreamed nailing had the highest probability of being the best treatment, followed by reamed nailing, external fixation, and plate fixation. The estimates of malunion and infection risk were very wide, and therefore no conclusive results could be made based on these data.(18).

A retrospective study done in Greece (2009) to evaluate the effectiveness of unilateral external fixator as primary and definitive treatment for open tibial fractures showed that incidence of

nonunion and delayed union was 8.18 and 9.54%, respectively. They concluded that unilateral external fixators can be used as primary and definitive treatment for tibia shaft fractures and are associated with a low deep infection rate. There is no need of Re-operation or change to another fixation device unless there is a slow callus formation(7).

A study in Sweden (1999) compared union rate after intramedullary nailing and external fixation of open tibial fractures. The mean time to fracture union was longer in the retrospective external fixation group and the delayed union rate was twice as high. Further procedures were required. There were also unsatisfactory fracture reduction in 6 of 31 (19 %) patients and re-displacement in 3 (9.6 %). Further operative procedures were done. In the prospective nailing group an unsatisfactory fracture reduction was shown in 4 of 31 (12.9 %) patients and re-displacement occurred in 1 patient. There were 5 wound infections in the external fixation group, 3 deep and 2 superficial. 11 patients had also pin track infection. In contrast there were 5 wound infections, 2 deep and 3 superficial in the nailing group (19).

There is a retrospective study of 32 patients with segmental tibial shaft fracture both closed and open treated with unilateral external fixation in Serbia (2018). Two proximal and 2 distal pins were applied and 1 or 2 pins for the segment based on surgeons decision. Alignment adjustment was needed in 4 patients after 4 weeks of external fixation. 2 cm bone defect was observed in one open fracture, resolved by spongioplasty. They found 5.9 months average time of union for closed fractures and 6.4 months for open ones. Union rate was 26 (81.25%), nonunion 6 (18.75%) and malunion 1 (3.12%). Open fractures had higher nonunion rate. Delayed union was observed in 6 (18.75%) cases. Compartment syndrome was clinically diagnosed in 6 patients (18.75%) with closed fractures. No deep infections and osteitis but Pin tract infection was seen 7 (21.85%) cases. One or two pins exchange were needed in 3 cases after debridement of the pin site, followed by oral antibiotics (20).

Bratislav Stojković and et al. applied external fixation for 49 patients with tibial shaft fractures in Serbia (2006) from which 14 (28.57%) were open. They showed union rate of 83.68% and nonunion rate of 12.24% , 6 patients from which 4 were open and 2 segmental fractures.4 (8.16%) patients developed pin tract infection . they also observed compartment syndrome in 1 (2.04%) patient which was closed (21).

Ali Çağrı Tekin and his colleagues from turkey (2016) studied outcome of type 3 open diaphyseal fractures treated using limb reconstruction system retrospectively. 50 patients were enrolled to the study. They followed them for an average period of 23 ± 12 months (range: 11–44). Full union was achieved with the LRS in 48 (96%). No shortness or deformity was observed. Ankle and knee range of motion in all patients at the final follow-up were full. The mean time to union was 20.4 ± 4 weeks (range: 16–24) and mean time of external fixator use was 20 weeks (range: 16–24 weeks) (8).

Similarly another retrospective case series of 153 patients having GA grade III B open tibial fractures treated with external fixators from Jan 2010 to May 2014 in northern India was done to evaluate the effectiveness of unilateral external fixator as primary and definitive treatment for such fractures. The average time to union was 22.13 ±2.68 weeks, superficial pin track infection occurred in 11 Patients & deep infection with loosening of Schanz screw in 2 patients. Two patients had delayed union whereas non-union was seen in 3 patients which needed secondary operation (22).

