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Open tibial fractures in major trauma centres: A national prospective cohort study of current practice

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ABSTRACT

Aims: To assess current national practice in the management of severe open tibial fractures against national standards, using data collected by the Trauma and Audit Research Network.
Materials and methods: Demographic, injury-specific, and outcome data were obtained for all grade IIIB/C fractures admitted to Major Trauma Centres in England from October 2014 to January 2016.
Results: Data was available for 646 patients with recorded grade IIIB/C fractures. The male to female ratio was 2.3:1, mean age 47 years. 77% received antibiotics within 3 h of admission, 82% were debrided within 24 h. Soft tissue coverage was achieved within 72 h of admission in 71%. The amputation rate was 8.7%. 4.3% of patients required further theatre visits for infection during the index admission. The timing of antibiotics and surgery could not be correlated with returns to theatre for early infection. There were significant differences in the management and outcomes of patients aged 65 and over, with an increase in mortality and amputation rates.
Conclusions: Good outcomes are reported from the management of IIIB/C fractures in Major Trauma Centres in England. Overall compliance with national standards is particularly poor in the elderly. Compliance did not appear to affect rates of returning to theatre or early infection. Appropriately applied patient reported outcome measures are needed to enhance the evidence-base for management of these injuries.

Introduction

Open tibial fractures can be limb threatening and have a substantial impact on long term health-related quality of life [1]. These complex injuries are a challenge to systems of care because they require early involvement of both senior orthopaedic and plastic surgeons.

The current standards of management of open fractures was published in 2009 by the British Orthopaedic Association (BOA) and the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS) working party [2]. This led to the production of the guidelines "British Orthopaedic Association Standards for Trauma (BOAST) 4 – The Management of Severe Open Lower Limb Fractures". Due to lack of process data, the BOA, BAPRAS and the Trauma Audit and Research Network (TARN) made changes to the collection of data relevant to open lower limb fractures. In September 2014, a revised data collection tool was launched (The BOAST 4 specialist screen) which closely reflects the BOAST 4 guidance. Re-organisation of trauma care in England into Major Trauma Networks has dramatically improved care of the multiply injured patient, including those with open lower limb fractures [3]. Until now no national perspective of the management of these injuries has been available.

This aim of this article is to assess the current national practice against the BOAST 4 standards, using the data collected by the TARN specialist screen from October 2014 to January 2016.

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Materials and methods

All patients admitted to the twenty-seven Major Trauma Centres (MTCs) in England with injuries coded by TARN as Gustilo-Anderson grade IIIB/C open lower limb fractures were included. All BOAST 4 data from non-MTC hospitals was excluded. In addition to the BOAST 4 data, other TARN data reviewed included; age, gender, modified Charlson comorbidity index (a scale used to weight pre-existing medical conditions) [4], mechanism of injury, injury severity score (ISS), intensive care unit (ITU) admission, and in hospital / thirty-day all-cause mortality. Follow up was to thirty days or day of discharge from index admission if this occurred after thirty days. Patients were categorised into elderly (65 years and older) and young (<65 years).

GraphPad Prism 5.0b (La Jolla, California, USA) was used for all analyses and $p < 0.05$ selected as the threshold for statistical significance. A D'Agostino and Pearson test for normality was conducted for all continuous data. Unpaired t-tests were performed for normally distributed data and Mann-Whitney U-tests for non-normally distributed data. χ^2 tests with Yates' correction for continuity were used for categorical variables. Data was tested for correlation using a Pearson or Spearman rank test where data were normally or non-normally distributed respectively. Where a correlation was found linear regression modelling was conducted.

TARN holds an HRA CAG Section 251 approval for research on anonymised data submitted by member hospitals, therefore no further ethics committee approval was required.

