Time to Initial Debridement and wound Excision (TIDE) in severe open tibial fractures and related clinical outcome: A multi-centre study

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Keywords

Open fracture; tibia; trauma; infection; orthoplastic; BOAST

Abstract

Background

Recent national (NICE) guidelines in England recommend that initial debridement and wound excision of open tibial fractures take place within 12 hours of the time of injury, a change from the previous target of 24 hours. This study aims to assess the effect of timing of the initial debridement and wound excision on major infective complications, the impact of the new guidance, and the feasibility of adhering to the 12 hour target within the infrastructure currently existing in four major trauma centres in England.

Methods

A retrospective review was performed of Gustilo-Anderson grade 3B open tibial fractures presenting acutely to four Major Trauma Centres in England with co-located plastic surgery services over a ten-month period. The incidence of deep infective complications was compared between patients who underwent initial surgery according to the new NICE guidance and those who did not. Patients warranting emergency surgery for severely contaminated injury, concomitant life-threatening injury and neurovascular compromise were excluded. Multi-variable logistic regression analysis was performed to assess the effect of timing of surgical debridement on development of deep infective complications.

Results

112 patients with 116 fractures were included. Six fractures (5.2%) suffered deep infective complications. 38% (n=44) underwent primary debridement within 12 hours and 90% within 24 hours. There was no significant difference in the incidence of major infective complications if debrided in less than or greater than 12 hours (4.5% *vs* 5.6%, *p*=1.00). Logistic regression found no significant relationship between timing of wound excision and development of deep infection. There was no significant decrease in mean time to debridement following introduction of new national guidance (13.6 *vs* 16.1 hours) in these four MTCs.

Conclusion

Overall, the rate of deep infection in high energy open tibial fractures managed within the four major trauma centes is low. Achieving surgical debridement within 12 hours is challenging within the current infrastructure, and it is unclear whether adhering to this target will significantly affect the incidence of severe infective complications. Debridement within 24 hours appears achievable. If a 12-hour target is to be met, it is vital to ensure dedicated orthoplastic capacity is adequately resourced.

Main text

Background

Open tibial fractures are limb-threatening injuries that often affect a healthy and previously employed population[1–3]. Limb salvage is attempted as a standard of care in appropriately selected patients. Outcomes are affected by a complex interplay between patient, injury and surgical factors. Deep infection in patients who have undergone limb salvage can lead to significant adverse sequalae such as readmission to hospital, further surgery and delayed amputation[4]. Such complications prolong the rehabilitation period and potentially lead to worse clinical outcomes[5]. This can have a significant health-economic burden such as loss of income, reliance on social support, long-term use of medication and increased health service use[6,7].

Advances in the approach to the management of open tibial fractures have focused on expedient, multidisciplinary management in specialist major trauma centres, to optimise fuctional outcome and minimise the risk of infection. In February 2016, the National Institute for Health and Care Excellence (NICE) reduced the recommended time to initial surgical debridement of high energy open tibial fractures (likely Gustilo-Anderson classification type IIIA or IIIB) that are not grossly contaminated, from 24 hours, the previous target, to 12 hours[1–3]. There is evidence supporting this and contradicting it: some studies have shown time to initial debridement to have a significant impact on clinical outcome, with one influential study, cited in the updated NICE guidance, calculating a 3% increase in risk of severe infection for every hour delay to surgery[8]. Other factors which are thought to be important, include time to antibiotics[9] and time to arrival at a specialist centre[10,11].

In the NHS, resources are finite, and the provision of plastic surgical care at Major Trauma Centres in England [11] and globally are varied. Combined consultant orthoplastic decision making at the initial debridement is crucial to ensure this key step is carried out comprehensively and a robust management plan is formulated. If the 12-hour target is found to significantly affect clinical outcome, more resources would need to be made available to achieve this reliably. If it does not significantly affect clinical outcome, resources should be redirected to factors that do.

