Title: The benefit of national clinical guidelines for open lower limb fractures in reducing healthcare burden: a length of inpatient stay cost-analysis

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Abstract

Introduction: Severe open lower limb fractures are complex and costly injuries. Studies reporting the costs associated with these injuries, the economic impact of complications, and the clinical benefit of adherence to national guidelines have been previously reported. However, the economic benefits of national guidelines and their relationship with length of inpatient stay have not been described.

Methods: An international retrospective cohort study, using length of stay as a proxy for in-hospital economic impact, comparing the duration of inpatient stay in countries with national guidelines and those without.

Results: In a cohort of 2641 patients from 16 countries, length of stay was 17% lower in countries with national guidelines, equivalent to 2-3 fewer inpatient days per patient. This difference was primarily driven by a lower incidence of deep infection observed in countries with national clinical guidelines.

Conclusion: The presence of national guidelines for the management of severe lower limb injuries is associated with both improved clinical outcomes and reduced length of stay and therefore healthcare burden. Whilst application and adoption of national guidelines is not without challenges, their implementation is associated with significant clinical and economic benefits.

Introduction

Trauma is the “forgotten pandemic” associated with significant economic burden to healthcare systems and society[1]. Whilst changes in the delivery of trauma care in OECD countries have shown remarkable improvements in survival rates[2,3], those that survive experience significant impact on their quality of life, function and ability to return to work [4]. Open tibial fractures have an incidence of 3.4 in 100,000 person years and most commonly occur as a consequence of high energy trauma, such as road traffic incidents, usually in working age males[5–8].These injuries can be limb threatening and have a substantial impact on long term health-related quality of life, and poor rates of return to full time employment[9,10].

Reducing complications and improving outcomes in this patient population is important both for reducing post-traumatic morbidity and also the socioeconomic consequences. This burden is in part due to the high incidence of fracture related infection, which can be as high as 36% [10–12]. The key driver of increased in hospital costs in this patient population is length of stay (LoS)[13–15]. Whilst LoS does not capture all the direct healthcare-related costs, it is a reasonable surrogate measure[16]. The variability of processes and means of recording of actual costs and indeed availability of such data across healthcare systems makes pooling such data impractical and inappropriate. LoS is both a straightforward and reproducible means of assessing resource burden across healthcare systems.

Using the large dataset collected for International Lower Limb Collaborative (INTELLECT) study[17], this study aimed to establish the savings of improved clinical outcomes in

healthcare settings with clinical guidelines for open lower limb compared to those without guidelines.

Methods

The INTELLECT study was a multi-centre, international study which gathered 2694 cases of open lower limb fractures. Data was obtained retrospectively from patient records, for cases admitted for treatment between the 1st of January 2017 to the 31st December 2018 in 62 hospitals, based in 16 different countries. These were divided into high income countries with guidelines, high income countries without guidelines and low and middle-income countries without guidelines, as per the World Bank Country and Lending Groups.

The LoS was calculated in days from date of admission to date of discharge. Knowing that the INTELLECT dataset did not present a normal distribution, a non-parametric statistical analysis was planned. Differences in LoS between the countries with national clinical guidelines in place and those without was assessed using the Kruskal-Wallis test for comparing continuous variables, using IBM SPSS Statistics (IBM. New York, USA). Two regression analyses were performed to assess if the increased incidence of deep infection in countries without clinical guidelines was a clinical factor for driving length of stay. The first comprised a linear regression multivariate analysis, with LoS as a continuous variable, adjusting for severity of injury, age of patient, time to debridement, seniority of surgeon. The second was a logistical multinomial regression, treating LoS as a categorical variable (0-15 days, 16-30 days and >30 days), again adjusting for severity of injury, age of patient, time to debridement, seniority of surgeon. Both regression analyses were performed using Stata, StataCorp. 2023 (Stata Statistical Software, College Station, TX: StataCorp LLC).

The financial impact of the variation in LoS was assessed by further analysing the data from the five countries contributing to the largest number of cases in the INTELLECT study. Two of these had clinical guidelines, whilst the remaining three did not. Hospital specific costs of overnight stay were collated, and the potential cost savings were calculated. All costs were converted to Euros using the CCEMG – EPPI-Centre Cost Converter[18]. Overnight stay cost was obtained for the three largest contributors to the “no guidelines high income” cohort from the respective principal investigators. Using the cost data and applying the infection rates and LoS data from the “with guidelines” cohort, the potential LoS reduction and subsequent cost savings per 100 patients were calculated

According to the HRA decision tool and The London School of Economics ethics committee this study did not required further ethical review, as the analysis was based on previously published research and the anonymity of the patients was maintained.