Results

A total of 646 patients with 661 fractures graded as open lower limb Gustilo-Anderson grade IIIB/C were recorded on the TARN BOAST 4 specialist screen from 1st October 2014 to 31st January 2016. The male to female ratio was 2.3:1, the mean age of male patients was 40.5 years (range 3.1–95.0), and mean age of females was 62.1 years (range 9.0–98.1). Fifteen patients sustained bilateral open lower limb fractures (2%). Of the 661 fractures 591 (89%) were grade IIIB and 70 (11%) were grade IIIC. 155 (24%) of patients were classified as having sustained polytrauma, defined by TARN as an Abbreviated Injury Score of three and above in more than one body region. 211 (33%) patients required an ITU admission, for an average of 7.6 days (range 1–54).

The primary mechanism of injury was road traffic collision, accounting for 61% of all injuries (394). Falls of less than two meters and greater than two meters accounted for 22% (139) and 9% (61) of injuries respectively. Other mechanisms of injury such as crush, blow and shooting accounted for 8% (52). Distribution of mechanism of injury by age and gender is shown in Fig. 1.

Ninety-six percent (617) of patients were taken directly from the scene of injury to the definitive MTC. Time from injury to arrival at MTC was recorded in 600 cases, of which 96% were admitted to an MTC within 3 h of injury, irrespective of direct or indirect transfer. More than half (55%) of patients arrived between the hours of 08.00 and 18.00. Fig. 2.

BOAST 4 specific data

A joint management plan made by the Orthopaedic and Plastic surgical teams was documented for 92% of the patients. The use of prophylactic antibiotics was not recorded in 94 cases (14.6%). Of the 552 cases in which it was, the timing of the first antibiotic administration was recorded in 283 cases, 77% received the first dose within three hours, Tables 1 and 2. Antimicrobial type was recorded in 523 cases, of which 85% received intravenous antimicrobials in accordance with the BOAST 4 guidance.

Time to debridement was recorded in 459 patients (71% of total cohort), of which 49% were debrided within 12 h and 82% within 24 h. There was a significant difference in the time to debridement between the IIIB and IIIC/bilateral cases, median and interquartile ranges were 12.8 h (5.6–21) and 6.08 h (3.77–19.6) respectively (p value, 0.015). A consultant surgeon was recorded as being present in theatre for 89% of the initial debridements performed between

