



**St. Paul Hospital Millennium Medical
College Graduate Study Program**

Prospective Cohort Study on Incidence and Risk factors of Pin Tract Infection after External Fixation of Fracture at AaBET Hospital, 2022G.C.

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A Thesis Submitted to the Department of Orthopaedics and Traumatology; Presented in Partial Fulfillment of the Requirements for the Certificate of Specialty in Orthopedics and Traumatology; St. Paul Hospital Millennium Medical College

May, 2022

Addis Ababa, Ethiopia

Acknowledgements

First of all, I would like to thank SPHMMC and AaBET Hospital Orthopedics department for giving me an opportunity to be involved in research activity. I would also like to thank **Dr. Tilahun Desta** and **Dr. Dawit Alemayehu** who revised the clinical aspect of document and gave me comments timely. Equally my respect and thank goes to **Dr. Yoseph Worku** who revised the whole document in detail, timely and properly, and gave me comments that moved this project to a next level. The assistance provided by some Orthopedics and traumatology consultants was greatly appreciated. I am also thankful to **Dr. Samuel Kebede** for guiding me guidance throughout research process. I am also so thankful to all patients who participated in the study.

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Acronyms and Abbreviations

AaBET: Addis Ababa Burn Emergency and Trauma

EX-Fix: External Fixation

G.C: Gregorian calendar

ICU: Intensive Care Unit

GA: Gustilo and Anderson

MRN: Medical Record Number

OR: Odds ratio

COR: Crude odds ratio

AOR: Adjusted odds ratio

PACU: Post Anesthesia Care Unit

PI: Principal Investigator

PTI: Pin tract infection

PTIs: Pin tract infections

SPHMMC: St Paul`s Hospital Millennium Medical College

SPSS: Statistical Package for Social Science

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Abstract

Introduction: Pin site infection (PTI) is by far the most common complication that arise after external fixation (Ex-Fix) that puts a significant burden on the patient and healthcare system. This infection may require more number of clinic visits required during a patient's course of treatment, requires additional treatment such as antibiotics and surgery, and most importantly can compromise patient outcomes should osteomyelitis or instability result from pin loosening, or need for pin or complete construct removal. There is no study that determined the magnitude of incidence of PTI locally, neither is there a study that looked into risk factors for these infections.

Objectives: To determine incidence and risk factors of PTI among patients who have undergone Ex-Fix of fracture at Addis Ababa Burn Emergency and Trauma (AaBET) Hospital.

Methods: This was a prospective cohort study design that was done in AaBET Hospital. Study population including all orthopedic and traumatology patients for whom Ex-Fix was done from February–April 2022 for fracture treatment. The sample size was 40 patients for whom Ex-Fix was done during study period which was selected by consecutive sampling technique. Data on PTI and risk factors was collected and analyzed by Statistically Package for the Social Sciences (SPSS) v. 26. Graphs, tables and descriptive method of data were utilized to discuss the results. Fisher's exact test and logistic regression analysis were performed to assess association. Odds ratio (OR) was used to assess strength of association.

Result: An incidence rate of PTI was 65.0% (26 out of 40 patients). All PTI were minor infections, grade 1-grade 3 of Checketts-Outterburn grade. Grade 2 was seen in 17 patients (45.9%). Skin tension around pin site was seen in 26 (65.0%), of these 21 (52.5%) patients with skin tension around pin site developed PTI. Skin tension around pin site was risk factor for PTI with Fisher's Exact test=0.04, crude odds ratio (COR) =7.56, 95% CI: 1.75, 32.72, $p < 0.01$ and adjusted odds ratio (AOR): 5.04, 95% CI: 1.13, 22.50; $p < 0.05$.

Conclusion: PTI incidence rate is around 2/3 after Ex-Fix done for fracture which is significant problem. All PTI are minor infections, Grade 1-3. Grade 2 PTI is most commonly observed PTI grade. Skin tension around pin sites found is risk factor for PTI.

Recommendation: Proper surgical technique to relieve skin tension around pin sites is needed to reduce PTI. Further large and longstanding study on identification of risk factors and prevention of PTI are recommended for proper pin site care and PTI prevention.

Key Words: EX-Fix, incidence, pin tract infection, risk factors, fracture, AaBET Hospital

1. Introduction

1.1. Background

Ex-Fix is device located outside the body and is connected to the bone via transcutaneous pins or wires. Physicians have been using Ex-Fix to treat fractures for more than 2000 years. It was first described by Hippocrates as a way to immobilize the fracture while at same time preserving soft tissue integrity. Even if principles of external fixators remain the same, the design and biomechanics of Ex-Fix have changed dramatically over the years, eliminating its mechanical inadequacy. The primary objective of Ex-Fix is to maintain the length, alignment, and rotation of the fracture. It can serve provisional fixation or definitive fixation purposes. Mode of fixation and level of stability largely determine fracture healing physiology. Ex-Fix is based on relative fracture stability which results in secondary enchondral bone healing physiology. (1)

There are various frame types external fixator including: uniplanar, triangular, multiplanar, hybrid, and circular fixators. Uniplanar external uses bar, clamp and pin on single plane. Triangular or Delta frame uses linkage between frames in perpendicular planes or frames in which bars from ends of single pin attached to partial frame. (2, 3) Hybrid external fixator frame combines uniplanar and circulator frame types. (1, 4, 5)

Ex-Fix has become a crucial tool in the orthopaedic surgeon's modern equipment, being used both in traumatology and reconstructive surgery. (6) It is fast, relatively simple and cost-efficient device. (7) Ex-Fix can be used for various indications. It may be used in damage control orthopaedic, for temporary fracture stabilization, or definitive fracture fixation, open and closed fractures. It also indicated in soft tissue management, infection, immobilization of joint and bone after soft tissue flap, vascular and nerve repair, nonunion, malunion, deformity correction, and other elective surgery. (1, 4)

Ex-Fix has disadvantage as complications. The complications include pin tract infections (PTIs), frame or pin/wire failure or loosening, neurovascular injury, muscle or tendon tethering, delayed union, non-union, mal-union, compartment syndrome, osteomyelitis, septic arthritis, bending and psychological trauma. (1, 4)

PTIs are by far the most common complications that arise after Ex-Fix. It is defined as redness, warmth or discharge around the schanz screws of the external fixator, causing increasing pain, pin loosening or positive culture of discharge around the pins. There are many risk factors associated with PTIs. These include age, comorbidities, stability of external fixators, type of external fixators, fracture location, fracture type, fracture patterns, pin insertion techniques, duration of hospital stay, duration external fixator, use of prophylactic antibiotics, and pin site care. (1, 4, 6, 7)

PTI divided into two as major (deep infection) and minor (superficial infection). (8, 9) Major PTI, which averages 5.8%, is the one requiring hospital admission for parenteral antibiotic therapy, pin removal, or fixator removal. (7) The incidence of PTIs is largely variable in literature, 11.3%-100%. (4, 8-10)

1.2. Statement of the Problem

The current population of **Ethiopia** and Addis Ababa are estimated to be **119,141,337** and 5,005,524 respectively. (11, 12) Despite major strides to improve the health of the population, Ethiopia's population still face a high rate of morbidity and mortality and the health status remains relatively poor. Tertiary care level, comprised of specialised Hospitals, is one current component Ethiopian health tier system where trauma treatment is being given. (13)

Acute trauma is a major cause of death and disability worldwide especially among young and productive individuals. (5, 14) Fractures accounting for the majority of trauma in developing nations. In Addis Ababa, Ethiopia, extremities are the most common body regions injured, accounting for 45.1 % following road traffic accident. (15) Ex-Fix has become a crucial tool in the orthopedic surgeon's modern equipment, being used in traumatology surgery, either for saving patient life or limb. (16) PTIs are by far the most common complications that arise after Ex-Fix that places a significant burden on the patient and healthcare system. Risk factors associated with PTIs including age, comorbidities, stability of external fixators, type of external fixators, fracture location, fracture type, fracture patterns, pin insertion techniques, duration of hospital stay, use of prophylactic antibiotics, and pin site care. (1, 4-7) The presence of a PTI reduces pin-bone interference which progresses to subsequent pin loosening and fixation failure, delays conversion of an external fixator to internal fixation until clearance of the infection is

achieved, severe pain, excessive medications, prolonged immobilization, septic arthritis and osteomyelitis which final compromise patient outcome. (4, 8, 9)

PTI was occurred in up to 100 % of the study group with Ex-Fix in one series reports. (6) The incidence of PTI in Africa was 7% - 87.7%. (4, 5, 7, 17, 18) Up to 71% incidence of deep infection has been reported following Ex-Fix conversion into intramedullary nail when performed after there has been evidence of a PTI, and 5.9 % when this has been done in absence of PTI. (9) This study assessed the incidence and risk factors for this challenging complication in resource limited setting.

