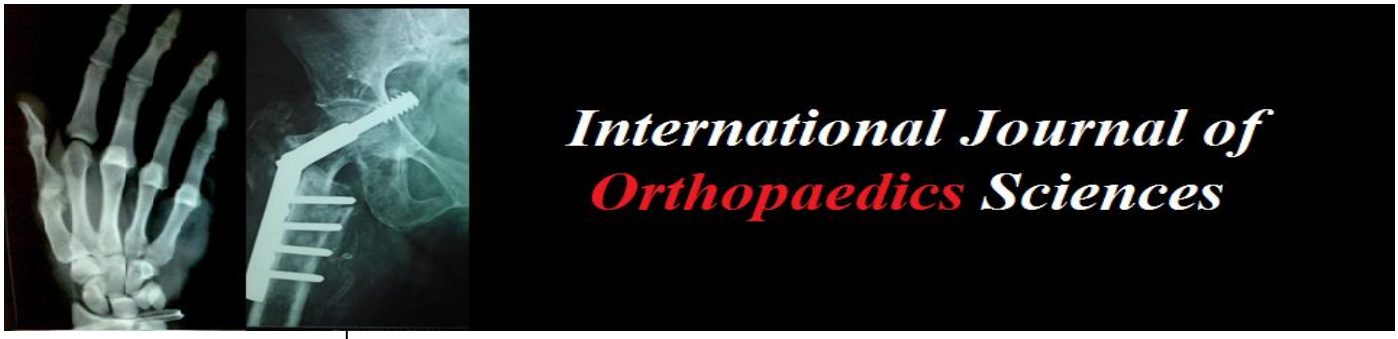

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Timing of debridement of open tibial fractures during the COVID-19 lockdown in India

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Abstract
Introduction and Purpose: Open tibia fracture is a common orthopedic emergency, requiring management with adequate surgical debridement, fracture stabilization, and the administration of intravenous antibiotics to ensure good outcome. They are more prone for non-union due to poor soft-tissue coverage, blood supply and increased risk of post-operative infection. The 6-hour golden rule for debridement has been the norm, despite lacking strong evidence to support it. The COVID -19 pandemic has challenged this age-old dictum due to resource constraints. Early debridement may preclude COVID testing and pose unjustified risks to patient and hospital staff. Delayed surgery in these times might be a more pragmatic approach.
Aim: The primary focus of this study was to analyse the outcomes of open tibial fractures at 5months post-operatively with respect to infection and fracture union.
Material and Methods: Study was designed as a prospective cohort study with convenience sampling during the period of 54 days of lockdown starting from 25 March 2020 at a tertiary care trauma centre in Kerala, India. All patients with open tibial fractures were managed with advanced trauma Life Support (ATLS) protocol. Intravenous antibiotics were administered within 6 hours. Adequate surgical debridement and low pressure irrigation was done after COVID testing (TRU-NAT/CB-NAAT/RTPCR) as per hospital protocol.
Results: Of a total two hundred forty four patients, thirty two patients satisfying inclusion criteria with unilateral open tibial fracture were considered. Average time to surgical debridement was 5hr 52min + 2hr 58min. Majority of the patients being brought to the referral center within 12 hours. Four (13 %) patients were brought after 12 hours but within 3 days of the incident. All had deep infection and nonunion at end of 5 months. Those debrided <12hrs had statistically significant (p value=0.0055) better union and lower infection rates. Contrary to expectations, the <6hrs and 6-12 hrs groups had no statistically significant difference in outcome.