A paper from mandya done in Sri Adichunchangiri hospital and Research centre after treating 157 cases of open fractures of both bones of legs out of which 45 cases of type IIIA and type IIIB were selected for the study between June 2007 and July 2010. They did wound debridement and fracture stabilization with LRS external fixator aiming to achieve anatomical reduction, stable fixation and early soft tissue coverage to allow early mobilization. Fixator was kept for 24 weeks, using the principle of compression distraction osteogenesis, fracture union was enhanced by doing compression and distraction at the rate of 1 mm for every 10 days alternatively. They followed patients regularly per modified Andersons and Hutchins criteria. Results showed overall 90% of union rate well. While good to excellent results were seen in 28 cases amounting to 72%, moderate and poor results were observed in 18% and 10% of the cases respectively (23).

A retrospective cohort study by Zi-Chen and et al. in china (2016) compared treatment of open tibial diaphyseal fractures by external fixation combined with limited internal fixation versus simple external fixation. A total of 152 patients were included in the analysis, and there were 85 patients in the simple external fixation group and 67 patients in the EF-LIF group. Their indicators were direct cost of hospitalization and the times of first surgery, full weight bearing, and complete union. Combined fixation resulted shortened time to bear full weight and achieve

complete bone union but requiring additional first surgery time. No significant difference was found in infection rates or direct cost of hospitalization. Delayed union and non-union in the EF-LIF group were significantly decreased (20.9% versus 40.0, 1.5% versus 14.1%). Reduced malreduction, loss of reduction, and malunion in patients with combined fixation were found (24).

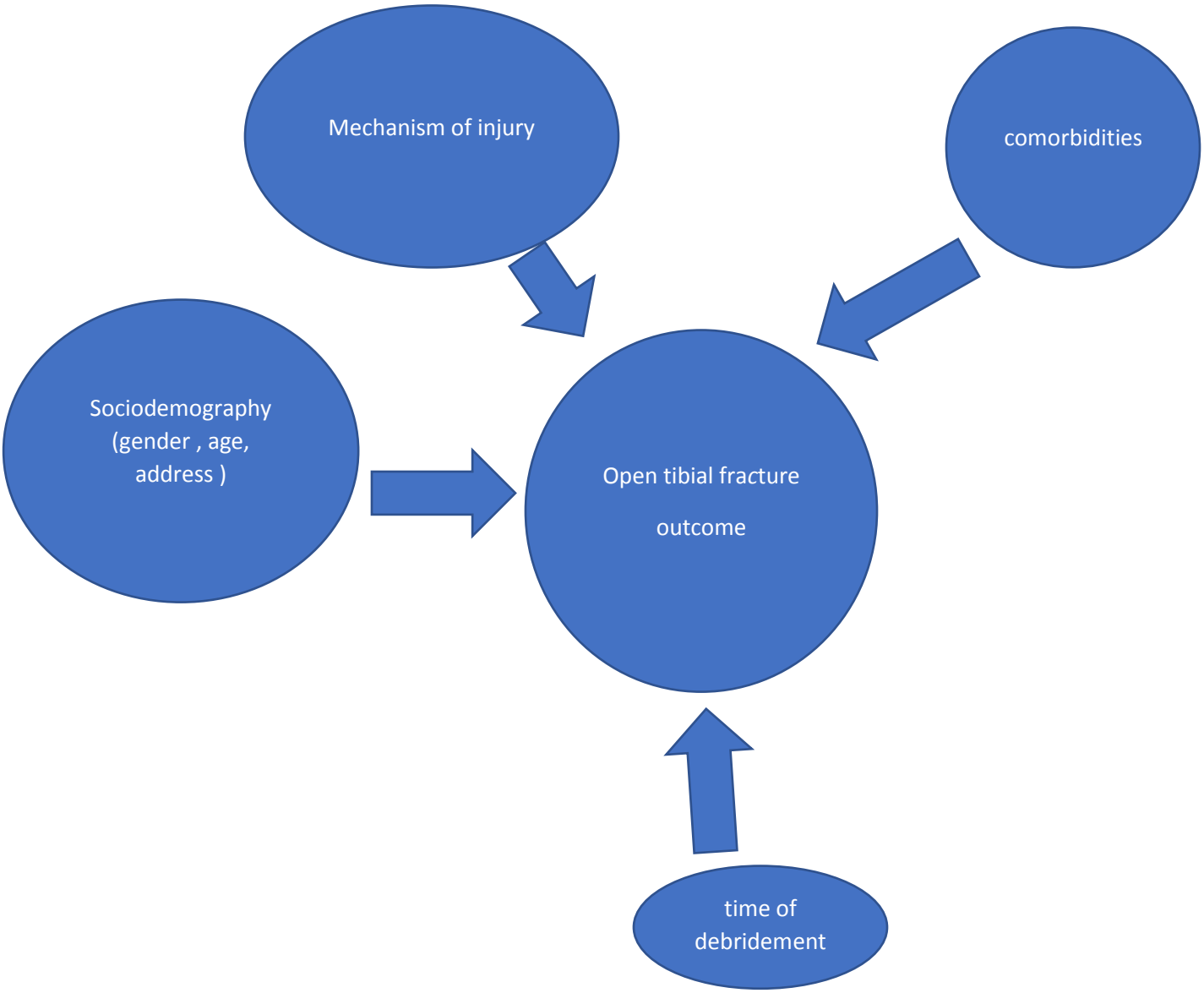
From January 1990 to June 1991 seven patients with eight complicated traumatalogical sequelae of the limbs were treated at Sololo Hospital, Kenya with external skeletal fixation. Limbs were grossly contaminated. They found all wounds healed, free of infection, and the healing time to bony union, defined by unsupported weight-bearing, ranged from 3.5 to 7 months(25).