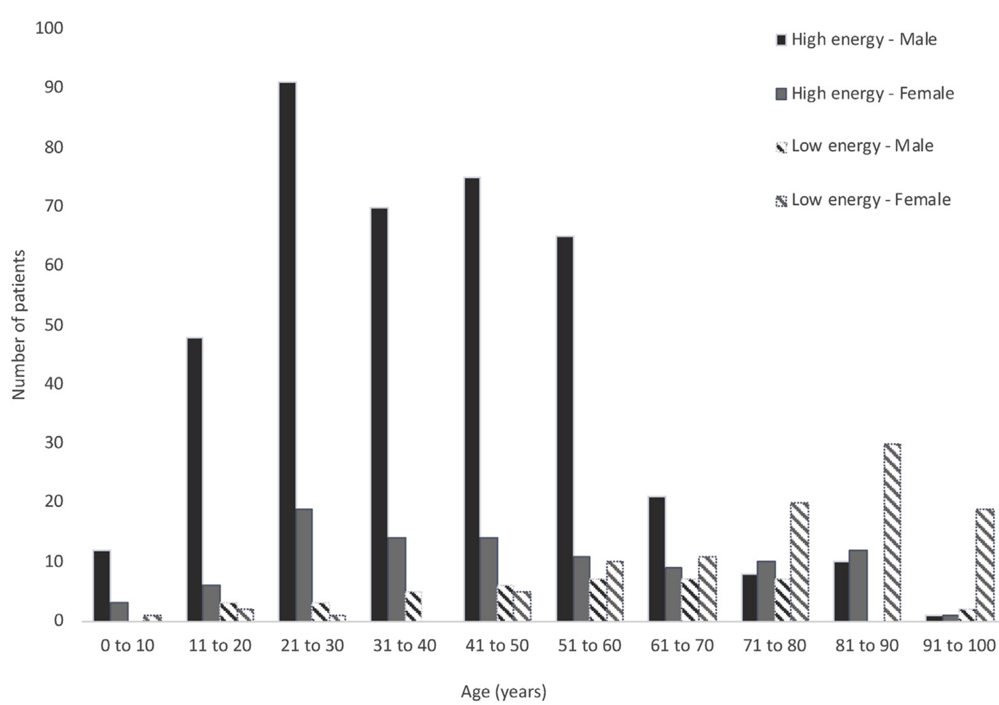

Fig. 1. Mechanism of injury by age and gender for IIIb/c fractures admitted to Major Trauma Centres. n = 639. High energy: road traffic collision; fall greater than two meters; crush, blow or shooting. Low energy: fall less than two meters. Other accounted for 7 cases.

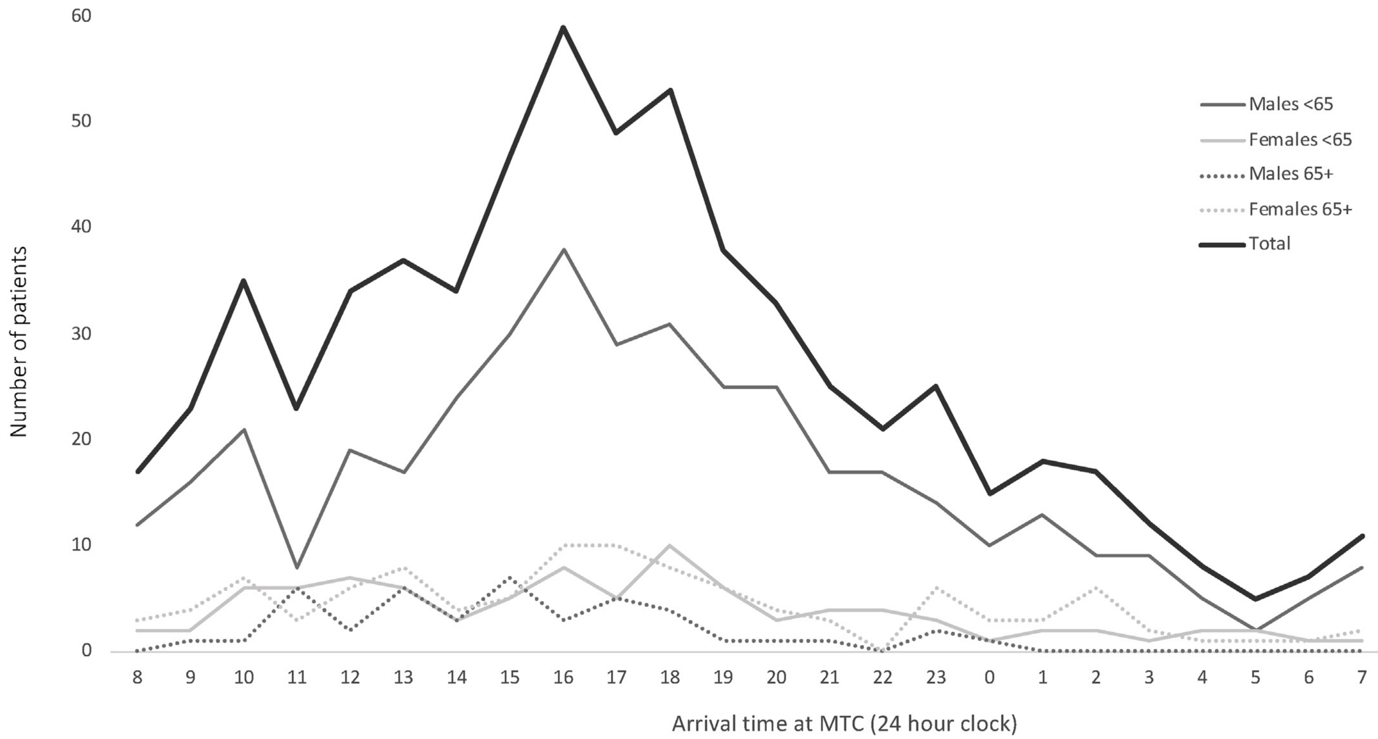

Fig. 2. Time of arrival at Major Trauma Centre (MTC) stratified by age and gender. n = 646.