Keywords: Timing of debridement, open tibial fractures, COVID-19 lockdown

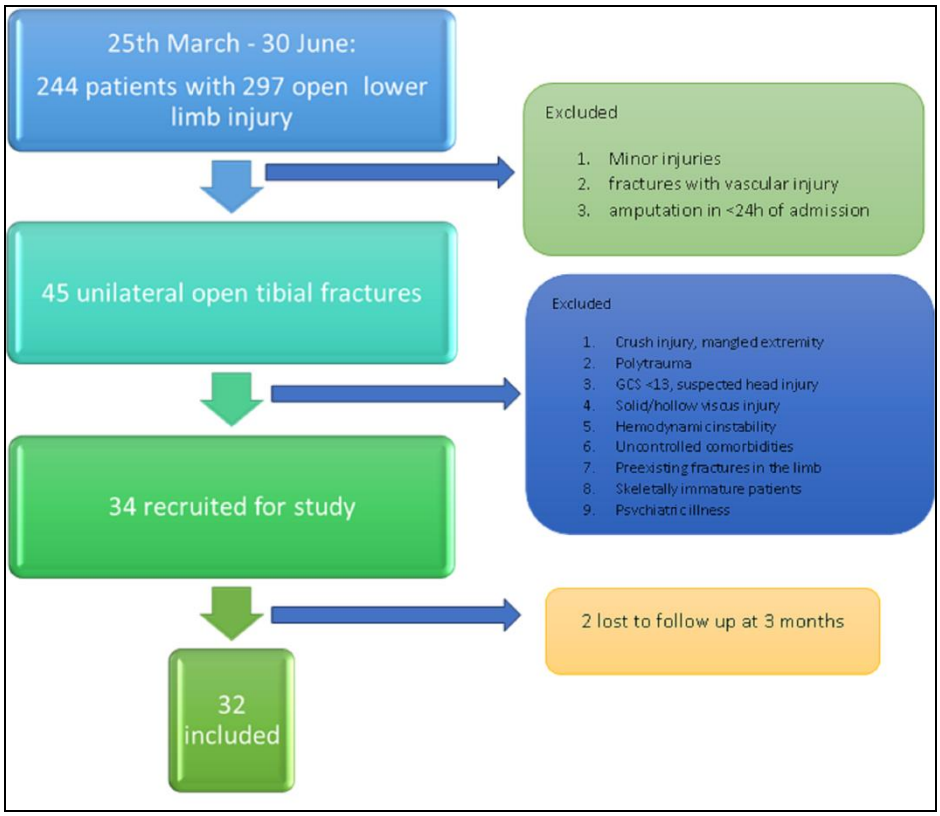
1. Introduction
Open fractures are considered orthopedic emergencies that are traditionally treated with surgical debridement within <6hrs, fracture stabilization, and the administration of intravenous antibiotics and tetanus prophylaxis. But this proclaimed ‘‘6-h rule’’ is not based on rigorous scientific evidence; it originated from a study conducted by Friedrich on guinea pigs in the pre-antibiotic era in 1898 This experiment has multiple drawbacks it was done as an animal trial, lack of antibiotic usage and use of no standardized source of infectious agents (He used garden soil and dust to inoculate the guinea pigs) [1].
Open fractures require prolonged hospital stay, protracted surgeries and frequent hospital visits. Variety of factors affect union in tibial fractures including impaired vascularity of soft tissue, bone loss, infection. Less than 6 hour surgical debridement might not be realistically possible in the present COVID pandemic situation. Disruption in emergency and elective surgical practices due to workforce and resource shortage has lead to need for rationalization of all surgeries. Time can be a key determinant in such situations as pristine co-ordination is required to ensure safety of the patient, the health care workers and OT staff in management of patients prepped for emergency orthopedic procedures. Furthermore there is considerable lag owing to the delay in shifting patient from peripheral centers, lack of transport during

lockdown, shunting of primary health care services to treat COVID patients, and time required for the COVID 19 testing(TruNAAT /RTPCR) at the referral center.

This study was conducted to to assess the early functional and radiological outcome of open tibial fractures treated during the COVID 19 pandemic lockdown in India.

2. Material and methods

This was a retrospective analysis of open lower limb fracture cases treated during the period of 90 days of lockdown starting from 25 March 2020 at a tertiary care trauma centre in Kerala, India. Institutional ethics committee approval was obtained before commencement of study. No patients were included in our study and only records and data available from hospital Our center has a trauma team consisting of Emergency medicine, Orthopedist, Surgeon, plastic and vascular surgeon available 24hrs. The patients included only those directly admitted to our emergency/orthopedic casualty after the trauma and those who have been referred from peripheral center within 3hours of trauma. Patient data included age gender, mechanism of injury, time of incident, fracture location,, Gustilo-Anderson fracture grade, time elapsed between the time of trauma and emergency surgery, type of surgical procedure performed at the initial treatment; presence of infection in 5months after trauma. Exclusion criteria included patient death within 12hrs of admission, pediatric fractures and patients with uncontrolled comorbidities, Low GCS and chest/abdomen injuries.



All patients with open tibial fractures were managed with ATLS (Advanced trauma Life Support).

Intravenous, antibiotics was given within 3 hours of arrival at the trauma center whichever was earlier. The antibiotics was again repeated 1 hour before the start of the debridement and continued till a minimum of 72hours or until primary closure of the wound. The Surgical debridement performed was performed under spinal/general anesthesia with adequate removal of devitalized muscle and necrotic bone. Low pressure irrigation was done in all cases with normal saline (3-10L) depending on the type of injury and contamination as per. On call plastic surgery assistance was taken as and when needed. Weekly follow up of the patient was done till wound healing there after monthly follow up till bony union was achieved.