Previous studies on this topic have failed to isolate a homogeneous cohort of patients making it more difficult to draw meaningful conclusions to guide clinical practice. This study aims to assess the impact of time to initial surgical debridement in high energy open tibial fractures on incidence of deep infective complications in this high risk group. In addition, this study aims to assess the impact of the introduction of new national guidance on time to debridement at four Major Trauma Centres, and the feasibility of adhering to a 12-hour target.

Methods

Study design

A retrospective study was performed of Gustilo-Anderson grade 3B open tibial fractures presenting acutely to four UK Major Trauma Centres (MTCs) with co-located plastic surgery services over a ten-month period spanning the introduction of updated NICE guidance in February 2016. Data were collected by local teams of clinicians at each study site from both case notes and the Trauma Audit and Research Network (TARN) national database.

Inclusion and exclusion criteria

Adult patients (>16 years old, no upper age limit) with acute Gustilo-Anderson grade 3B open tibial fractures were included. Gustilo-Anderson grading was performed after the first surgical debridement and wound excision. Patients were included if they presented directly to one of the four study sites, or if they received initial emergency management (including initial surgical debridement/wound excision and/or skeletal stabilization) at a regional referring centre and were transferred acutely (within 48 hours of injury) to one of the four study sites for further wound excision, soft tissue coverage and definitive skeletal stabilisation. Time to first surgical debridement and wound excision was included in the dataset in an identical manner regardless of whether this performed at a regional referral centre or at the definitive MTC.

Patients were excluded from the study if they warranted emergency surgery for farmyard-, marine- or sewage-contaminated injury, concomitant life-threatening injury and neurovascular compromise (Gustilo-Anderson grade 3C injuries). Patients were excluded if they were lost to follow-up or died of causes not related to the tibial fracture(s) in less than ninety days post-injury, as not all deep infections are clinically apparent within a shorter timeframe (Fig. 1).

Clinical protocol

All four centres manage open tibial fractures according to a combined orthoplastic approach, with a plastic surgeon and an orthopaedic surgeon present at first surgical debridement and definitive reconstruction. Patients are followed up in designated combined orthoplastic clinics until clinical union

occurs. The centres vary in the availability of a regular, designated orthoplastic operating list and in the availability of resident on-call orthopaedic and plastic surgery consultants out-of-hours.

Definitions

Time to debridement is calculated in hours from the time of injury to the induction of anaesthetic on the first surgical wound excision and debridement. Time to antibiotics is calculated in minutes from the time of injury to the time of administration of the first intravenous antibiotic recorded.

'Major deep infection' was defined as patients requiring removal or exchange of metalwork for infection, delayed flap failure (partial or complete) due to infection, or deep infected collection requiring surgical drainage. Clinically diagnosed superficial infections that resolved with the administration of antibiotics (e.g., cellulitis) were not included.

Patients were categorized as having a risk factor for infection if case notes recorded one or more of the following: current smoking status, diabetes, peripheral vascular disease, or any immunosuppressive condition or medication.

Statistical analysis

Multi-variable logistic regression analysis (R version 3.3.3[12]) was performed to assess the effect of timing of surgical debridement on development of deep infective complications. Time to administration of intravenous antibiotics, patient co-morbidities including diabetes and immunosuppressive conditions, current smoking status and ISS were controlled for statistically. Time to surgical debridement and time to administration of intravenous antibiotics were analysed as continuous variables. Complete time to antibiotic data was collected for 95 fractures; therefore, all analyses including this variable were performed using this smaller dataset.

The groups of patients debrided in less than and greater than 12 hours, and those presenting before and after the introduction of NICE guidance in February 2016, were also compared. Categorical variables were compared using a two-

tailed Fisher's exact test and continuous variables using a Student's *t* test. *P*-values of <0.05 were considered significant.

Results

Cohort demographics

112 patients with 116 fractures were included (mean age 50 years [range 17 – 98 years], male : female ratio = 1.8 : 1). The median ISS was 9 (range 9 – 66). Mean follow-up was 19.7 months (range 2.9 months – 38.3 months). Forty-four fractures presented initially to a regional referral centre and were transferred acutely (within 48 hours) to a MTC, and 72 presented directly to a MTC (62%).