A study done in Ethiopia (2010), assessed Adult limb fractures in Tikur Anbessa Hospital caused by road traffic injuries. Total of 422 patients who attended the surgical and orthopedic outpatient emergency department of Tikur Anbessa Hospital were enrolled to the study. Injuries to the upper limb alone accounted for 41.1% were upper limb injuries and 57.4% were lower limb injuries.1.5% of patients were having both upper and lower limb injuries. The commonest were femur fracture, 32 (15.8%) followed by tibio-fibular 29 (14.4%) and humerus 26 (12.9%). There were many causes of fracture from which RTA took the largest proportion , 202 (47.9%) of injured patients (6).

External fixation of fractures of the tibial shaft is not a new concept. It was stated by Hippocrates about 2,400 years ago as a method of stabilization of tibial fracture externally. Soft tissue inspection and coverage will not be interfered by external fixation. Modern external fixation goes back to the 19th century when Malgaigne mentioned it as a mechanism having clamp which connects metal prongs to manage patellar fracture. After the Second World War, observation of many pin site infections and fracture nonunion discouraged its use. External fixation of long bone fractures was described by many authors in North America which attracts people to use it. That was due to better techniques, and knowledge of indications, better metals, stronger pins and a variety of frame size and configuration. Currently used external fixation devices are based on initial designs of inventors, mainly Hoffman and Ilizarov. External fixation is mainly indicated in open fractures and closed fractures with severe soft tissue injuries or compartment syndrome as well as for polytrauma patients to immobilize long bone fractures temporarily (3, 16).

CONCEPTUAL FRAMEWORK

Figure 1. conceptual framework



3. OBJECTIVE

3.1. General objective

The general objective of this study was to assess the outcome of open tibial shaft fractures treated by external fixation from January 2019 to June 2020 in TGSH, Bahir Dar Ethiopia.