Follow up included complete clinical and wound site evaluation to rule out signs of infection (redness, warmth, swelling or presence of secretion with infectious aspect) further laboratory investigations (ESR-Erythrocyte sedimentation rate, CRP-C Reactive protein and Total Leucocyte counts counts) were done to confirm it. Serial Pus cultures were taken in case of infection and treatment with appropriate antibiotics and repeat debridement's.

For those patients who were unable to attend follow-up OPDs during COVID Lockdown. Assessment was done using tele-communication by Phone calls and WhatsApp to assess the functional and wound status. Those with suspected complications were immediately referred to nearest Specialist hospital for treatment.

3. Data analysis

The data analysis was carried out using SPSS 19 software from the data entered in Excel 2010.The primary focus being to analyse the outcomes of open tibial fractures at 5months post-operative with infection and union of the fractures being the terminal point. Basic descriptive analysis was done to get the average time to debridement, the distribution of open fractures and percentage of union. The hypothesis testing was done using Analysis of varience (ANOVA) testing with post ad-hoc to estimate the variation and difference between the different time groups (<6hours,6-12hrs,>12hrs)Post ad-hoc Tukey analysis was done to point out the group with better ourcomes. Statistical significance level of 0.05 (5%) was taken as a cut-off.

4. Results

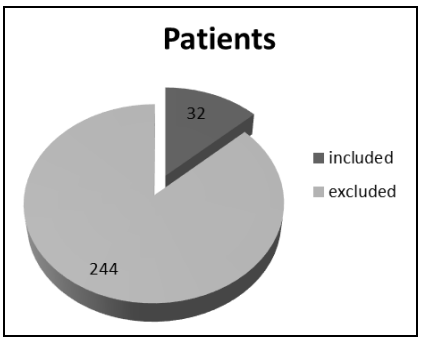


Fig 1: Pie-chart showing selected section of the patients.

A total of two hundred forty four patients with two hundred and ninty seven open lower limb fracture were considered. Only patients who satisfied inclusion critera were selected.32 patients with unilateral open tibial fracture were included in the study. The average age of patients was (36.81+15.85 years) range (2-69yrs). Out of which 28 (87.5%) of the patients were males with most of them suffering a road traffic accident as mechanism of injury. This could be due to the fact that lockdown forced only young healthy males out for essential services and daily needs.

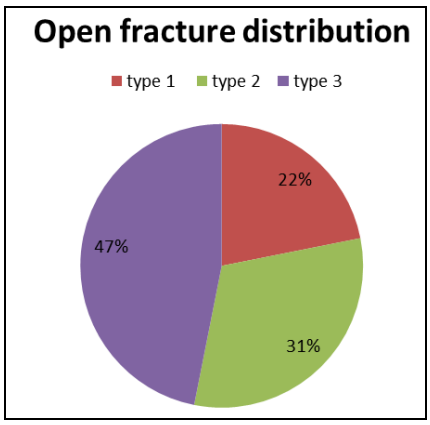


Fig 2: Showing open fracture distribution pattern.

Gustilo-Anderson type 3 A and B were the most common type of fractures accounting for nearly half of the cases (47%).Average time from trauma to surgical debridement was 5hr 52min + 2hr 58min with majority of the patients being brought to the referral center within 12 hours. 13 %(4 patients) of patients were brought after 12 hours but within 3 days of the incident. All these 4 patients in this category had deep infection and nonunion at end of 5 months. All patients were given antibiotics coverage within 6 hours of trauma or within 3 hrs of their arrival at the casualty.

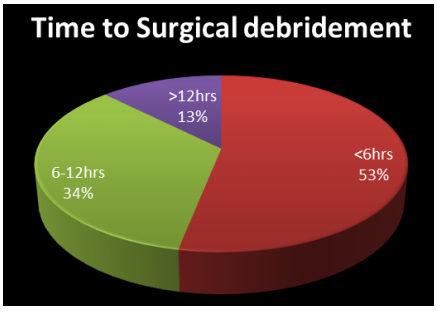


Fig 3: Distribution of patients according to timing of debridement (<6hours, 6-12hours, >12hours)

Comparison of variables was done with fracture union as the primary outcome. One-way ANOVA test was applied with post-hoc Tukey analysis to assess the outcomes at <12hrs, >12hrs; it showed a significant difference with those debrideded <12hrs having better union with p value 0.0055. On bivariate analysis, the union rates did not differ with regard to age, sex, type of stabilization and number of co-morbidities. Patients in the >12 hrs category had significant higher degree of infection which was statistically significant ($p < 0.01$). There was no correlation between early infection and union. Patients with Gustilo -Anderson Type-III tibial fractures had poor fracture union with p-value (0.0321) ($p < 0.01$).