Time to initial wound excision and development of deep infection

Six fractures (5.2%) suffered deep infective complications. 38% (n=44) fractures underwent primary debridement within 12 hours, although there was variation between the four centres (range 22-77%) and 90% (n=60) within 24 hours. There was no significant difference in the incidence of deep infective complications in fractures debrided in less than or greater than 12 hours (4.5% *vs* 5.6%, p=1.00). The two groups had similar characteristics including age, time to antibiotics, number of co-morbidities and ISS (Table 1). Four of the six fractures that developed deep infection presented first to a regional referral centre and two directly to a MTC. One MTC recorded no deep infections during the study period, and the remaining three MTCs recorded two deep infections each. The clinical details of the six deep infections are found in Table 2.

When comparing fractures that developed deep infection to those that did not, there was no statistically significant difference between the two groups in mean age, ISS, time to debridement or time to antibiotics (Fig. 2a-d).

Binary logistic regression analysis was unable to find a relationship between time to initial wound excision and development of deep infection when controlling for age, time to antibiotics, presence of co-morbidities including diabetes, immunosuppressive conditions, and current smoking status, and ISS.

Quasi-binomial logistic regression analysis found a statistically significant

relationship between increasing time to antibiotics and decreased risk of deep infection when controlling for age and ISS, and after accounting for sample size underdispersion present in the model (p=0.004). However, the predictive power of this model is low, due to the small proportion of patients in this study suffering from deep complications.

Impact of new guidance

63 fractures presented in the five-month period before the introduction of February 2016 NICE guidance and 53 fractures in a later 5-month period. There was no significant change in mean time to debridement following the introduction of the February 2016 NICE guidance (13.6 *vs* 16.1 hours, p=0.1).

Three infections occurred in the 'before' cohort (4.8%) and three in the 'after' cohort (5.6%). Mean ISS (13.8 *vs* 13.8, p=0.99) and time to antibiotics (172 minutes *vs* 174 minutes, p=0.95) were not statistically different between the two groups.

Feasibility of achieving 12-hour target

Twenty-five fractures (22%) underwent initial wound excision out-of-hours (17:00 – 08:00). Of these, 24 were performed by consultant surgeons. Nearly twice as many fractures (n=48, 41%) would have required out-of-hours debridement in order to meet the 12-hour target (arrival in the emergency department after 17:00 but exceeding the 12 hours post-injury before 08:00 the following day).

Discussion

The deep infection rate of 5.2% reported in this multi-centre cohort of patients with high energy open tibial fractures is low and reflects the orthoplastic approach that has been adopted in managing these high risk injuries. Although there was no statistically significant difference in the incidence of deep infection in the group debrided within 12 hours of injury and the group debrided between 12 and 24 hours of injury, the infection rate was low, making it difficult to detect any small effect.

This study suggests that achieving initial surgical debridement within 12 hours of injury is challenging with only 38% of cases achieving this. In this study, 41% of cases would need to have had initial debridement between the hours of 17:00 and 08:00 to meet the 12 hour target. This has resource implications for major trauma centres which will need to ensure theatre availability, appropriate anaesthetic cover and consultant plastic and orthopaedic surgical availability in order to achieve this target safely and maintain consultant-level decision making at the crucial initial debridement. There was variability within the four centres in their ability to achieve initial debridement within 12 hours, reflecting variation in the resources available between the centres.

A decreased time to administration of antibiotics was significantly correlated with an increased risk of infection in this study. This is a counterintuitive finding, and may indicate that A&E staff are inclined to administer antibiotics more urgently to patients with more severe fractures. There was no significant correlation between ISS and time to antibiotics, although ISS does not distinguish between different levels of severity of open long bone fracture[13].

No other variables analysed in this study were shown to have a significant impact on the development of deep infective complications in severe open tibial fractures. Open tibial fractures are complex injuries, and clinical outcomes depend on a complex interplay between patient, injury and surgical factors. Only six patients developed a deep infection in the cohort studied, so it was not possible to attribute any measured factor to risk of infection with statistical confidence.