1.3. Rationale of the Study

Knowledge of incidence and risk factors of pin tract infection in our locally setting can be used to prevent pin tract infection development. This in turn helps to prevent more advanced complications that may arise from a simple PTI.(6) The Knowledge helps to do proper patient evaluation preoperative to identify risk factors, follow operative room (OR) principles to keep sterility, follow appropriate surgical techniques, give proper post-operative and pin site cares. The high incidence of PTIs in patients undergoing Ex-Fix poses significant morbidity and costs associated with the sequelae. So the awareness of incidence and risk factors reduces this consequence through PTI prevention and early treatment. It also reduces PTIs associated Hospital resource expenditure. This is helpful for program manager of the Hospital and policy maker interims of resource management and human resource training. The study initiate further research on how to prevent pin tract infection after external fixation.

The incidence of pin tract infection is highly variable worldwide including Africa. Because of less ideal circumstances in hospitals in Ethiopia, there is a concern that incidence of pin tract infection is higher or equal. The incidence and risk factors of PTIs are not known at local setting and there is scarcity of data or published data at country level in Ethiopia despite it is being mentioned as the most common complication. (1, 4-7)

2. Literature Review

2.1. Pin Tract infection (PTI)

PTIs are by far the most common complications that may arise from percutaneous pins or wires, arise because of skin barrier disruption that place a significant burden on the patient and healthcare system. (4, 6, 8, 9) According to Nikolas et al. there is no universally accepted definition of PTI which resulted in incidence range from 11.3%-100%. This associated with difficult of making comparisons among different study results. Such a lack of a universal definition and reporting of infection rates (per patient versus per individual pin site) may pose challenges to conducting proper incidence determination. (6, 10)

Three levels of skin reaction to percutaneous pins has been reported by Kazmers et al. including: pin site reaction, pin site colonization, and pin site infection. (6) But these definitions are boring for clinical practice. Daves.et al. and Nikolas et al. tried to define PTI as redness, warmth or discharge around the schanz screws or wires of the external fixator, causing increasing pain, pin loosening or positive culture of discharge around the pins or wires that requires treatment with antibiotics, pin removal, or debridement. (6, 19) Various classification systems may be employed to describe the severity of the infection once the infection confirmed but Checkettes–Outerburn more commonly used and gives treatment guidelines. (6, 8)

Table 1: Two commonly used classification systems to describe pin site infections. (6, 8, 20)

Ward (1998)		
Minor	Prolonged drainage, crusting, swelling, and erythema. Considered benign	
Major	Resolution requires removal of affected pins	
Checketts-Otterburn classification (1999)		
Grade	Characteristics	Treatment
Minor infection		
I	Slight redness and little discharge	Improved pin site care
II	Redness of the skin, discharge, pain and tenderness in the soft tissue	Improved pin site care and oral antibiotics
III	Grade II but no improvement with oral antibiotics	Giving IV antibiotics.

		Affected pin or pins re-sited and external fixator can be continued
Major infection		
IV	Severe soft tissue infection involving several pins, sometimes with associated loosening of the pin	Check x-ray to rule out radiographic changes. Debridement, IV antibiotics, external fixation must be discontinued
V	Grade IV but radiographic changes, osteopenia around pins	Debridement, IV antibiotics, external fixator must be discontinued
VI	Infection after fixator removal. Pin track heals initially, but will subsequently break down and discharge in intervals. Radiographs show new bone formation and sometimes sequestrums.	Curettage of the pin tract/Overdrilling(10)

2.2. Magnitude of PTI

Alhammoud et al. conducted prospective cohort study in Syria from 2011-2016 on 955 patients with open long bone fractures and followed 404 patients till union or Ex-Fix removal; showed PTI was 16.7%. (21) Shah et al. also did prospective study over a year on 117 patients with open fracture and treated with Ex-Fix in Pakistan, and reported PTI incidence to be 23.9%. (8) Study done in China on 130 patients prospectively by Liu et al. documented that the incidence of PTI was 44.8%. (22) Schalamon et al. in Austria and Antoci et al. in America did retrospective study on 30 pediatric age group patients, and 88 patients who underwent lengthening using Ex-Fix reported incidences were 52% and 96.6%, respectively. (22, 23)

Regionally studies reported the incidence of PTI to be 7% - 87.7%. (1, 8-10, 18) Norrish et al studied 47 patients with open fractures treated with external fixator prospectively in Blantyre, Malawi. The study showed the overall rate of severe infection to be 7%. (18) Ferreira and Marais

did two retrospectively studies on 80, and 229 patients in 2012 ,and 2014 in south Africa to determine pin tract sepsis incidence, and the effect of HIV infection on incidence and severity of circulator external fixator pin tract sepsis, respectively. They reported PTI incidences were 26.25% and 22.7 %, respectively. (24, 25) A one year prospective cohort study was conducted at the Tokoin Teaching Hospital in Lomé, Togo by Abalo et al. on 50 trauma patients treated by external fixators. It revealed that the incidence rate of PTIs was 59.1%. (7) Prospective study done in Sudan on 31 patients with Ilizarov Ex-Fix documented PTI incidence 71%. (17) A prospective cross-section study done in Kenya, Nairobi, by Mohammed R. on 73 patients with uniplanar Ex-Fix in 2016 and followed for 6weeks showed that the incidence of PTI was 87.7%. (4)

2.3. Factors Associated With Pin Tract Infections

Many factors may be associated with pin tract infections which include comorbidity, type of fracture, biomaterials used for external fixations, insertion techniques, construct stability, Ex-Fix related factors, pin site care and post-operative education.

2.3.1. Comorbidity

Shah et al. did prospective study which quoted PTI was 25% among diabetics and 39.2% among smokers. (8) Brueggeman et al. observed that patients with diabetes mellitus, chronic venous insufficiency, peripheral vascular disease, and a poor soft tissue envelope due to trauma are an increased risk for developing chronic non-healing wounds after removal of half pins or even fine wires. (10)The studies done by Norrish et al. and Ferreira et al. quoted no effect of HIV infection on PTI. (18, 24)

2.3.2. Type and site of fracture

Prospective cohort study done by Abalo et al. reported that femur fracture is the most common fracture site for PTI with an incidence of 87.5% followed by tibial, 57.5%. Open fractures have higher incidence of PTI, 75.9% compared to closed fracture, 20.5%. (7)Alhammoud et al. conducted prospective cohort study and it showed PTI 18.6% in open femur, 18.1% in open tibia, and 5.8% in open humerus fractures. (21)

2.3.3. Biomaterials of external fixators

The biomaterials also determine the development of PTI. Piesk et al and Kazmers et al. mentioned that titanium alloys have fewer incidences of PTI than stainless steel pins. (6, 26)

There is competition between tissue cells and bacteria to attach to pin surface. Titanium alloys has poor surface for bacterial attachment, and poor surface for biofilm formation. (27) Considering biomaterial, carbon fibre bars improve stiffness as compared to stainless steel. (1, 28) The stiffer construct, the more it reduces stress at pin-bone interference and PTI. (1, 4) Silver and nitric oxide coated pins have lower PTI incidence due to bactericidal properties and antibacterial activity, respectively. (4, 29, 30)

2.3.4. The method of pin insertion

The method of pin insertion is other determining factor to PTI development. Pin and wire insertion should be as low energy and atraumatic as possible, with minimal damage to skin, soft tissue, and bone. (10) Pin loosening is associated with thermal necrosis during drilling process when using power drill than manual insertion. (4, 30) Matthews et al. quoted pin insertion heat generation that could cause heat necrosis can be reduced by pre-drilling before pin insertion. (31) Increasing temperature above 60° associated with thermal necrosis. A start-stop technique or continuous irrigation of drilling site with normal saline to allow bone cooling avoids thermal necrosis. (19)

2.3.5. Stability of external fixators

Major determinant of determinants for subsequent development of PTI is its rigidity. Unstable construct is more likely to develop PTI than stable due to pin sit irritation of surrounding soft tissues. (10) Stability of external fixators depends on many factors:

- Increasing rods number, pin number, pitch of threads and core diameter of pins (4, 18, 32, 33)
- Using hydroxapatite coated pins, tapering of pins, carbon fibre biomaterial used (29, 34, 35)
- Repeated clamp use reduces stability by reducing clamp mechanical performance. (36)
- Stability of external fixator construct by resisting forces from various angle is improved using two frames at different plane. (4)
- Predrilling (even self-drilling pins) can provide the most stable long-term fixation. (10)

An unstable fracture pattern increases likelihood of PTIs as it increases pin loosening by increasing stress at pin-bone interference. (4)