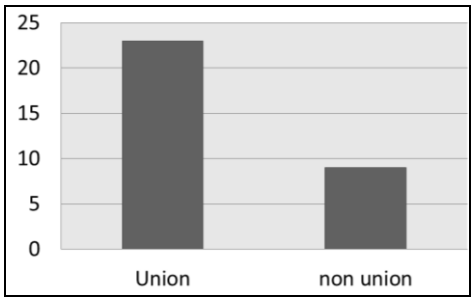


Fig 4: Histogram showing majority of patients (72%) achieving union at 5 months.

Majority of open fractures(72%) achieved union at 5 months from last procedure with the rest requiring further procedures with no signs of radiological union.70% of patients with nonunion had superficial or deep infection and required repeat debridement.

5. Discussion

The main outcome criteria for assessing open tibial fractures in the literature include infection and non-union. The outcome of open fractures is also a good indicator of the effectiveness of trauma care system and quality of care in any institution.

According to recent BOAST (British Orthopedic association Standard for Trauma) recommendation the timing of debridement can be classified according to the velocity of injury and contamination. They recommend time from trauma to surgery to be <12 hrs for high energy and <24 hrs for low energy for low energy trauma. In our study majority of the patients were high velocity (Road –Traffic accident/Fall from height/Crush Injury)we found no significant difference between those debrided <6hrs and >6hrs.However the analysis of <12hrs and >12hrs groups showed significantly lower infection rates among patients with type 3 open fractures in <12 hrs category with better union rates. This shows that 12 hours may be the be better cut-off point [2].

While patients with type 1 or 2 open fractures a delay upto 24 hours maybe acceptable. Infection risks also differ by fracture type and have been reported to be ranging from 0 to 2% for Type I fractures, 2 to 10% for Type II fractures, and 10 to 50% for Type III fractures [2-5]. More recent studies have shown that the rates of clinical infection increased to 1.4% (7/497) for Type I fractures, 3.6% (25/695) for Type II fractures, and to 22.7% (45/198) of Type III fractures [6]. In our study the infection rates varied from from 20% for type 1 to 33% for type 3, the higher infection rate in type one fractures could be due to several reasons. Firstly we have included all infections including superficial, deep and pin tract related into a single category to avoid overlooking any sort of local incidence of infection. Secondly, most of our

patients had suffered road traffic accidents (85%) which are inherently prone to higher infection compared to low energy falls.

Schenker *et al*. carried out a meta-analysis to investigate the association between time to surgical debridement of open fractures in adults and infection. Their review of 16 studies showed no association between late surgical debridement and higher infection rates when all infections, deep infections, injury severity, anatomical location and more severe open fractures were considered [7].

A meta-analysis of nine prospective and 6 retrospective studies showed no statistically significant difference between early and late debridement regarding the overall infection rate and union [8]. Reuss and Cole, however, found that delayed operative management of up to 48 h did not adversely affect nonunion and infection rates in their study of 81 cases of open tibial shaft fractures as long as adequate open fracture care and early initiation of antibiotics along with standardized and thorough debridement in the operative theater was performed [9]. In contrast, those debrided within 12 hours had a significantly better union rate (p- value0.0055) in our study.

Patzakis and Wilkins reviewed more than 1,000 open fractures and concluded that "The single most important factor in reducing infection rate was the early administration of antibiotics". In their study, patients who were administered antibiotics within 3 h of injury had an infection rate of 4.7 %, compared to 7.5 % in those whom antibiotic treatment was administered 3 h or more after injury [6]. In our study all patients received the patients included in the study received antibiotics within 3 hours of injury.

There are deferred opinions regarding the ideal cut-off time for debridement and perhaps large sixed multi-centric studies are needed to ascertain the same.The understanding of direct correlation between timing of first debridement and its influence on fracture union and early infection is partial and despite multiple studies being done in this regard there is no one cut-off time which been accepted universally.

Our study is an attempt to highlight this fact and the need for multicentric data analysis especially in Indian sub-continent to make a uniform, practical and acceptable protocol for open fractures in general and tibial fractures in particular. This could also help in resourceful management of manpower, material and money especially in these post-COVID times.

6. Conclusion

1. Early transfer to trauma centre for Type III open fractures reduces the infection rate.
2. During the COVID pandemic, <12hrs maybe a realistic cutoff to attain good outcomes for open tibial fractures. (timing of debridement might not be an independent determinant in such cases)
3. Early administration of antibiotics, thorough surgical debridement, adequate low pressure irrigation with an experienced surgical team may be the key to attain early union.

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