08.00 and 18.00, and 90% of those occurring outside these hours. Of the 26 wounds which were heavily contaminated, 62% (16) were debrided within 12 h. Mean time to debridement was greater in patients requiring an ITU admission (p value <0.005).

Time to stabilisation was recorded in 562 patients. 84% were stabilised within 24 h of admission, 41% (231) were initially stabilised with external fixation. Time to definitive soft tissue cover was recorded in 509 patients, 71% were definitively covered within 72 h of admission, 91% within one week. Method of soft tissue cover; direct closure, skin graft or flap reconstruction, was recorded in 544 patients, see Table 3. A consultant surgeon was recorded as being present in theatre for 411 (81%) of the cases. No correlation was demonstrated in length of ITU stay nor ISS and time to definitive soft tissue cover (p values, 0.11 and 0.69 respectively).

Elderly cohort

Twenty-three percent (150) of the cohort were 65 years or over. Comparisons between the elderly and those under 65 years are shown in Tables 1 and 2. There were significant differences in the mean times from injury to MTC ($p < 0.001$) and time to initiation of antibiotics ($p < 0.01$) but not with respect to time to debridement and time to soft tissue cover.

Unadjusted risk ratios for specific BOAST 4 criteria and outcomes between the cohorts were as follows; Antibiotics within 3 h 1.74 (1.13–2.67), debridement within 12 h 1.23 (1.01–1.49), soft tissue cover within 72 h 8.3 (4.79–14.44). Amputation 2.30 (1.40–3.80), in hospital / thirty-day mortality 4.51 (2.12–9.61).

Outcome

Patients were followed up to thirty days or date of discharge if hospital admission exceeded thirty days. 481 (74%) patients were discharged at or prior to thirty days. Of the 165 (26%) patients whose admission exceeded thirty days, the median length of follow up was 47 days (inter-quartile range 37–62).

The in hospital / thirty-day mortality rate was 4% (26). The overall amputation rate was 8.7% (56). Five percent (31) of all IIIB injuries underwent amputation, compared with 38% (25) of all IIIC injuries. Amputation rates were no different between those who received antibiotics within three hours and those who received them after 3 h (p value, 0.60), nor were they different in those who received definitive soft tissue coverage within 72 h (p value, 0.20). Patients who received debridement within 12 h had a relative risk of amputation of 2.3 (1.23–4.26) (95% Confidence Interval) (p value, 0.004) compared with those debrided after 12 h.

Return to theatre for infection during the index admission occurred in 28 cases (4.3%) of which eight subsequently underwent an amputation. Rates of returning to theatre for infection were no different between those who received antibiotics within three hours and those who received them after three hours (p value, 0.74), nor were they different between those who were debrided within 12 h or not (p value, 0.22), or in those who received definitive soft tissue coverage within 72 h compared with those who did not (p value, 0.20).

Discussion

This study demonstrates that in a system that cohorts majorly injured patients, over 70% of those with severe, open tibial fractures achieve definitive soft tissue cover and stabilisation within 72 h. It provides an assessment of the treatment of this injury on a national level and compares it previously set standards.

Time from injury to admission to the definitive trauma centre has been reported to be a significant predictor in the outcome of infection within the first three months after injury [5]. 96% (573) of the 600 patients who had admission timings recorded, including those transferred from a referring hospital, were admitted to the definitive MTC within three hours of injury.

Time from injury to initiation of antimicrobial therapy may also be an independent predictor of infection at 90 days [6]. There was poor recording of both the use of antibiotics, and of the timing of its

Table 1
Descriptive statistics of continuous variables.

