

Impact of the 6 Hour Rule upon the Infection Rate in Open Tibia Shaft Fractures

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Abstract

The tibia is the most frequent site of an open fracture, with incidences ranging from 49.4% to 63.2%. This is attributable in part to the relatively thin soft-tissue covering along its anteromedial surface. The tibia is also more susceptible to infection, with a reported infection rate 10 to 20 times higher than open fractures in other areas. The management of open fracture tibia represents an orthopaedic emergency. Early aggressive management of these debilitating injuries within the first 6 hours has been encouraged in order to minimise the risk of infection and long term sequelae. Debridement and lavage of the wound, followed by stabilisation of the bone and closure of the soft-tissue envelope are all considered essential. However, the available scientific evidence supporting the timing of the management of open fracture and the "Six-hour rule" itself, are unclear. The purpose of this study was to evaluate the infectious outcome of open tibia fractures relative to the time from injury to operative lavage and debridement. Eighty nine patients with consecutive open tibia fractures were retrospectively reviewed. Gustilo - Anderson classification was followed. Of these, 53 patients were operated within 6 hours of the time of injury and 36 patients beyond 6 hours of injury both within maximum of 24 hours with an average follow-up of 6.3 months. Fourteen patients (15.73%) developed infection out of which 8(9%) patients were from <6 hour group and 6(6.7%) patients from >6 hour group which was statistically insignificant. The result indicates that the time of surgical treatment from time of injury does not have impact upon the infection rates in open tibia fractures.

Keywords: *Tibia, Open Fracture, Six Hour Rule, Debridement,*

I. INTRODUCTION

Open fractures are surgical emergencies that perhaps should be thought of as incomplete amputation. Five eras of open fracture treatment are: life preservation, limb preservation, infection avoidance, functional preservation, rapid and high volume trauma care[3]. Tibia is the most commonly fracture long bone because 1/3 of the surface of tibia is subcutaneous, open

fractures are more common in it than any other major long bone. Emergency operative measures have long been the standard of care for open fractures of the tibia as deep infection is the most important complication. While there is unanimous agreement with regards to early operative debridement of wounds, there have been only a few articles reflecting timing [2,4]. Debridement of the open wound within six hours after the injury is a widely accepted standard of care [1]. The precise origins of the so-called "six-hour rule" are unclear. Some claim that it stems from an 1898 experiment during the Spanish-American war by German military surgeon Friedrich [9], in which guinea pigs with contaminated soft-tissue wounds had lower rates of infection when debridement was performed within six hours. Others however point to a 1973 study by Robson et al., who reported that 10^5 organisms per gram of tissue was the open-fracture infection threshold, which was reached in an average of 5.17 hours [7]. There have been credible articles to date showing evidence that the 6-hour rule should not be cast in stone [8]. This paper reviews open fractures of the tibia and compares infection rates in those that were operated on within 6-hours and those operated on after 6-hours.

II. MATERIALS AND METHOD

A retrospective study was conducted upon 89 numbers of consecutive open fractures of tibia in the PG Department Of Orthopaedics, VSSIMSAR, Burla from November 2014 to October 2016.

A. Inclusion Criteria:

1. Age of patient >16 yr and <65 yr
2. Open tibia shaft fracture

B. Exclusion Criteria:

1. Age <16 yr and >65 yrs
2. GCS<15
3. Polytrauma
4. Third degree burn
5. Medical comorbid conditions
6. Admission of the patient 24 hr after injury
7. Gustillo Anderson Grade -3 fractures

Gustilo et al. classified open fractures into three categories: [10,11]

- (i) Type I: open fracture with a skin wound less than 1 cm long
- (ii) Type II: open fracture with a laceration more than 1 cm long without extensive soft tissue damage, flaps, or avulsions,
- (iii) Type III: either an open segmental fracture, an open fracture with extensive soft tissue damage, or a traumatic amputation. Gustilo stated that Type III open fractures were too complicated and hence further stratified these wounds:

IIIa: adequate soft tissue coverage of a fractured bone despite extensive soft tissue lacerations or flaps, or high energy trauma irrespective of the size of the wound. This includes segmental fractures or severely comminuted fractures;

IIIb: extensive soft tissue injury loss with periosteal stripping and bone exposure. This is usually associated with massive contamination;

IIIc: open fractures associated with vascular injury requiring repair for limb salvage.