2.3.6. Type of external fixators

Type of external fixators determines incidence of external fixator PTI. Parameswaran.et al. documented that ring external fixators has lower incidence of PTI than monolateral and hybrid fixators. Unilateral external fixator and hybrid external fixator have an incidence of PTI 12.9% and 20% respectively but statistical not significant (37)

2.3.7. Location of external fixator pins

The study done by Shah et al. also documented that distal tibia and proximal tibia pins were two commonly infected pin site areas, 53.6% and 24.3% respectively. (8) Pin insertion at areas of significant soft tissue movement, such areas where tendons lie, should be avoided as pins placed at these sites have a high risk of pin tract infections. Failure to put muscle under stretch during pin insertion through muscle compartments to avoid tethering of muscles and also to prevent pin movement during muscle contraction increases PTI incidence. Pin placement is in areas that possess thin subcutaneous tissue layers and thickest portions of cortical bone increase risk of pin site infection. (10) Pins placed near fracture sites have higher incidence of PTI. This is because of pins placed near fracture sites are expected to experience a higher chance of loosening as they are exposed to higher levels of stress. Pin loosening associates with subsequent soft tissue irritation and infection. (4, 25)

2.3.8. Duration of Ex-Fix

The longer an external fixator remains in place, more probability of infection. Bibbo et al. mentioned that PTI finally becomes an avoidable as the duration of Ex-Fix increased. (10) Longer duration of Hospital stay may also influence PTI development because of longer duration of exposure to hospital acquired pathogens. (4)

2.3.9. Skin tenting and soft tissue impingent

All pin sites (both fine wire and half pin) must be free of skin tenting and soft tissue impingent. Failure to accomplish pin skin relaxation may ultimately require replacement of the pin. (10, 38)

2.3.10. Pin site care

Different literatures showed that Chlorihexidine, chlorihexidine/sulfadiazine, silver sulfadiazine, diluted povidone iodine, normal saline, alcohol, dry dressing, bathing and antimicrobial dressing can reduce PTIs even though their effect may be different. (4, 9 39-42) To avoid skin irritation and pin site morbidity, pin-site care needs to be performed only once daily. (10)

2.3.11. Post-operative education

Regional postoperative edema control is vital to ensuring that the peri-pin skin seals. Applying daily edema control wraps, elevating, and limiting limb dependent position time reduce edema and supports healing at pin insertion sites which covers pin tract from external environments. (10, 16) Patient education on pin site care may be useful. The incidence of PTIs is expected to be lower in patients who are educated on pin site care. (4)

2.3.12. Other associated factors

Male, non-urban living, lower education level, agricultural work, alcohol, hypertension, BMI > 25, were significantly associated with the incidence of PTI. (22)

Once PTI diagnosed, it will be managed according to Checketts-Outterburn classification. (20) This study may be best conducted using prolonged prospective cohort study method because of the patients can be followed till time of Ex-Fix remove and large sample size also can be obtained. There is no study done in our country on incidence and risk factors of PTI even if Ex-Fix is one the most common orthopedic surgeries being done in this setting and country. Even though it is one of the most common orthopedic surgeries being done in this setting and country, it associates with many devastating complications like PTI which should be prevented. Therefore, this study is very important to our local setting and country.

3. Objectives

3.1. General Objective:

To determine incidence and risk factors of pin tract infection among patients who have undergone external fixation of fracture at AaBET Hospital.

3.2. Specific objectives:

1. To determine incidence of pin tract infection in patients who have undergone external fixation of fracture at AaBET Hospital
2. To determine risk factors of pin tract infection in patients who have undergone external fixation of fracture at AaBET Hospital

4. Methods

4.1. Study Setting:

This study was conducted in AaBET Hospital, orthopedics wards and outpatient clinic, Addis Ababa, Ethiopia. Ethiopia is an east African country which is among the most populous countries. (13) Addis Ababa is the capital city of Ethiopia where AaBET Hospital (an affiliate of SPHMMC) is located. It was inaugurated as a public hospital under SPHMMC in 2015 G.C as tertiary referral and teaching Hospital. It is one of the first health sectors with an entire trauma and burn unit. Its location is Dej Zewde Aba Koran St, Addis Ababa, 12721. The Hospital is organized and equipped with emergency room (ER), wards, and intensive care unit (ICU) with more 200 beds. It also has operative rooms equipped with 4 operation tables along with post anesthesia care unit (PACU) that has 5 beds for emergency service and 4 beds for elective service.

The Orthopedic department of the hospital is involved in giving services at ER, orthopedic wards, and orthopedic outpatient. Orthopedic wards have 63 beds, 49 beds for adult and 14 beds for pediatrics, respectively. The department uses 2 OR tables. The human source of the department comprises of 14 consultants and 40 orthopedic surgery residents of different year of study. The department is one of the few governmental facilities giving operative services for both emergency and elective orthopedics patients referred from all over the country.

4.2. Study Period:

The study was conducted from February 2022 -April 2022 G.C.

4.3. Study Design:

Prospective cohort study with consecutive patient sampling.

4.4. Study Population:

4.4.1. Source population:

All orthopedics and traumatology patients that came to AaBET Hospital.

4.4.2. Actually Study population:

All orthopedics and traumatology patients for whom Ex-Fix was done during study period.

4.4.3. Inclusion Criteria:

Both sexes and all age groups of orthopedics and traumatology patients for whom external fixator was done during study period included.

4.4.4. Exclusion Criteria:

Patients for whom 0

Sample size was calculated using Epi Info Version 7 with confidence interval of 95%, 80% power and ratio of unexposed and exposed equal to 1 from different literatures for cohort study.

Table 2: Sample size calculated using Epi Info version 7

Exposure	Non-exposure	Outcome	Sample size	Reference
Open fracture	Closed fracture	PTI	30	(7)
Femur fracture	Tibia fracture	PTI	24	(7)
Distal Pin	Proximal pin	PTI	98	(8)

Sample size was 40 according to the patients underwent Ex-Fix procedure during the study period.

4.5. Sampling Procedures:

Consecutive sampling of all eligible patients was used.

4.6. Measurement

4.6.1. Study Variables:

4.6.1.1. Independent variables

- Socio-demographic factors
- Comorbidity
- Stability of external fixator
- External fixator biomaterials
- Fracture sites requiring Ex-Fix
- Type of fracture
- Type of External fixator
- Patient related factors: smoker and alcohol usage
- Pin insertion techniques
- Pin insertion sites
- Pin site care and patient education

4.6.1.2. Dependent Variable

- PTI

4.6.2. Instruments:

Structured type questionnaire and observation was used. Questionnaire was prepared and availed in hardcopy and softcopy. The data collection languages was English, Amharic and Afan Oromo. The questionnaires components included socio-demographic factors, and dependent and independent study variables.

4.7. Data Collection and Procedures:

All patients for whom Ex-Fix was done during study period recruited within few days after surgery. The patient medical record number (MRN) was used as identification number. Data was collected by seeing patients' folder, interviewing the patients or attendants or surgeons or residents, and clinical examination by data collectors (Orthopedics and Traumatology surgery residents) using data collectors administered questionnaire at orthopedics wards and outpatient clinic. The questionnaire was structured questionnaire.

Data collection was conducted from February - April 2022. All information on questionnaire sheet except pin tract infections related information was filled on initial contact. The data on presence and grading of PTI was collected according to simplified PTI definition given below during follow up at 1st, 2nd, and 6th week by data collectors.

All information was obtained and documented by data collectors under principal investigator (PI) supervision. Then these data was entered to computer by data entry clerk. To improve data quality, training and supervision were done.

All patients had a follow up X-ray, anteroposterior and lateral, 6weeks post-operative to rule out bone involvement around pins. The X-ray was taken at AaBET Hospital, X-ray room.

Table 3: Simplified Checketts-Otterburn grading of PTI, AaBET Hospital, 2022.

Grade	Clinical signs
0	Normal appearance
1	Redness, tenderness but no discharge
2	Redness, tenderness and presence of discharge
3	The Same as to Grade 2 but no improvement with oral antibiotics
4	Severe soft tissue infection with pin loosening
5	Grade 4 but with radiological osteopenia around pins
6	Osteomyelitis on X-ray (sequestrum and involucrum)

4.8. Operational Definitions:

PTIs are redness, warmth or discharge around the schanz pins of the external fixator causing increasing pain, and pin loosening requiring increasing the frequency of local cleansing, protecting the pin site with dressing, using an antibiotic, removing the pin, or performing surgical debridement according to Checketts-Otterburn grading of PTI (Table 3). (6, 8, 24)

Fracture is broken bone which can be complete or incomplete. (42)

Incidence refers to the occurrence of new cases of disease or injury in a population over a specified period of time. Incidence divided into incidence proportion and incidence rate. (44)

Risk factor is something that increases a person's chances of developing a disease. (45)

Pin site (tract) is percutaneous wound where a wire or screw transfixes the skin and bone. (46)

Uneducated: Those cannot read and write

4.9. Data Quality Control and Management:

The data collection was conducted by two data collectors. The data collectors were trained for half a day. The training manual for the data collectors included an overview of the whole proposal document with due emphasis on the study objective and how to fill the data collection form. The data that was collected using questionnaires and observation, and was checked by the PI to identify any incompleteness and inconsistencies, so that it was corrected. Data that was collected during each time of patient contact was entered to computer by data entry clerk who was trained. The follow up and a check X-ray were read by PI and confirmed by orthopedic consultant (clinical advisor).