Gender and age	Variable	N	Mean	(SD)	(25th	50th	75th)
Males <65							
	Age	404	36.55	14.65	25.10	36.65	49.33
	Charlson comorbidity index	404	2.05	0.49	2.00	2.00	2.00
	ISS	404	15.09	10.87	9.00	9.00	18.00
	Time to MTC	373	1.62	0.92	1.15	1.50	1.92
	Time to antibiotics	181	2.56	2.20	1.60	2.07	2.67
	Time to debridement	295	19.11	29.40	5.06	11.33	20.26
	Time to stabilisation	356	19.40	32.22	5.18	10.62	20.00
	Time to soft tissue cover	331	61.25	77.29	10.74	39.17	75.00
Females <65							
	Age	92	39.13	15.75	26.08	40.65	51.65
	Charlson comorbidity index	92	2.10	0.58	2.00	2.00	2.00
	ISS	92	16.10	12.37	9.00	9.00	18.00
	Time to MTC	85	1.64	0.61	1.25	1.48	2.12
	Time to antibiotics	38	2.68	1.21	1.83	2.36	3.12
	Time to debridement	59	29.80	89.25	6.08	11.68	20.40
	Time to stabilisation	79	14.82	12.09	5.94	13.05	19.13
	Time to soft tissue cover	72	71.20	104.20	10.31	21.58	84.42
Males 65+							
	Age	44	76.51	8.05	68.85	77.80	81.40
	Charlson comorbidity index	44	2.73	0.92	2.00	3.00	3.00
	ISS	44	11.59	7.11	9.00	9.00	10.00
	Time to MTC	43	3.77	13.47	1.31	1.62	2.12
	Time to antibiotics	19	7.30	20.40	1.73	2.60	3.85
	Time to debridement	36	28.00	39.53	5.89	18.63	25.94
	Time to stabilisation	39	20.89	26.59	5.51	18.00	22.00
	Time to soft tissue cover	30	54.66	54.59	12.47	34.14	74.54
Females 65+							
	Age	106	81.97	8.62	75.15	82.75	89.08
	Charlson comorbidity index	106	2.73	0.92	2.00	2.50	3.00
	ISS	106	10.65	4.56	9.00	9.00	9.00
	Time to MTC	99	2.28	1.82	1.46	1.90	2.42
	Time to antibiotics	45	3.63	4.06	1.98	2.58	3.58
	Time to debridement	69	17.39	17.21	5.52	15.53	20.08
	Time to stabilisation	88	18.19	21.13	6.63	16.07	20.85
	Time to soft tissue cover	76	89.37	154.17	15.56	37.29	97.02
All							
	Age	646	47.09	22.87	27.93	44.30	61.75
	Charlson comorbidity index	646	2.22	0.69	2.00	2.00	2.00
	ISS	646	14.27	10.28	9.00	9.00	14.00
	Time to MTC	600	1.88	3.77	1.22	1.57	2.03
	Time to antibiotics	283	3.06	5.82	1.67	2.18	2.88
	Time to debridement	459	20.93	41.78	5.39	12.12	20.92
	Time to stabilisation	562	18.67	28.23	5.52	11.79	20.37
	Time to soft tissue cover	509	66.47	95.84	11.70	33.75	77.90

Abbreviations: ISS Injury severity score, MTC major trauma centre. All ages are in years and times in hours.

Table 2
Descriptive statistics of categorical variables.

Variable		Males <65	(%)	Females <65	(%)	Males 65+	(%)	Females 65+	(%)
Direct to MTC		398	98.5	90	97.8	37	84.1	92	86.8
Poly trauma		113	28.0	28	30.4	5	11.4	12	11.3
G-A grade	IIIb	353	87.4	83	90.2	40	90.9	99	93.4
	IIIc	43	10.6	4	4.4	4	9.1	5	4.7
	Bilateral	8	2.0	5	5.4	0	0.0	2	1.9
Antibiotics within 3 hours*		150	82.9	26	68.4	6	31.6	29	64.4
Debridement+	< 12 hours	155	52.5	30	50.8	13	36.1	30	43.5
	< 24 hours	243	82.4	49	83.1	25	69.4	59	85.5
Return to theatre for infection		16	4.0	8	8.7	1	2.3	3	2.8
Amputation		28	6.9	5	5.4	6	13.6	17	16.0
In hospital / 30 day mortality		8	2.0	3	3.3	2	4.5	13	12.3

Total cohort N = 646, * Time to antibiotics N = 238, + Time to debridement N = 459. Abbreviations: MTC Major trauma centre, G-A Gustilo-Anderson.

initiation but in those in whom it was recorded, over three quarters had it administered within three hours of admission. There did not

Table 3
Time to definitive soft tissue cover and method of cover by Gustilo-Anderson grade.