3.2. Specific objectives

- To determine the magnitude of malunion , nonunion , infection ,and stiffness following open tibial shaft fractures treated using external fixation.
- To assess factors associated with open tibial shaft fracture external fixation

4. METHODS AND MATERIALS

4.1.Study area and period

Our study was conducted in the department of orthopedics and traumatology in TGSH, the University hospital, Bahir Dar, Ethiopia. Bahir Dar, one of the tourist destination areas of the country, is the capital city of Amhara national regional state located 565 km northwest of Addis Ababa. TGSH is one of the biggest teaching hospitals in Ethiopia which was established in 2018 G.C. around 7 KMs from the center of Bahir Dar. The hospital which has more than 500 beds , is serving for more than five million populations in the catchment area (ARHB 2015), nearly 2000 patients per day in both inpatient and outpatient services. Department of orthopedics has both inpatient and outpatient services. There are 66 beds in the inpatient, total of 8 orthopedic surgeons (2 of them are on fellowship) and 35 orthopedic specializing residents. Operations are done 4 days in a week as elective case and daily for emergency cases. The department have its own major operation room with two operating tables.

The study period was from July 2019 to November 2020.

4.2. Study design

Institution based retrospective cross-sectional study design was conducted. Charts of patients with open tibial shaft fractures treated by External fixation were reviewed, and we have interviewed patients by phone.

4.3. Source population

Patients who have open tibial fractures and treated using External fixation

4.4. Study population

Patients who have open tibial shaft fractures and treated using external fixation

4.5. Inclusion and exclusion criteria

Inclusion criteria

All patients sustained open tibial shaft fractures and managed using external fixation

Exclusion criteria

- Study subjects with incomplete medical records (Incomplete chart, missed chart)
- Pathologic fractures

- Stress fractures
- Associated femur fractures

4.6.Sampling size and procedure

There is no previous study on the outcome of open tibial shaft fractures treated using external fixation in Ethiopia. So we used 50 % proportion and the assumptions made for the sample size calculation are 95% confidence interval and 5% margin of error. The minimum number of sample required for this study will be determined by using single population proportion formula as follows.

Sample size $n = \frac{Z^2 p(1-p)}{d^2} = \frac{1.96^2 x 0.5 x (1-0.5\ )}{(0.05*0.05)}$ = 384.

However, the total source population during the study period was 60 only. So all 60 cases were included to the study.

4.7. Study variables

4.7.1. Dependent variables

Outcome of open tibial shaft fractures treated using external fixation

4.7.2. Independent variables

- Socio demographic features(gender , age)
- Mechanism of injury
    1. RTA
    2. Bullet injury
    3. Fall down accident
    4. others
- GA classification
- others

4.8.Operational definition

- Clinical union - walking without pain
- Normal healing - healing within 6 months
- delayed union - healing between 6 and 9 months
- Nonunion - fractured bone that did not completely heal within 9 months of injury, as well as showing in apparent progression towards healing over three consecutive months on serial radiographs(17, 26, 27)
- open fracture - fracture in which there is an open wound or break in the skin near the site of the broken bone(3)

4.9. Data collection /extraction tools and procedures

Data collection was done using a well-designed adopted checklist (annex) accomplished by patient's medical record review and patient interview. Data was collected by two trained general practitioners after being trained before data collection in the study period. The data collectors were given training about research objective, the questioner, how to review chart and fill the data to assure the quality of data. We have followed the data collection process, data extraction completeness and consistency of the check list. Some charts were checked for completeness before the main data retrieval started.

4.10. Data quality, processing and analysis

Data was coded, entered and analyzed using SPSS windows version 20. Frequency and cross tabulation were used to summarize descriptive statistics. Means and percentage were used for continuous data. Graphs, pie charts and tables were used for data presentation and dissemination. Cross tabulation was used but chi-square test as well as binary logistic regression were not used for the presence of associations between variables because of limited sample size.

4.11. Ethical clearance

Ethical clearance was obtained from IRB of BDU research ethical committee. However, confidentiality was maintained when handling each case files.

5. RESULT

This paper shows the results of the external fixation of 53 open tibial shaft fractures treated using External fixation in TGSH from January 2019 to June 2020. Seven patients were excluded from the study. One elderly patient who died due to chest injury, two patients for whom below knee amputation was done after failed vascular repair and other four patients who lost from follow-up.

5.1 Sociodemographic data

The average age was 34 ± 14 years, with Thirty six (67.9%) male and seventeen (32.1 %) female. Most patients were in age range of 21 to 40 years.