4.10. Data Analysis Plan and Procedures:

To assess incidence and risk factors for pin tract infections at AaBET Hospital, all data of eligible cases for whom Ex-Fix were done during the study time frame made ready for the data analysis. The data collected was entered into a computer, cleared, categorized and analyzed. The data was summarized and described using tables and graphs. Point estimate for incidence rate of pin tract infections was computed. Fisher's Exact test, binary and multiple logistic regression were performed to assess the relation between potential risk factors and outcome of interest with COR and AOR to assess strength of association. Univariate analyses of the categorical outcome

(development of pin tract infection) and each individual associated factor was conducted interims of descriptive statistics like frequency and percentage, mean, median and standard deviation will be used to put results of the study in the form of findings. All statistical analyses was performed using the SPSS V. 26. The level of statistical significance was set at $p < 0.05$.

4.11. Ethical Consideration:

Ethical clearance was obtained from the Research Directorate of SPHMMC, and research committee of orthopedic and traumatology department of SPHMMC and permission was obtained from the Medical director office of AaBET hospital. The objective of the study was explained by data collectors for participants. Participation in study was purely voluntary in nature. The participants were free to participate or withdraw from the study which was planned not to affect their treatment or management. Informed verbal consent was obtained from patients themselves if adult and from parental or guardian if under 18. Patient's data confidentiality was kept strongly.

5. Result

Forty (40) patients for whom external fixation done were recruited into the study during 3 months study period, from February –April 2022.

5.1. Sociodemographic characters

Out of 40 patients, 21 patients (52.5%) were in age group of 20-39 and 10 (25.0 %) in age group 40-59. Thirty four (85.0%) patients were male. Twenty three patients (57.5%) were from Oromia, 13 (32.5%) were from Addis Ababa and 3 (10.0%) were from different regions. Sixteen (40.0%) patients elementary school while 11 (27.5%) secondary school regarding educational status. Occupationally 8 (20.0 %) were driver, and 7 (17.5%) farmer (**Error! Reference source not found.**).

Table 4: Frequency distribution table of socio-demographic characters of patients underwent Ex-Fix at AaBET Hospital, 2022 (n=40)

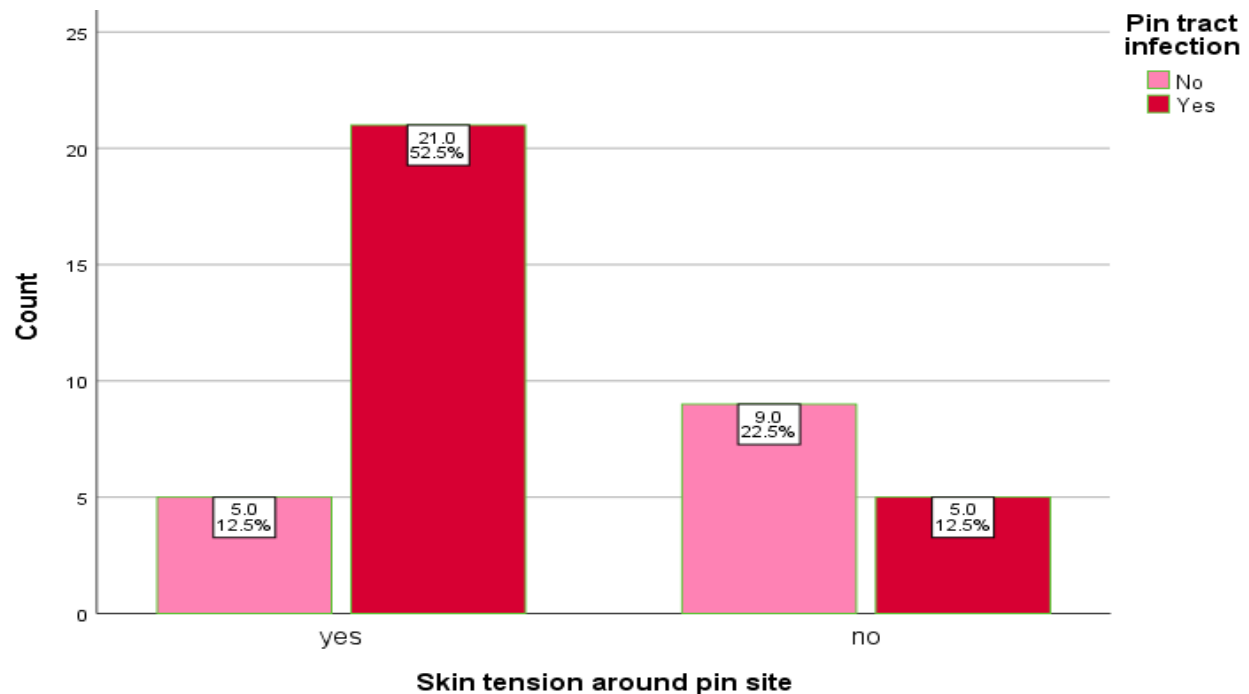
Sociodemographic character		Total Count	Total %
Age	0-19	5	12.5%
	20-39	21	52.5%
	40-59	10	25.0%
	> or =60	4	10.0%
Sex	Female	6	15.0%
	Male	34	85.0%
Address	Addis Ababa	13	32.5%
	Amhara	2	5.0%
	B/Gumuz	1	2.5%
	Oromia	23	57.5%
	SNNP	1	2.5%
Educational status	Uneducated	10	25.0%
	Elementary school	16	40.0%
	Higher education	3	7.5%
	Secondary school	11	27.5%
Occupation	Civil Servant	4	10.0%
	Daily laborer	6	15.0%
	Driver	8	20.0%
	Farmer	7	17.5%

	Merchant	3	7.5%
	Other	12	30.0%

5.2. Behavioral and Clinical Profile of Patients

Skin tension (tenting) around pin site was seen in 26 (65.0%) patients, of these 21(52.5%) developed PTI while 5 (12.5%) out 14 (35.0%) patients without skin tension around pin site developed PTI (**Figure 1**).

Figure 1: Bar chart distribution of PTI with skin tension around pin site after Ex-Fix at AaBET Hospital, 2022 (no=40)



Open type of fracture was 37 (92.5%) compared to closed fracture 3 (7.5%). Open type fractures had PTI incidence rate of 60.0% versus 5.0% of closed fractures (**Figure 2**). According to Gustilo and Anderson (GA) classification of open fracture GAII were 9 (24.3%) with PTI incidence rate of 16.2% and GAIII, 25 (67.5%) of which GA IIIB 17 (45.9%) with PTI incidence rate of 27.0% (**Figure 3**). Proximal and distal pins infected in 11 (42.3%) patients when occurred together, distal pins from all categories in 16 (61.5%) and proximal pins alone in 6(23.1%) (**Figure 4**). Biplanar and joint spanning, and unilateral external fixation types were 14 (35.0%) each which had PTI incidence rate of 30.0% and 20.0% in the order already mentioned (**Figure 5**). All pins were inserted manual and stainless steel. All patients were received pin site care and postoperative education to reduce edema. Only one patient (2.5%) was smoker. Fifteen

patients (37.5%) were alcohol user whereas 25 (62.5%) were non-alcohol user, of these 11 (27.5%) and 15 (37.5%) patients developed PTI in relative manner.