Resources are finite, and the provision of plastic surgical care at Major Trauma Centres in the UK is varied, with numbers of full-time equivalent consultant plastic surgeons varying between one and 22 surgeons per centre [14]. The four centres included in this study offer a designated and coordinated orthoplastic service, and are therefore likely to represent higher volume units that may offer more coordinated care to severe open tibial fractures. In addition, a substantial proportion of the fractures reported here would require out-of-hours

debridement in order to achieve the 12-hour target. If consultant-level subspecialist care is to be provided in all Major Trauma Centres in the UK with stricter compliance to NICE than that reported here, it is likely that additional resources will need to be made available. Future larger studies, or possibly an open tibial fracture registry is recommended to assess whether debridement within 12 hours of injury significantly affects clinical outcome in these injuries. If it does not resources could be redirected to factors that do.

Limitations

Previous studies on this topic have failed to isolate a homogeneous cohort of patients making it more difficult to draw meaningful conclusions to guide clinical practice. Although the cohort studied was large given the strict inclusion and exclusion criteria, the deep infection rate was low. Only six patients developed infections, and therefore it was not possible to conclude which of the studied factors likely significantly increased the risk of infection. Future studies should aim to increase the sample size while maintaining the same strict inclusion criteria.

Conclusion

The overall rate of deep infection in high energy open tibial fractures is low at specialist Major Trauma Centres in the UK despite the majority of cases undergoing initial surgical debridement and wound excision greater than 12 hours post-injury. Larger studies are needed to clarify whether adhering to the 12 hour target has a significant impact on clinical outcome.

Conflict of Interest

None

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Figure Legends

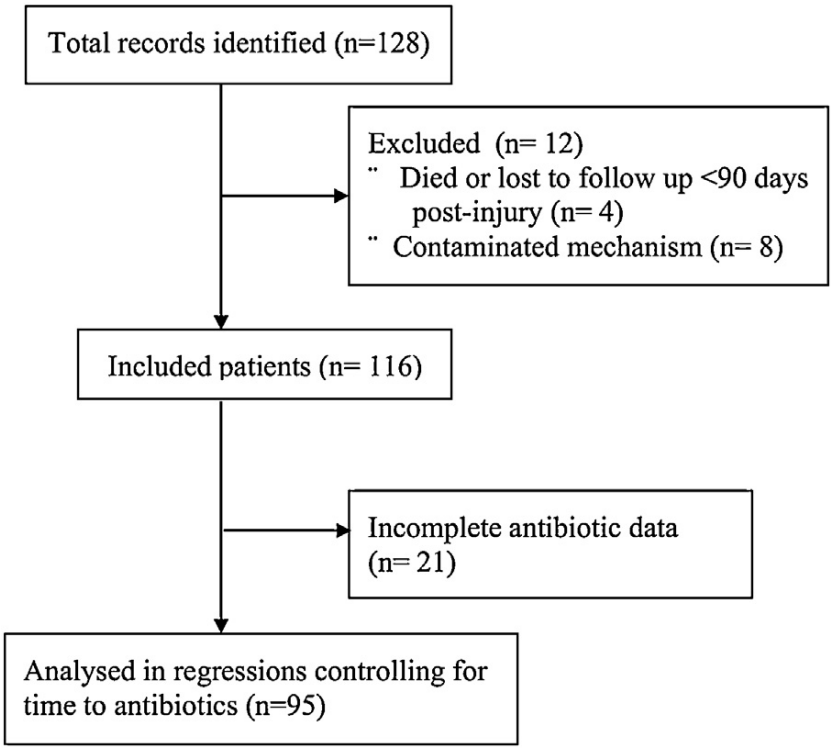

Figure 1 Flow diagram of patients excluded from the study.

Table 1 Comparison of patients debrided in less than and greater than 12 hours post-injury.