Table 1. describes sociodemographic data of study subjects.

Variable		Frequency	percentage
Age (years)	< 20	8	15.1
	21-40	26	49.1
	41- 60	17	32.1
	>61	2	3.8
Sex	male	36	67.9
	female	17	32.1
Address	urban	18	34.0
	rural	35	66.0

5.2 injury and treatment characteristics

The leading cause of the injuries was road traffic accident 19 (35.8%) followed by bullet, 15 (28.3 %) patients. In more than 2/3 of the patients included in the study debridement was done within 24 hours.

Variable		Frequency	Percentage
Mechanism of injury (cause of injury)	Bullet	15	28.3
	FDA	10	18.9
	RTA	19	35.8
	Others	9	17.0
Antibiotics	Yes	52	98.1
	No	1	1.9

Time of debridement	< 8 hours	9	17.0
	8- 24 hours	29	54.7
	>24hrs	15	28.3
Type of EXFIX	Uniplanar	50	94.3
	Biplanar	1	1.9
	Delta frame	2	3.8
EXFIX duration	<6wks	5	9.4
	6-12 wks	12	22.6
	>12 wks	36	67.9

*others = stick, horn

Table 2. injury and treatment variables.

More than half of the patients (58.5 %) under study were GA IIIA type and there were no GA I tibial shaft fracture which were treated using External fixation.

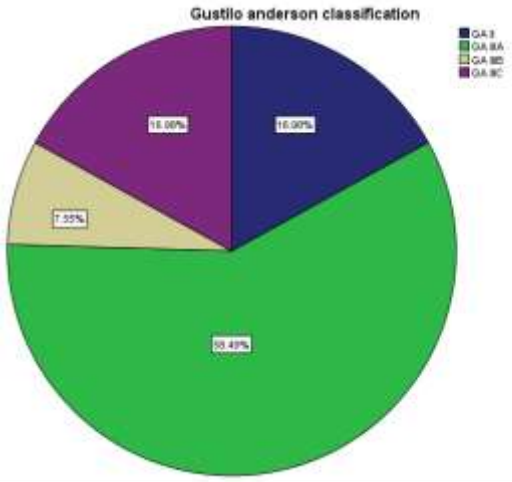


Fig. 2. Gustillo Anderson classification of open tibial shaft fractures treated by External fixation in TGSH.

5.3 Outcomes of injury

Malunion was found in 8 (15.1 %) patients. Thirty three (62.3 %) patients complain mild pain and 22 (41.5 %) patients were having insignificant limping during their follow-up period.

Repeated surgery was needed in most patients, but in only 9(17 %) patients external fixation was changed to IMN.

Variables			Frequency	Percentage
Infection		yes	34	64.2
		no	19	35.8
Infection type		Pin site	18	51.4
		Superficial	13	40.0
		deep	3	8.6
Mal Union		Yes	8	15.1
		No	45	84.9
Nonunion		Yes	13	24.5
		No	40	75.5
Joint mobility	Knee	Normal	45	84.9
		Decreased	8	15.1
	Ankle	Normal	37	69.8
		Decreased	16	30.2
Pain		None	13	24.5
		Mild	33	62.3
		Moderate	6	11.3
		Severe	1	1.9
Gait		Normal	25	47.2
		Insignificant limp	22	41.5
		Significant limp	6	11.3
Revision surgery		Yes	36	67.9
		No	17	32.1
Change to IMN		Yes	9	17.0
		No	44	83.0

Table 3. outcomes of treatment of open tibial shaft fractures using External fixation in TGSH.

Thirty four (64 %) of patients included in the study were having infection from which pin site was the commonest , 18 (51.4 %) followed by superficial infection, 13 (40 %).