Figure 2: Bar chart of type of fracture versus PTI after Ex-Fix at AaBET Hospital, 2022 (n=40)

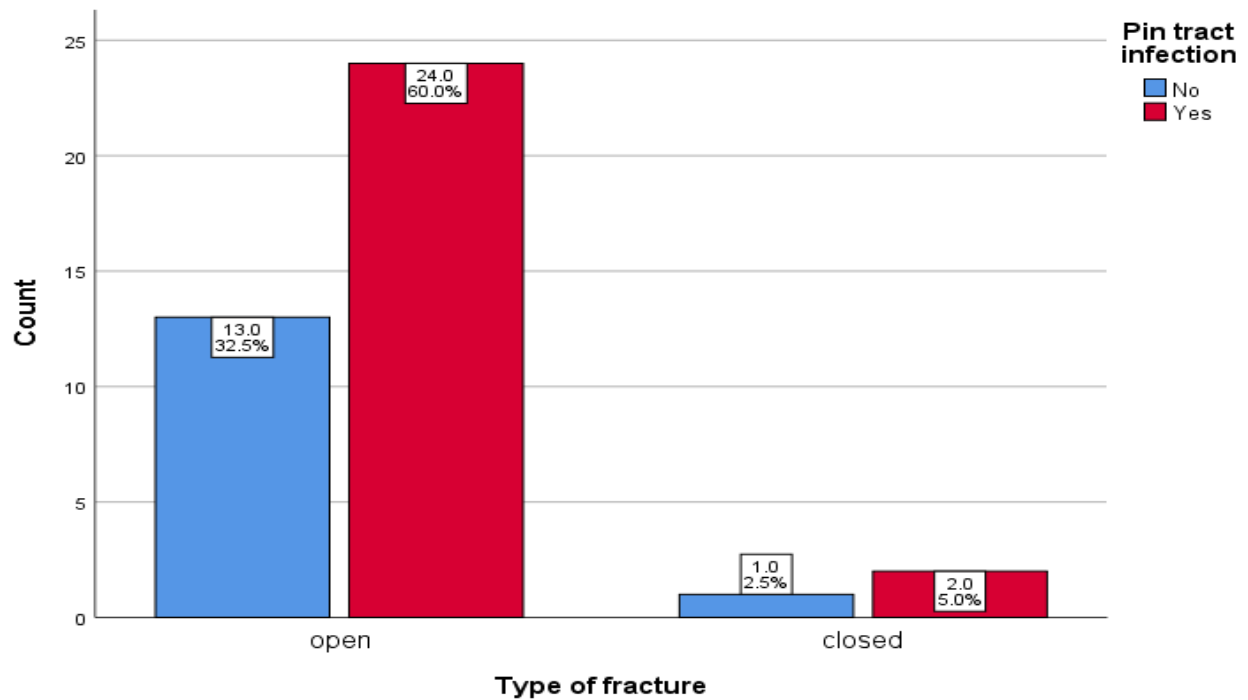


Figure 3: Bar chart distribution of PTI among GA classification after Ex-Fix at AaBET Hospital, 2022 (n=40)

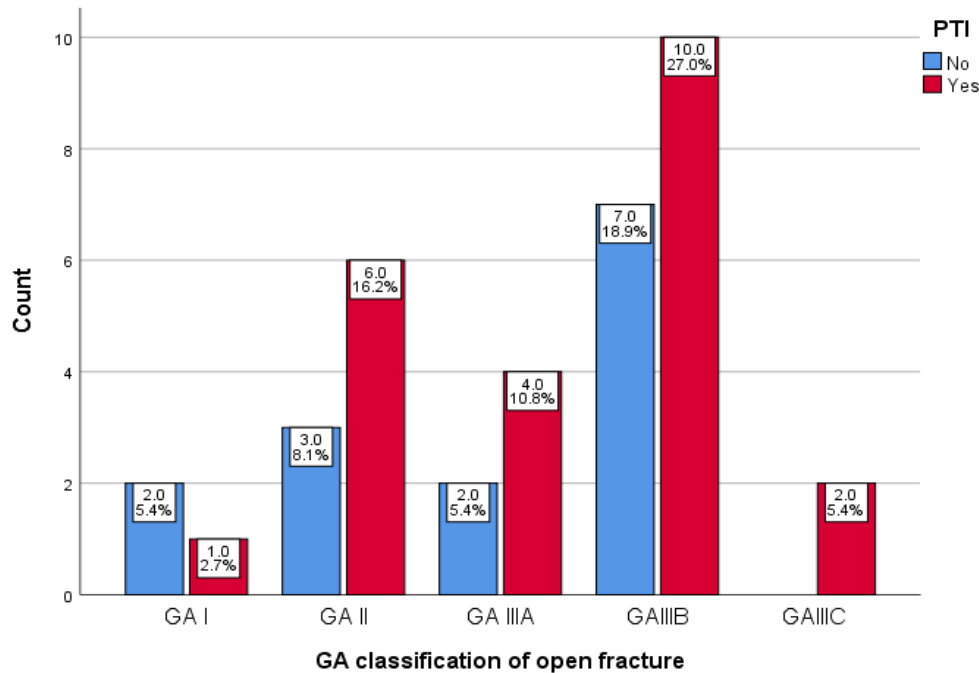


Figure 4: Bar chart of infected pin location of PTI after Ex-Fix at AaBET Hospital, 2022 (n=40)

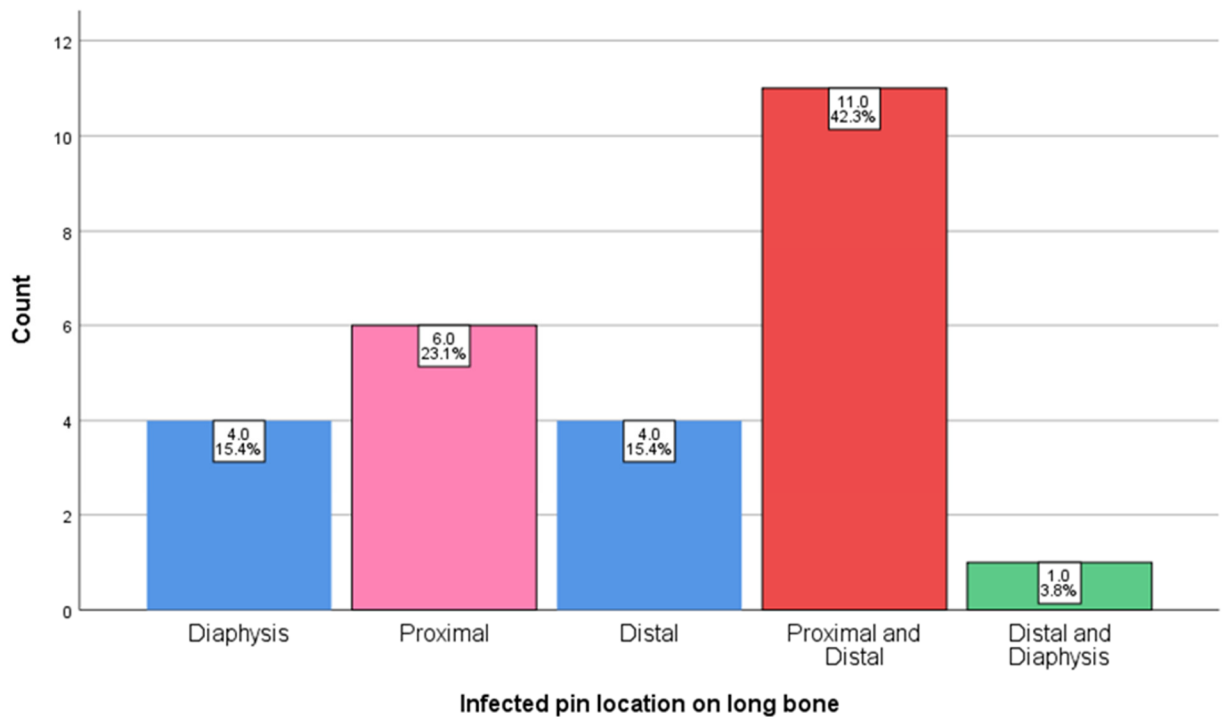
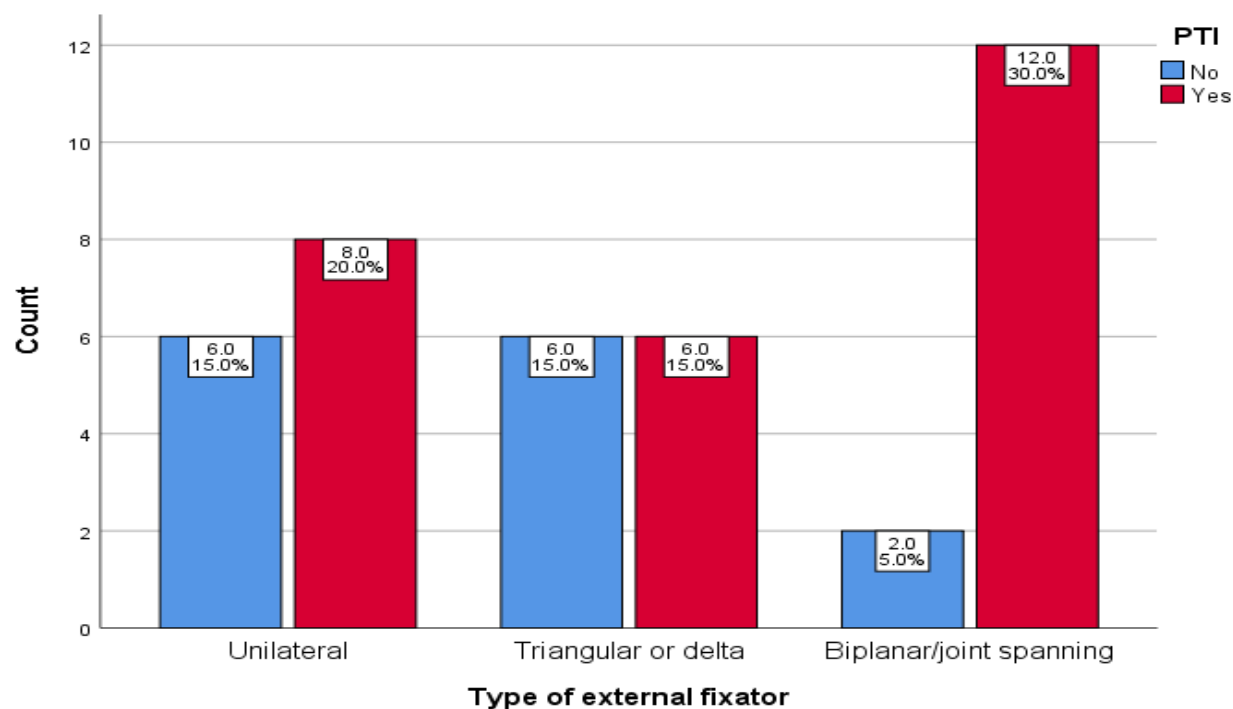