All the open fractures of tibia were treated as below

- (1) Administration of intravenous broad-spectrum antibiotics, either 2 g of Cefuroxime or 2 gm of Cefoperazone two times a day for a minimum of 3 days, followed by 500 mg of cefuroxime orally twice daily for one week after discharge,
- (2) Thorough wound lavage in the casualty department with normal saline,
- (3) Intraoperative wound debridement and thorough irrigation with normal saline as per Gustilo grade,
- (4) Primary closure of clean wound whenever possible,
- (5) The heavily contaminated wounds were kept open and secondary closure was done latter,
- (6) The stabilization of the fracture was done with internal fixation, external fixation or cast immobilization with plaster window,
- (7) Analgesia and intravenous fluids on an as-required basis,

After discharge, patients were followed-up in the outpatient department for wound review and suture removal at the 12-days. Irrespective of culture report infection was documented as per the findings below.

- (1) Purulent discharge / oozing
- (2) Wound dehiscence
- (3) Abscess or collection
- (4) Infected hardware where applicable
- (5) Osteomyelitis

Patients were divided into two groups. One being those who were taken to emergency operation room within 6-hours, and the other consisting of patients taken to operation room after 6-hours of injury.

III. OBSERVATION

In our study of 89 consecutive open fractures of the tibia, 53 patients were operated within 6-hours and 36 patients after 6-hours. Out of the 43 patients with Grade I fractures, 16 were operated upon during the first 6 hours, and 27 were operated on after 6 hours. There were 27 patients with Grade II fractures, of which, 18 were operated upon within 6 hours, and 9 were operated on after 6 hours. There were 19 patients with Grade III fractures, of which, 10 were operated upon within 6 hours, and 9 were operated after 6 hours (Figure 1).

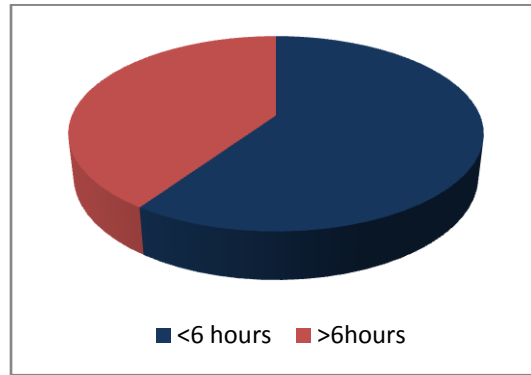


Fig.1-No. of Infected Patients

The mean time to surgical intervention in the “within 6-hour group” was 4.15 hours (2 to 7 hours). The mean time to surgical intervention in the “post 6-hour group” was 10.15hours (7 to 18.5 hours). Out of the total 89 cases, 14 cases sustained infections(15.73%) 8 of which were taken up for surgery within 6-hours, and 6 after 6-hours (Figure 2).`

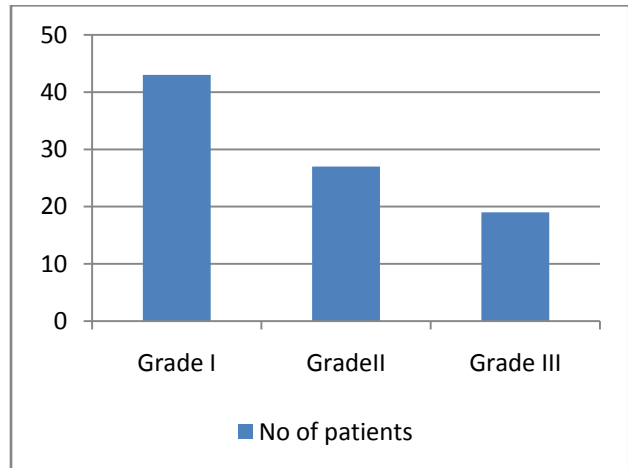


Fig.2-No. of Patients as Per Gustilo- Anderson Grade

From these 14 cases, one was a Grade I fracture (7.1%), four were Grade II fractures (28.5%),

and the remaining 9 were Grade III fractures (64%) (Figure 3).