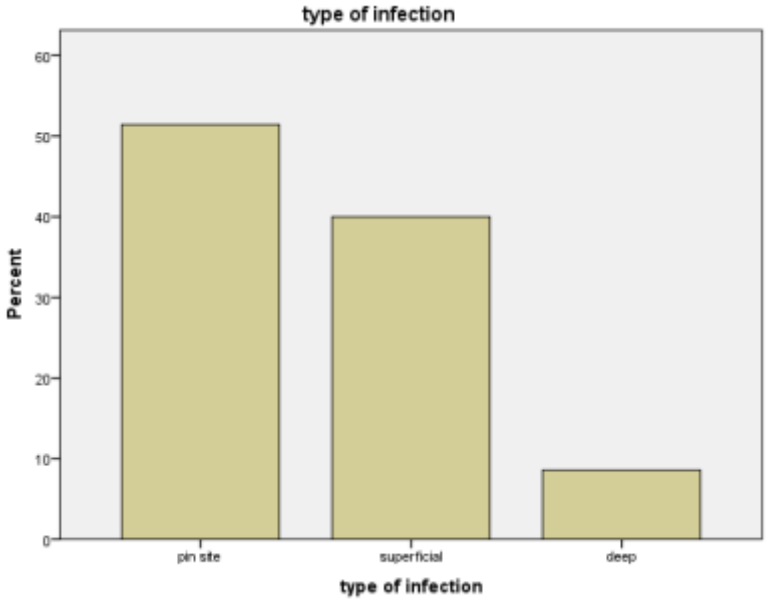


Fig. 3. type of infection after external fixation of open tibial shaft fractures in TGSH.

Of fifty three patients nonunion was seen in 13 of them who needed further treatment.

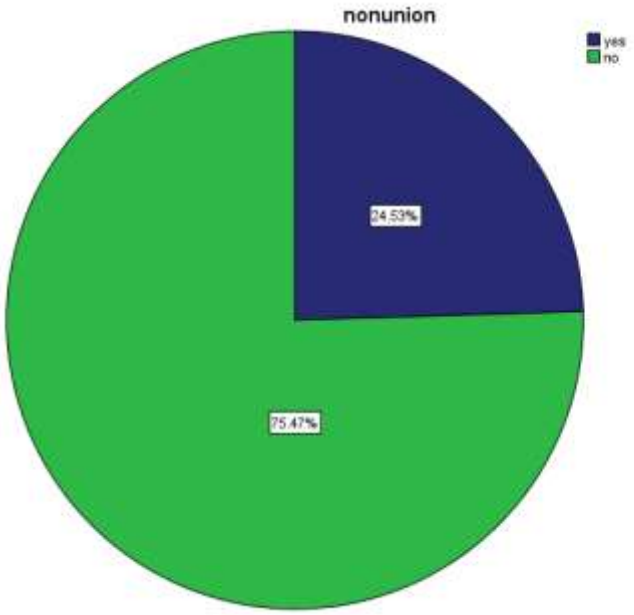


Fig. 4. Nonunion after external fixation of open tibial shaft fractures in TGSH.

5.4 Association between other factors and outcome

Out of all independent variables only sex fulfilled the chi-square assumption and become fit for the logistic regression. Sex has significant association with having infection following external fixation of open tibial shaft fractures. Accordingly females are more likely to have infection compared to males with an odds ratio of 4.3 (p=0.05 , 95 % CI, 1.3 – 14.6). (table 4).

Other than sex, all other factors didn't fulfil the chi-square assumption for logistic regression.

Table 4: Factors associated with open tibial shaft fractures treated using external fixation

Variables	Categories	Outcome infection		p-value	COR (95% CI)
		Yes	No		
Age (years)	< 20	6	2		
	21-40	16	10	.99	
	41- 60	10	7	.99	
	>61	2		.99	
Sex	Male	27	9		1.3
	Female	7	10	0.02	14.6

COR: crude odd ration; CI: confidence interval

Table 5: factors associated with infection following external fixation of open tibial shaft fractures

Variables	Categories	Outcome infection		Chi-square (P-value)
		Yes	No	
Age (years)	< 20	6	2	0.6
	21-40	16	10	
	41- 60	10	7	
	>61	2	0	
Sex	Male	27	9	0.017
	Female	7	10	