Figure 5: Bar chart showing type of Ex-Fix with PTI at AaBET Hospital, 2022 (n=40)



One patient had diabetes mellitus and hypertension as comorbidity (2.5%). Of all bar biomaterials used, 25 patients' bars (62.5%) were stainless steel, 6 patients' bars (15.0%) were carbon fiber and the rest both type. Only 2 (5%) patients with carbon fiber biomaterial had PTI and 18 Ex-Fix (45.0%) with stainless still developed PTI. Twelve (30.0%) patients' pins were inserted to thick muscle area versus 28 (70.0%) patients' pins into non muscle area of which 7 (17.5%) and 19 (47.5%) developed PTI respectively. Twenty nine (72.5%) patients had pin insertion into far from tendon sites and 18 (45.0%) developed PTI whereas in 11 (27.5%) patients inserted near tendon area and 8 (20.0%) developed PTI. Thirty six (90.0%) Ex-Fix were stable against 4 (10.0%) unstable. Twenty four (60.0%) of stable Ex-Fix and half of unstable Ex-Fix had PTI (Error! Reference source not found.).

Table 5: Distribution of characters considered risk factors for PTI after Ex-Fix at AaBET Hospital, 2022 (n=40)

		Pin tract infection			
		No		Yes	
		Count	Table Total	Count	Table Total
			N %		N %
Pin insertion techniques	Manual	14	35.0%	26	65.0%
	Power drill	0	0.0%	0	0.0%
Pin site care	Yes	14	35.0%	26	65.0%

	No	0	0.0%	0	0.0%
Post-operative education to reduce edema	Yes	14	35.0%	26	65.0%
	No	0	0.0%	0	0.0%
Smoker	Yes	0	0.0%	1	2.5%
	No	14	35.0%	25	62.5%
Alcohol usage	Yes	4	10.0%	11	27.5%
	No	10	25.0%	15	37.5%
	Total	14	35.0%	26	65.0%
Diabetes mellitus	Yes	0	0.0%	1	2.5%
	No	14	35.0%	25	62.5%
Hypertension	Yes	0	0.0%	1	2.5%
	No	14	35.0%	25	62.5%
Type of pin biomaterials	Stainless steel	14	35.0%	26	65.0%
	Titanium alloy	0	0.0%	0	0.0%
Type of bar biomaterials	Stainless steel	7	17.5%	18	45.0%
	Carbon fiber	4	10.0%	2	5.0%
	Both	3	7.5%	6	15.0%
Thicker muscle area	Yes	5	12.5%	7	17.5%
	No	9	22.5%	19	47.5%
Near tendon	Yes	3	7.5%	8	20.0%
	No	11	27.5%	18	45.0%
EX-Fix stability	Stable	12	30.0%	24	60.0%
	Unstable	2	5.0%	2	5.0%

According to diagnosis for which external fixation done, tibiofibular fracture was 19(47.5%) which had PTI incidence rate of 12 out of 26 (46.2%) PTI patients followed by floating elbow in which all 4 (15.4%) patients developed PTI (**Table 6**).

Table 6: Custom table showing orthopedic diagnosis versus PTI after Ex-Fix at AaBET Hospital, 2022 (n=40)

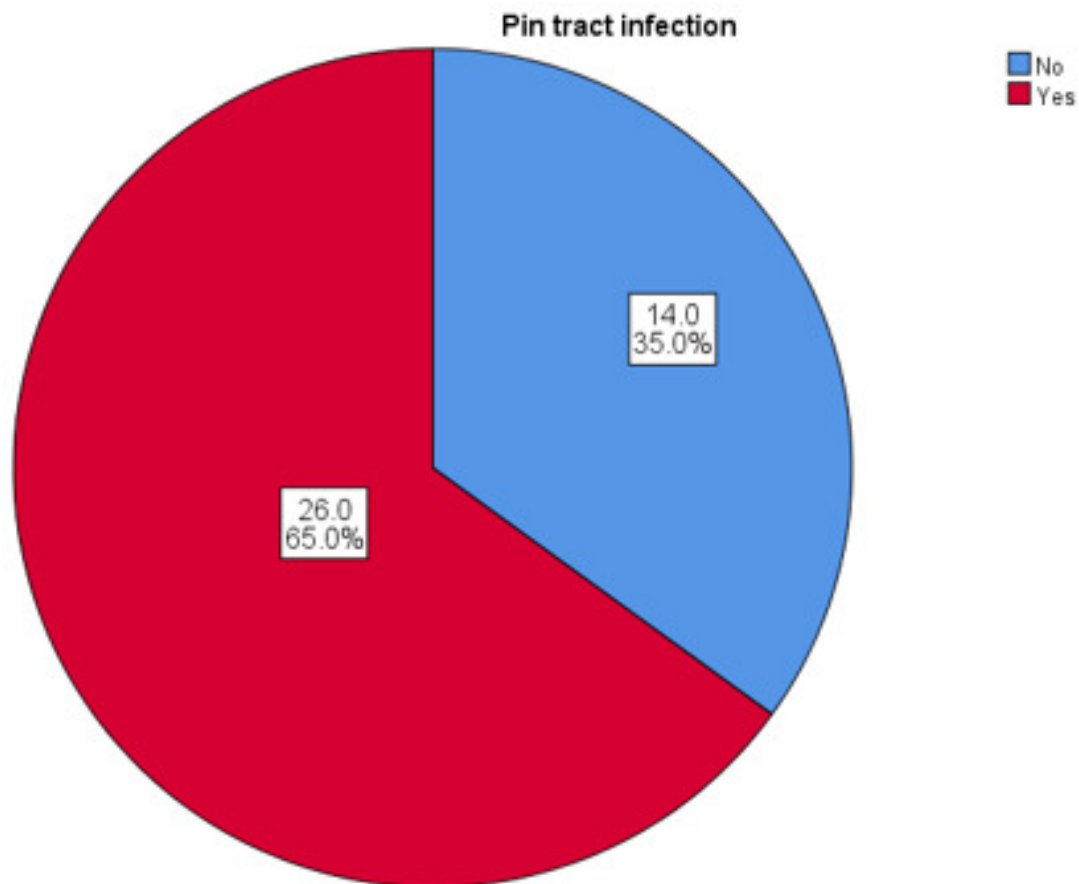
Orthopedics diagnosis	Pin tract infection					
	No		Yes		Total	
	Count	Percent	Count	Percent	Count	Percent
Femur fracture	0	0.0%	1	3.8%	1	2.5%
Ankle fracture	2	14.3%	1	3.8%	3	7.5%
Elbow fracture dislocation	0	0.0%	1	3.8%	1	2.5%
Extensive degloved soft tissue injury and metatarsal fracture	1	7.1%	0	0.0%	1	2.5%

Femur fracture	0	0.0%	3	11.5%	3	7.5%
Floating elbow	0	0.0%	4	15.4%	4	10.0%
Floating knee	1	7.1%	1	3.8%	2	5.0%
Humerus fracture	1	7.1%	2	7.7%	3	7.5%
Infected tibial pathological fracture	1	7.1%	0	0.0%	1	2.5%
Radioulnar fracture	1	7.1%	1	3.8%	2	5.0%
Tibiofibular fracture	7	50.0%	12	46.2%	19	47.5%
Total	14	100.0%	26	100.0%	40	100.0%

5.3. Magnitude of PTI

Out of 40 patients who have undergone external fixation for fracture management, 26 patients developed PTI. This made incidence rate of PTI to be 65% (**Figure 6**).