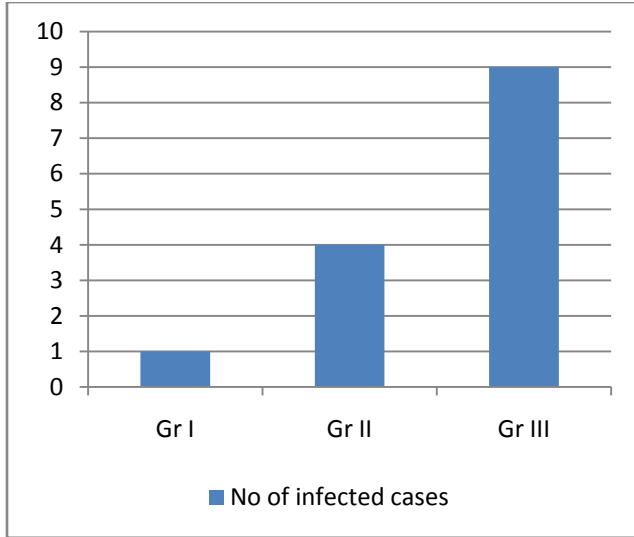


Fig.3- Number of Patients Developing Infection within each Gustilo Grade.

For the patients who sustained infections, the individual time to debridement with respect to Gustillo is included in the Table 1.

Table – 1: The Number of Infected Patients Stratified as Per Gustilo-Anderson Grading and their Time to Debridement.

Infected cases	Gustilo Anderson grade	Time to debridement(hours)
1	I	18.5
2	II	5
3	II	9
4	II	17
5	II	12.5
6	IIIA	8
7	IIIA	12.5
8	IIIA	8.5
9	IIIA	6
10	IIIB	2
11	IIIB	9
12	IIIB	13.5
13	IIIB	4
14	IIIB	8

Out the 14 cases there was occurrence of cellulitis in 5 cases, wound dehiscence in 2 cases, purulent discharge in 4 cases and infected hardware 3 cases. The Infection rate of patients taken up for surgery within 6- hours was 9% whereas that of those operated on after 6- hours was 6.7% (P>0.05) showing no statistical significance. There was also no statistical significance when comparing patients with infection in the Grade IIIA and IIIB categories. From the 14

patients who sustained infections, 11 had no previous significant medical illnesses such as diabetes, obesity, or hypertension. Only two patients were diabetic and one patient was hypertensive. The methods of fracture fixation such as casting with window, internal fixation, intramedullary devices or external fixators were opted as per individual circumstances. There was no statistical relation to infection amongst the different treatment strategies.

IV. DISCUSSION

Open fractures of the tibia do represent a challenge to even the most highly experienced orthopaedic surgeons. Emergency debridement has long been the standard of care for open fractures of the tibia as infection is an important complication. The timing of operative debridement is a debated issue. Adequate quantity of lavage fluid must be used for cleaning on the principle that “solution for pollution is dilution”. The basis of the 6 hour rule is based upon animal study where a threshold of 10³ organisms was found to be critical to establish infection. This 6 hour rule is challenged by many recent studies [13].

According to Crowley et al no obvious advantage in performing debridement within 6 hour compared to debridement performed between 6 and 24 hours after injury. Werner et al found the effect of dealing debridement >24 hours is however is not clear.

The data gathered over the last decade indicates that there was no significant difference in terms of timing of surgery. Only a few studies have questioned the validity of this so-called 6-hour rule, mentioning that there is suggestion that infection rates are not dependent on timing of surgery [4, 12]. One study [4] had their data set comprising of fractures of both the tibia and femur, whereas we conducted this study on tibial fractures alone. However there are two studies those strong advocated for early operative debridement of open fractures claiming that infection rates can be lowered [5,6]. It is widely accepted that antibiotics should be administered as soon as possible. This study is significantly different to others. Firstly it focuses solely on open fractures of the tibia in adults with one similar study existing and it has a large data of patient studied. Also, there is no statistical difference to the outcome of infection when measuring the method of fixation and patient comorbidities. There are of course numerous limitations in this study. The type of skin closure, level of contamination, surgeon discretion, other life threatening head and chest or abdominal injuries. Patient comorbidities and type of fixation did not prove statistically significant in this data set. It would also not be ethical to perform a randomized

control trial to determine infection rates after open fractures of the tibia.

[13] Rockwood and Green's fractures in adults, Eighth edition, vol. 1, pp.371, 2015

V. CONCLUSION

Dealing with open tibia fracture casualty and planning for the definite management is a challenging issue. The initial basic interventions such as wound irrigation in the emergency department, sterile antiseptic dressings, and most importantly, early administration of intravenous broad-spectrum antibiotics plays a crucial role in infection prevention of open fractures of the tibia. Thorough debridement is the gold standard to predict the outcome of the management. But when it comes to the time of surgery from the time of admission, we did not find any increase in infection rate related to it. We are of the opinion that the 6 hour rule does not have any impact on rate of infection in open tibia fractures.

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