	<12 h (n=44)	**> 12h (n=72)**	**p**
Deep infection (n, %)	2, 4.5%	4, 5.6%	1.00
Age, *years* (mean, [range])	47 [18–98]	53 [17–93]	0.17
Presence of risk factors (n, %)	17, 39%	32, 44%	0.57
Time to antibiotics, *minutes* (mean, [range])	162 [27–378]	180 [15–539]	0.30
ISS (median, [range])	9 [9–66]	9 [9–54]	

Figure 2 Box plots comparing mean age (a), ISS (b), time to debridement (c) and time to antibiotics(d) of fractures that developed deep infection to those that did not.

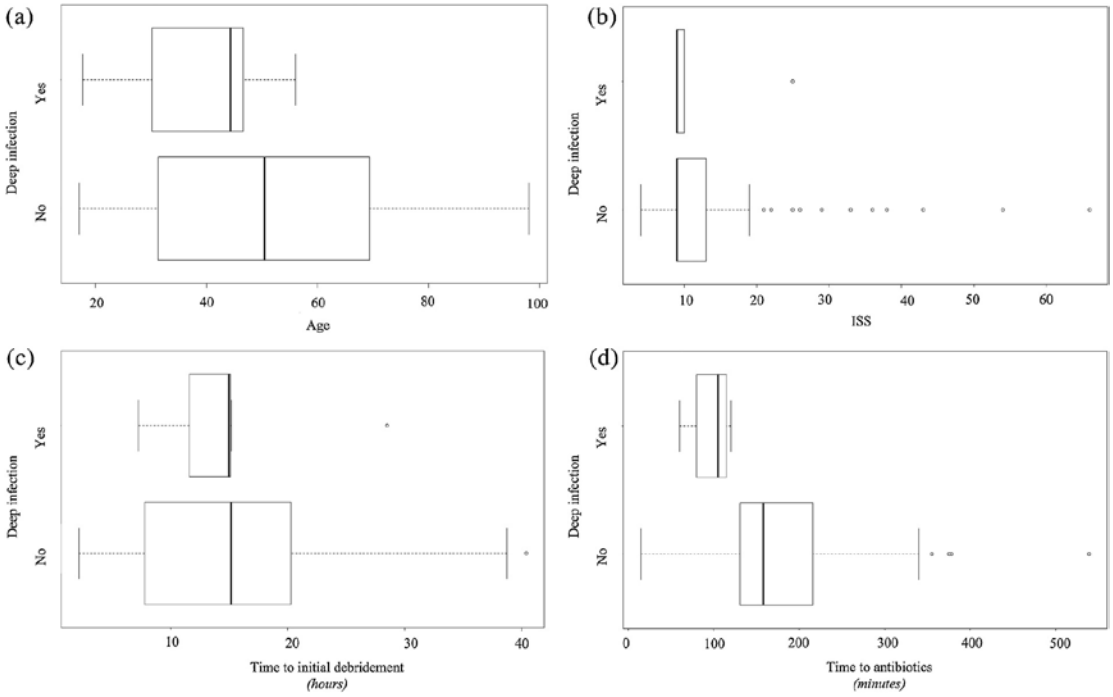

Table 2 Demographics and clinical details of the six patients who developed deep infection (*MTC = one of the four participating Major Trauma Centres; TU = District General Hospital, i.e. a regional referral centre).

Patient age/ gender	First treatment centre*	Risk factors for infection	ISS	Time to initial debridement & wound excision	Time to definitive soft tissue cover	Time to deep infection	Details of infection/Surgical management
17 M	MTC	None	9	8.9 h	17.4 h	73 days	Infected deep collection
44 M	MTC	None	9	14.3 h	81 h	26 days	Removal of metalwork
27 M	DGH	Active smoker	10	28.5 h	81 h	86 days	Infected deep collection Removal of metalwork
32 M	DGH	None	25	7.2 h	37.2 h	149 days	Removal of metalwork
45 M	DGH	Immuno-suppressed	10	15.2 h	62 h	44 days	Removal of metalwork
56 F	DGH	None	9	15 h	39 h	50 days	Flap failure Removal of metalwork