	Direct wound closure (n 214)				Skin graft (n 118)				Flap (n 212)			
Time (hours)	IIIB	%	IIIC	%	IIIB	%	IIIC	%	IIIB	%	IIIC	%
0 to <12	82	38.3%	14	6.5%	8	6.8%	2	1.7%	20	9.4%	3	1.4%
12 to <24	52	24.3%	1	0.5%	18	15.3%	0	0.0%	29	13.7%	0	0.0%
24 to <48	21	9.8%	1	0.5%	9	7.6%	0	0.0%	35	16.5%	1	0.5%
48 to <72	12	5.6%	1	0.5%	16	13.6%	3	2.5%	32	15.1%	3	1.4%
72 to 1 week	9	4.2%	2	0.9%	31	26.3%	3	2.5%	51	24.1%	5	2.4%
>1 week	5	2.3%	1	0.5%	17	14.4%	5	4.2%	14	6.6%	3	1.4%
Time not recorded	12	5.6%	1	0.5%	5	4.2%	1	0.8%	16	7.5%	0	0.0%
Total	193	90.2%	21	9.8%	104	88.1%	14	11.9%	197	92.9%	15	7.1%

Flap = local flap, pedicled flap or free tissue transfer. N = 544.

appear to be any correlation between timing of antibiotics and early infection (requiring return to theatre) or amputation. It is not possible to infer causality from this study. It may be that the data was not sensitive enough to detect this, or that the thirty-day / in hospital follow up period used in this study is too short to determine. It may also be that because of the system where over 70% were definitively covered and fixed in 72 h that the timing of antibiotics is not an independent predictor.

Early debridement is a standard of care in most systems dealing with open fractures but there remains a paucity of data demonstrating a significant difference in overall infection rates in those debrided expediently [7,8]. The 2016 NICE standard of care for open lower limb fractures outlines that debridement of high-energy open fractures (likely Gustilo–Anderson classification type IIIA or type IIIB) which are not highly contaminated should occur within 12 h of injury [9]. Only half the open fractures recorded were debrided within 12 h, IIIC or bilateral injuries were more likely to be debrided earlier than IIIB. Given that over half of all injuries arrived within office hours, on the whole practice seems to be to undertake this on the next day's operating list. This is something that requires further study but with such low infection and amputation rates it would be very difficult to demonstrate that changing this practice would lead to a clinically significant change in these rates.

Delays in wound coverage are associated with increased rates in infection [6]. The lower limb standards of care state that wound closure should take place within 72 h and not exceed seven days, 95% of cases met this standard. However, the remaining 5% of the cohort did not have increased rates of early infection after delayed soft tissue coverage. As before, although it is difficult to draw inferences from this kind of data, this may be a feature of the system approach to major trauma.

Amputation rate in this cohort was 8.7%, which is equivalent to that of other studies of IIIB/C fractures [10]. However, this does not include those who may have subsequently undergone a delayed amputation after the initial admission as TARN data does not currently include long term follow up. Patients who underwent debridement within 12 h had an increased rate of subsequent amputation. This is likely a reflection of the severity of these injuries.