Figure 6: Pie-chart of PTI incidence after Ex-Fix at AaBET Hospital, 2022 (n=40)



Totally 199 pins were used in 40 patients with range 6, minimum 3, maximum 9, mean 4.98, and standard deviation 1.21. Out of 199 pins used during external fixation application, 64 pins (32.2%) were infected with minimum 1, maximum 6 and mean 2.46 (**Table 7**).

Table 7: Descriptive statics of number of pins used and infected after Ex-Fix at AaBET Hospital, 2022 (n=40)

	Range	Minimum	Maximum	Sum	Mean	Std. Deviation	Variance
Number of pins	6	3	9	199	4.98	1.21	1.46
No pins infected at follow up	5	1	6	64	2.46	1.33	1.78

5.4. Clinical Characters of PTI

All PTI were minor infections, grade 1 to grade 3 of checketts-Outterburn grades. Out of 65%, 1 grade 1 (2.5%), 17 grade 2 (42.5%) and 8 grade 3 (20%) were found (**Figure 7**). The duration Ex-Fix at diagnosis of PTI: at 1st week 9 (34.6%), at 2nd week 15 (57.7%), and at 6 week 2 (7.7%) (**Figure 8**).

Figure 7: Bar chart distribution of simplified Checketts-Otterburn grading of PTI after Ex-Fix at AaBET Hospital, 2022 (n=40)

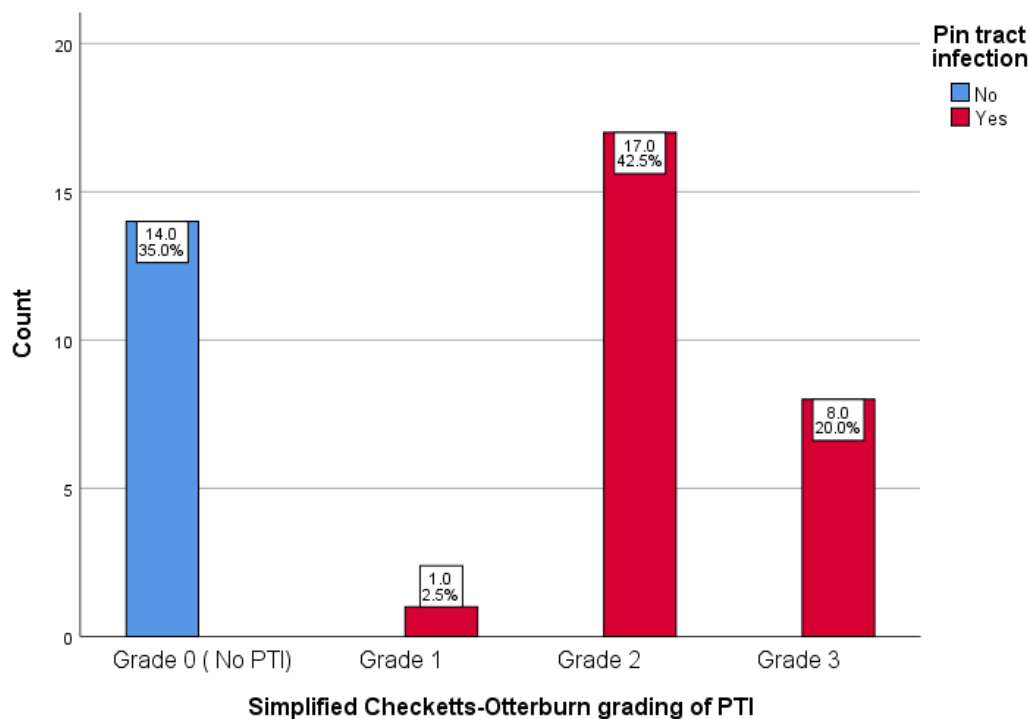
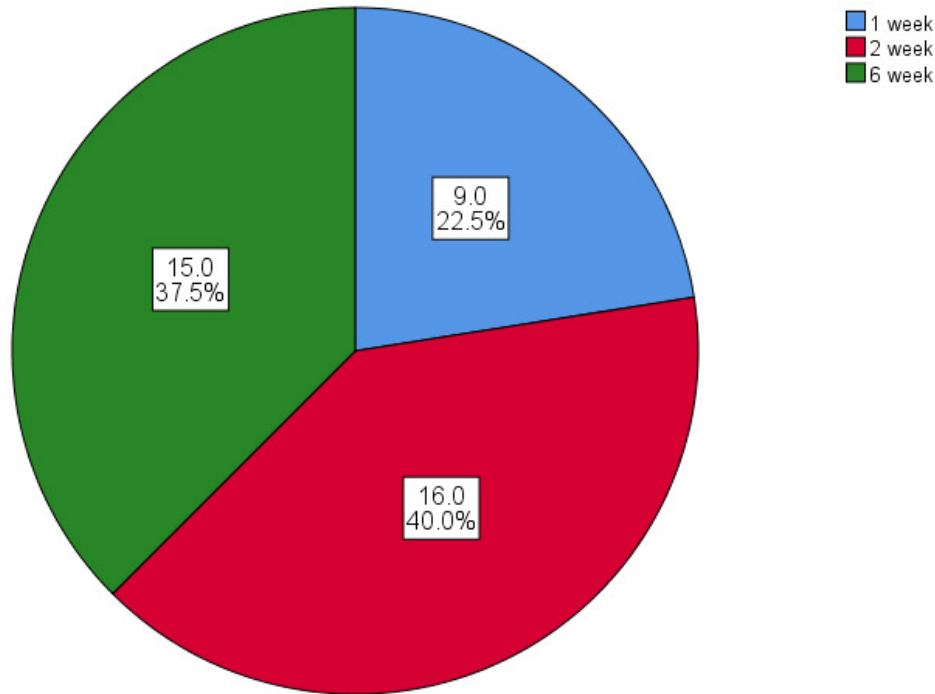


Figure 8: Pie-chart showing duration of Ex-Fix at diagnosis PTI at AaBET Hospital, 2022 (n=40)



5.5. Factor Associated with PTI

Skin tension around pin site (skin tenting) was significantly associated with PTI with Fisher's Exact test = 0.04, and binary and multiple logistic regression analysis of COR: 7.56; 95% CI: 1.75, 32.72; $p < 0.01$, and AOR: 5.04, 95% CI: 1.13, 22.50; $p < 0.05$ respectively. The following factors were not significantly associated with PTI: sex, occupations, education status, fracture type, Ex-Fix type, Ex-Fix stability, thicker muscle area, alcohol usage site of fracture, and bar biomaterial (**Table 9**).

Table 8: Binary logistic regression analysis results showing characters not significantly associated with PTI after Ex-Fix at AaBET Hospital, 2022 (n=40)

Variables/character	COR	95% CI	p-value
Age (lower groups versus >or 60=age group)	4.50	0.51, 80.57	0.31
Sex	0.92	0.15-5.76	0.93
Lower education status	0.30	0.03, 3.45	0.33
Open type of fracture	1.09;	0.09, 13.34	0.95)
Type of Ex-Fix(unilateral versus Biplanar)	1.05;	0.22, 5.00	0.95

Ex-Fix stability	6.82	0.62, 73.06	0.11
Thicker muscle area	1.51	0.37, 6,08	0.56
Alcohol usage	0.89	0,23, 3.42	0.86
Site of fracture	0.26	0.40, 1.61	0.15
Carbon fiber versus stainless steel bar biomaterial	0.22	0.02, 2.24	0.22
Lower versus higher educational status	4.167	0.34,50.62	0.26

6. Discussion

PTIs are by far the most common complications that arise after Ex-Fix, arise because of skin barrier disruption that place a significant burden on the patient and healthcare system. (1, 4 - 9) In this study the incidence rate of PTI was 65.0% (26/40 patients). This is comparable with the prospective cohort study done in Togo on 50 patients with an incidence of 59.1%. (7) It is also compared to the study done by Abbas et.al.in Sudan on 31 patients over 2years which showed an incidence of PTI to be 71%. (17) But it is higher than most studies done in developed and developing countries. Study done in China on 130 patients prospectively by Liu et al. documented that the incidence of PTI was 44.8%. (22) Alhammoud et al. conducted prospective cohort study in Syria from 2011-2016 on 955 patients with open long bone fractures and followed 404 patients till union or Ex-Fix removal; showed PTI was 16.7%. (21) Shah et al. also did prospective study over a year on 117 patients with open fracture and treated with Ex-Fix in Pakistan, and reported PTI incidence to be 23.9%. (8) Norrish et al studied 47 patients with open fractures treated with external fixator prospectively in Blantyre, Malawi. The study showed the overall rate of severe infection to be 7%. (18) Ferreira and Marais did two retrospectively studies on 80, and 229 patients in 2012 ,and 2014 in south Africa to determine pin tract sepsis incidence, and the effect of HIV infection on incidence and severity of circulator external fixator pin tract sepsis, respectively. They reported PTI incidences were 26.25% and 22.7 %, respectively. (24, 25) The incidence rate of this study was also lower than few studies done in developed and developing countries. Antoci et al. in America did retrospective study on 88 patients who underwent lengthening using Ex-Fix reported incidences was 96.6%, respectively. (23) A prospective cross-section study done in Kenya, Nairobi, by Mohammed R. on 73 patients with uniplanar Ex-Fix in 2016 and followed for 6weeks showed that the incidence of PTI was 87.7%. (4) These differences may be because of there is no universally accepted definition of PTI which resulted in incidence to vary largely from different studies. (6, 10)