Address	Urban	11	7	0.74
	Rural	23	12	
Gustillo Anderson classification	GA II	5	4	0.37
	GA IIIA	19	12	
	GA IIIB	2	2	
	GA IIC	8	1	
Debridement time	< 8 hours	5	4	0.7
	8 – 24 hours	20	9	
	> 24 hours	9	6	

6. DISCUSSION

External skeletal fixation is a standard method for the stabilization of open tibial fractures except for type I open fractures, when internal fixation can be applied as well (16).

Rates of complications seen with External fixation of tibial fractures vary considerably among studies. 51 type III open tibial fractures treated by external skeletal fixation was analyzed in 1990 by Court-Brown et al. 35 % of their patients have showed signs of pin tract infection which is similar to our study (34 %) although we studied not only GA type III but all types of open tibial fractures. When we see deep infection its much less in our patients(5.7 % vs 17.6 %) but our follow-up duration is shorter(14).

In other papers both the pin site and deep infection rate were lower comparing to our study. External Fixation of High-Energy Tibia Fractures were retrospectively studied by Stuart H. Myers and et al. in Children's Hospital of Philadelphia (2007) which resulted 29 % pin tract infection rate(17).

A retrospective study of 32 patients with segmental tibial shaft fractures treated with unilateral external fixation in Serbia showed 21.85 % pin tract infection and there were no deep infection. In contrast to our study they included both open and closed tibial shaft fractures(20).

With regard to pin site infection rate, while not formally recorded in the chart, many of the patients who come for follow-up may exhibit some varying degree of pin site infection which might be treated with oral antibiotics.

Many reported union rates using external fixation for definitive treatment were quite high. Ali Çağrı Tekin and his colleagues from turkey studied outcome of type 3 open diaphyseal fractures retrospectively after treated using limb reconstruction system. Union rate was 96%. There were No deformity and they also reported full ankle and knee range of motion in all patients at the final follow-up (8). We found significant rates of malunion and nonunion comparing to the rate in literatures (15.1 %, 24.5%) respectively. We also noticed decreased knee (15.1 %) and ankle (30.2 %) mobility in our study.

The above mentioned study by Stuart H. Myers and et al. in Children's Hospital of Philadelphia reported 10 % of both major malunion and nonunion rate whereas 18.75 % nonunion rate was documented in Serbian study of segmental tibial shaft fractures. Bratislav Stojković and et al. applied external fixation for 49 patients with tibial shaft fractures in Serbia from which nearly only 30 % were open. Nonunion rate they found were 12.24%. Another retrospective cohort study by Zi-Chen and et al. in china where they compared treatment of open tibial diaphyseal fractures by external fixation combined with limited internal fixation versus simple external fixation found 14.1 % nonunion rate in the simple external fixation group (17, 20, 21, 24). The increased malunion and nonunion rate in our study might be due to lack of appropriate follow-up, infection and being all our patients were open tibial fractures.

A Network Meta-analysis by Clary J. and et al. done in Canada showed highest reoperation rate comparing to reamed and undreamed nailing and lower comparing to plate for open tibial shaft fractures. In our study the revision rate was 67. 9 % (18). The revisions probably were for repeated debridement's than due to External fixation issues. They reported that there estimates of malunion and infection risk were very wide, and therefore no conclusive results were made based on their data.

A retrospective study done in Greece to evaluate the effectiveness of unilateral external fixator as primary and definitive treatment for open tibial fractures concluded as it can be used as primary and definitive treatment for tibia shaft fractures and are associated with a low deep infection rate which is not consistent to our study as mentioned above(7). There were no need of

Re-operation or change to another fixation device. In contrast to this in our study EXFIX were changed to IMN in nine patients (17 %).

Thirty three (62.3 %) patients complain mild pain and 22 (41.5 %) patients were having insignificant limping during their follow-up period. Repeated surgery was needed in 36 (67.9 %) patients and in nine patients (17 %) EXFIX were changed to IMN.