There were clear differences between the young and elderly cohorts both with respect to gender distribution, comorbidities (as recorded by the Charlson comorbidity index), mechanism of injury, management and outcome. The younger group were predominantly male patients who had been victims of high energy trauma. Age is a known bias to trauma care triage [11], and these data appear to support that. Compliance with the BOAST 4 guidelines was less consistent in the elderly cohort, with significant differences in time to MTC and initiation of antibiotics. Patients under the age of 65 were more likely to be debrided within 12 h and have received soft tissue definitive coverage within 72 h. It is not possible to determine from the data exactly why these differences occurred, but they may be due to the previously mentioned age bias. In addition, the definitive fixation and soft tissue cover in this age group is often extremely difficult and this may also lead to delay. The in-hospital / thirty-day mortality rate of the elderly cohort was almost five times that of the young, and is similar to that of the neck of femur fracture thirty-day mortality [12]. The shift in mechanism from high energy to low energy with age, and the increase in mortality and amputation rates suggests that perhaps this cohort of fragility open fractures require treatment in line with that of neck of femur fractures, with multidisciplinary care and early orthogeriatric input.

This study has several important limitations inherent in the design of retrospective database analyses. TARN data is validated on input and undergoes regular post-input validation checks. To prevent loss to follow up for those discharged prior to thirty days TARN quality assures the data with the Office for National Statistics. Any infection requiring surgery which occurred post discharge outside of the MTC network would not be captured. There is scope for improvement in the completeness of this data set. This data set has a short follow up of either thirty days (74%) or for those admitted for thirty days or longer (26%) median length 47 days. Only infections which required a return to theatre and/or amputations occurring during this limited follow up were recorded. There was a substantial amount of missing data in this cohort; only 44% of cases had antibiotic timings documented, 29% did not provide time to debridement, time to stabilisation and soft tissue cover was missing in 13% and 21% of the cases respectively. Subsequently reporter bias may result in this data being a positively skewed representation of MTC management of open fractures. As TARN BOAST 4 reporting improves, and subsequently the data completeness improves, this data set will be invaluable. But, in its current state the results must be interpreted with an appreciation for its validity.

A complete national picture of BOAST 4 guideline compliance was not possible. TARN data completion at Trauma Units (TU) is not yet comprehensive, of the 160 TUs only 33 contributed a total of 64 cases to the BOAST 4 data set during the study period, therefore TU data was excluded. The extent to which TU contribute to the national caseload of open tibial fractures is yet to be accurately quantified, and this will only be possible once all TUs are contributing to the BOAST 4 data set.

The Gustilo-Anderson classification system takes into consideration the energy of the fracture, soft-tissue damage, and the degree of contamination. It is the best-established system used for categorising these injuries, however it is frequently criticised for great observer variability. The exclusion of grade II and IIIA injuries by the TARN BOAST 4 data collection tool will no doubt result in some incorrectly classified cases being inadvertently included and excluded from this data set. Misclassification may explain the unexpectedly high direct closure rate in this cohort.

This study lacks any patient reported outcomes to assess whether the process of care improves patient experience and outcome. Previous (US based) studies have demonstrated that patient satisfaction following surgical management of open lower limb trauma is predicted more by level of function, pain and presence of depression at two years than by the injury and or treatment received [13]. As there is currently no consensus over the outcomes that should be collected following open lower limb fractures, a patient centred process is required to identify important outcomes that could be measured prospectively using the TARN infrastructure in the future. The generation of a core outcome set for open fractures of the lower limb would facilitate investigation into whether BOAST 4 compliance affects outcomes important to patients and stakeholders, enabling MTC targets to be shifted to evidence-based interventions that optimise patient outcomes.

Conclusions

In a national trauma system where the almost all open tibial fractures are cohorted into specialist units, definitive soft tissue and stabilistation was achieved in over 70% within 72 h of the injury. Previously published standards of care are not achieved in those over 65 years sustaining open tibial fractures. There is an increased mortality and amputation rate in the over 65 year olds suggesting that, this group requires further study. To enable thorough analysis of the management of open tibial fractures in the trauma network the BOAST4 data collection by TARN contributing MTCs and TU must be more comprehensive. This, alongside the development of a core outcome set and longer term follow up will enable the consequences of national standards compliance on outcomes to be established.

Conflict of interest

None of the authors has any conflict of interest.

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