The incidence of PTI among open fractures was 60.0% in this study. This was lower than study done in Togo over 1 year with an incidence of 75.9% among open fractures. (7) The may be due to study duration difference and variability of PTI definition. It was also lower than study done in Kenya, Nairobi, by Mohammed R. et al. in 2016 with an incidence rate of 87.7% for open fracture, but this study was done only on open type of fractures. (4)

All of PTI were minor infections, Grade 1, Grade 2 or Grade 3 according to simplified Checketts-Otterburn grading of PTI, which responded well to pin site care and antibiotic

treatment. These minor infections involve only soft tissue without bone involvement. The possible reason for these minor infections occurrence may be the short study period of 6 weeks which may be short for bone infection development. Similar result reported from a prospective cross-section study done in Kenya, Nairobi, by Mohammed R. et al. on 73 patients over 3 months with 6 weeks follow up. (4) A one year prospective cohort study done at the Tokoin Teaching Hospital in Lomé, Togo, on 50 trauma patients treated by external fixators showed grade 1 to grade 5 simplified Checketts-Otterburn grading of PTI. (7) This may be because of longer duration Ex-Fix for higher grade PTI development, bone involvement, is required. (4)

Proximal and distal pin locations were the most common locations of infected pins, 11 (43.2%) when occurred together. Proximal pin location alone constituted 6 (23.1%). Distal pin location made 16 (61.5%) when combined with different locations and alone results. This was comparable with the study done by Shah et al. which showed these two locations were the most common sites, 24.3% and 53.6% respectively. (8)

Unilateral external fixation had 20.0% of PTI incidence in this study, which was slightly higher than study done by Parameswaran AD et al. in 2003, 12.9% but this was retrospective study. (37) From GA classes, GAIII in the study was most commonly seen, 67.5% which was comparable with the study done in Kenya, Nairobi, with an incidence GAIII to be 61.6%. (4)

Interims of duration of Ex-Fix at diagnosis PTI infection, most PTI diagnosis made during 2nd week of follow up, 57.7% of all PTI in contrast to study done Mohammed et al in Nairobi, Kenya which showed 1st week was the most common time. (4) This probable related to excluding the progression of PTI from one grade to next grade.

Tibiofibular fracture was the most common diagnosis in this study which was similar with report from studies done by Mohammed et al and Abalo et al. (4,7)

Analysis from this study also showed skin tension around pin sites (skin tenting) found to be significantly associated with PTI (COR: 7.56; 95% CI: 1.75, 32.72; $p < 0.01$ and AOR: 5.04, 95% CI: 1.13, 22.50; $p < 0.05$). Kazmers et al. also mentioned that Skin tension around a pin site has been associated with greater infection rates. (6) Valentin A. put Hoffmann recommendation, relieving skin tension around pins in order to prevent infection. (38) Failure to accomplish pin skin relaxation may ultimately require replacement of pin. (10)

7. Limitations

The number of patients included in the study was relatively small and followed only for 6 weeks which may make the power of the study was not great enough to estimate the effect of less frequent variables and did not show higher grades of PTI. This study did not carry out observation of pin insertion techniques directly in operation room neither operation room sterility components. Despite these limitations this study was probable the first study to determine incidence and risk factors for PTI after Ex-Fix of fractures in Ethiopia which would be baseline study. This may encourage further large studies on incidence and risk factors of PTI, and on prevention of PTI.

8. Conclusion

PTI after Ex-Fix fracture is significant problem in AaBET Hospital wards and outpatient clinic, Addis Ababa, with an incidence rate of 65% which is higher than most studies done in developed and developing countries. All PTI are minor infections, Grade 1-3. Grade 2 PTI is more commonly observed infection grade. Skin tension around pin sites (skin tenting) found to be significantly associated with PTI.

9. Recommendation

Proper surgical technique to relieve skin tension around pin sites is needed to reduce PTI. Further large and longstanding study on identification of risk factors and prevention of PTI are recommended for proper pin site care and PTI prevention.

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11. Annexes:

11.1. Data collection format -Questionnaire

1) Socio-demographic characters

- a) Case No: _____ MRN: _____
b) Address: a) Addis Ababa b) Oromia c) Amhara d) SPNN e) other.....
c) Sex: i) male ii) female
d) Age i) 0-19 ii) 20-39 iii) 40-59 iv) >60

2) Date operation.....

3) Diagnosis at admission

- a) Fracture diagnosis-----
b) Addition diagnosis

4) Type of fracture

- a) Open fracture, if Yes Gustillo-Anderson /GA/ classification
i) GA I ii) Ga II iii) GA IIIA, B, C
b) Closed fracture

5) Location of fracture

- a) Proximal b) Diaphyseal c) Distal d) Pelvic and acetabular

6) Comorbidity

- a) Diabetes
b) HIV
c) Any other-Specify

7) Smoker : a) Yes b) No

8) Alcohol use: a) Yes b) No

9) Type of external fixator

- a) Unilateral
b) Triangular/delta
c) Others

10) Type of pin biomaterial

- a) Titanium alloy
b) Stainless steel

11) Type of bar biomaterial

- a) Carbon fibre
b) Stainless steel
c) Both

12) Pin insertion techniques

- a) Manual
b) Power drill

13) Skin tension around pin site

- a) Yes b) No

14) Number of pins

- a) 2 b) 3 c) 4 d) 5 e) 6 f) >6

15) Stability of Ex-Fix

- a) Stable
b) Unstable

16) Pin tract infections a) Yes b) No

- a) Simplified Checketts-Otterburn grading of PTI, at 1st week, Encircle the grade

Grade	Clinical signs
0	Normal appearance
1	Redness, erythema, tenderness but no discharge
2	Redness, erythema, tenderness and presence of discharge
3	The Same as to Grade 2 but no improvement with oral antibiotics
4	Severe soft tissue infection with pin loosening
5	Grade 4 but with radiological osteopenia around pins
6	Osteomyelitis on X-ray (sequestrum and involucrum)

b) No of pins involved

i) None b) 1pin C) 2pins d) 3pins e) 4pins d) 5pins e) 6pins f)>6pins

c) Simplified Checketts-Otterburn grading of PTI, at 2nd week, Encircle the grade

Grade	Clinical signs
0	Normal appearance
1	Redness, erythema, tenderness but no discharge
2	Redness, erythema, tenderness and presence of discharge
3	The Same as to Grade 2 but no improvement with oral antibiotics
4	Severe soft tissue infection with pin loosening
5	Grade 4 but with radiological osteopenia around pins
6	Osteomyelitis on X-ray (sequestrum and involucrum)

d) No of pins involved

i) None b) 1pin C) 2pins d) 3pins e) 4pins d) 5pins e) 6pins f)>6pins

e) Simplified Checketts-Otterburn grading of PTI, at 6th week, encircle the grade

Grade	Clinical signs
0	Normal appearance
1	Redness, erythema, tenderness but no discharge
2	Redness, erythema, tenderness and presence of discharge
3	The Same as to Grade 2 but no improvement with oral antibiotics
4	Severe soft tissue infection with pin loosening
5	Grade 4 but with radiological osteopenia around pins
6	Osteomyelitis on X-ray (sequestrum and involucrum)

f) No of pins involved

i) None b) 1pin C) 2pins d) 3pins e) 4pins d) 5pins e) 6pins f)>6pins

17) Location of infected pin

a) Thicker muscle area b) Near tendon

c) Proximal femur/tibia/forearm/humerus d) Distal femur/tibia/forearm/humerus

e) Diaphysis femur/tibia/forearm/humerus f) Calcaneus g) Specify others

18) Pin Site care a) No b) Yes

19) Post-operative education to reduce edema a) Yes b) No

20) External fixator duration at time of PTI diagnosis a) 1week b) 2weeks c) 6weeks