The most common age group affected was 21-40 years and RTA was the commonest cause of open tibial fractures which are consistent with the study by clelland et al (5).

Strength and limitations

Strength

- It is the first study in our country and study area as well per our search

Limitations

- Being a patient chart review study
- not enough fractures to achieve statistical significance for variables for which it is difficult to take the finding for the generalized population
- Lack of follow-up, missing data, lack of results regarding patient function, no consideration of comorbidities, no quantification of malunion,
- More difficult to use scores

7. CONCLUSION AND RECOMMANDATION

7.1. Conclusion

Open tibial shaft fractures are majorly caused by RTA followed by bullet injury, and common in the productive age group. Using External fixation for treatment open tibial shaft fractures as definitive one in our setup has lots of complications. Infection, nonunion and malunion rates are higher than other studies with significant reoperation frequency. Use of external fixation for definitive treatment of open tibial shaft fractures isn't reliable.

7.2 Recommendation

For Federal Ministry of Health and Amhara Regional Health Bureau

- Public awareness and measures to decrease the incidence of RTA and bullet injuries which are the commonest causes of open tibial fractures

For TGSH

- Our data documentation should be improved and become digital
- There should be management and follow-up protocol for open tibial shaft fractures
- We should strictly follow patients with open tibial shaft fracture treated using External fixation

For researchers

- It is a good area to do a research particularly prospectively to assess the outcome and comparing with these treated using IM nailing, as well as measuring the associated factors.

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Annexes

Annex 1 - Consent form for the assessment of outcome of open tibial fractures treated using external fixation at Tibebe Ghion specialized Hospital from 2019 to 2020.

Title of the Research Project: outcome of open tibial fractures treated using external fixation at Tibebe Ghion Specialized Hospital, Northwest Ethiopia.

Name of Investigator: Yeab Mulat (MD, orthopedic Resident)

Name of the Organization: Bahir Dar University, College of Medicine and Health Sciences.

Name of the Sponsor: Bahir Dar University

Introduction: this information sheet is prepared for Bahir Dar University, college of medicine and health sciences Administration to make concerned offices clear about the purpose of research, data collection procedures and get permission to conduct the research.

Purpose of the Research Project: To assess the outcome of open tibial fractures which are treated using external fixation

Procedure: In order to achieve the above objective, information which is necessary for the study will be taken from medical records of the patients.

Risk and /or Discomfort: Since the study will be conducted by taking appropriate information from medical chart, it will not inflict any harm on the patients. The name or any other identifying information will not be recorded on the questionnaire and all information taken from the chart will be kept strictly confidential and in a safe place. The information extracted will be kept secured by locked in to locker by key. After the data will be interred in to the computer by password. The information retrieved will only be used for the study purpose.

Annex 2. Questionnaire

Data collection format:

Part I; socio-demographic characteristics

1. card number----------
2. Age ¬¬¬¬¬¬¬¬¬¬¬¬¬¬¬¬¬--------- Sex ----------
3. Address a. urban b. rural

Part II clinical disease characteristics and functional results

4. Involved leg Side a. right b. Left c. Both
5. Mechanism of injury a. bullet b. FDA c. RTA d. others
6. GA classification -------
7. Antibiotics a. yes b.no

8. Time of debridement a. < 8 hrs b. < 24 hrs c. > 24hrs
9. Type of external fixation a. unilateral b. bilateral c. delta frame
10. External fixator duration----------
11. infection a. yes b. no
12. if yes a. pin site b. superficial c. deep
13. malunion a. yes b. no
14. nonunion /clinical a. yes b. no
15. mobility
    - knee a. normal b. decreased
    - ankle a. normal b. decreased
16. Revision surgery a. yes b. no
17. Pain a. none b. mild c. moderate d. severe
18. Gait a. none b. insignificant limp c. significant limp
19. change to IM nail a. yes b. no