Results

Length of stay data for 2641 patients with severe lower limb open fractures collected from 62 hospitals in a total of 16 countries were reviewed. Median LoS for the total cohort was 15 days (inter quartile range 7-30) (Table 1). There was a statistically significant difference in LoS when comparing high-income countries with guidelines and countries of similar income without guidelines. There was no significant difference between high-income countries without guidelines and LMIC, all of which did not have guidelines (Table 2). On average LoS was 17.6% lower in countries with national guidelines.

A total of 2635 cases from 16 countries accurately recorded absence or presence of deep infection and LoS (Table 3), representing 97.8% of the whole dataset. Linear regression with LoS as a continuous variable, adjusting for severity of injury, age of patient, time to debridement, and seniority of surgeon demonstrated that the presence of infection was associated with increased LoS. This association was more pronounced in the high-income cohort without guidelines and the LOS was even greater in the LMIC cohort ($p < 0.001$). Relative risk ratios were calculated using a multinomial logistic regression analysis with LoS as a categorical variable (0-15 days, 16-30 days and >30 days). This demonstrated that LoS beyond 15 days in settings with national guidelines was not associated with the presence of deep infection, but that it was associated with absence of guidelines, especially in LMICs ($p < 0.005$). The relative risk for length of stay over 30 days being associated with the presence of deep infection deep infection was 3.2 times and 4.8 times in the “no guidelines high income” cohort and “no guidelines LMIC” cohort respectively ($p < 0.001$).

Table four presents the potential cost-saving in three high-income countries that provided data for the INTELLECT study that do not have guidelines: Spain, Chile and Italy. Interestingly, there was wide variation in LoS cost, even across European countries. Considering the costs of overnight stay and the predicted benefit of clinical guidelines our analysis revealed substantial potential savings for these three settings.

Discussion

Resource allocation in healthcare systems poses a significant public and political challenge globally and severe open fractures of the lower limb are a complex and costly sub-group of injuries due to their high incidence and subsequent further costs of fracture related infection [5,8]. Our data show that in healthcare settings with national clinical guidelines for the management of severe open lower limb fractures have a significantly lower average LoS. The presence of deep infection was associated with significantly higher LoS in countries without guidelines compared to those with guidelines. Our data suggest that national guidelines could result in huge saving, as much as three million euros per 100 open fractures for the Italian health care system, by reducing deep infection and hence LoS.

The median LoS of the patient cohort reported here was 15 days (IQR 7-30), was much lower than that previously reported in systematic review of the economic burden of open tibial fractures, which included direct hospital costs from 14 different countries and 34 studies [10]. Of the included studies, 15 reported LoS, with a mean of 56 days (range 3 - 115).[18] LoS has previously been reported to be the most important driver of costs related to hospital care in a cohort of 358 tibial fractures[14]. The authors found that deep infection was the most important driver of LoS. In cases of deep infection, LoS accounted for 62% of healthcare costs.

The cost benefit of interventions is an important consideration during the process of guideline development by NICE. The cost analysis performed by NICE guidelines for the assessment and management of complex fractures guideline demonstrated that the costs of earlier debridement, and joint orthoplastic care are “far outweighed by the costs saved from complications avoided” by performing earlier and potentially out of hours surgery, and

by having the expertise of a plastic surgeon in addition to an orthopaedic surgeon in theatre (NICE 2016 Appendix L)[19].

The clinical guidelines for open lower limb fractures for the UK and the Netherlands were developed independent from each other. Due to the fact that they are based on the same body of primary evidence, their recommendations are very similar[20]. However, the development and publication of a national guideline does not mean that the guideline is necessarily adhered to in clinical settings. Considering that the INTELLECT study did not measure guideline compliance, we focused our analysis on the presence or absence of such resources.

The implementation of national guidelines for severe lower limb trauma is not simple and attempts to standardise pathways for the management of patients with severe limb injuries involves multiple challenges [21]. The hurdles associated with guideline adoption are likely to be greater in healthcare settings with scarce resources and dealing with greater trauma workload, such as many LMICs[11,22]. In these settings the level of adoption of clinical guidelines has been shown to be dependent upon the context of the guidelines, end-user engagement and alignment regarding the implementation of the guidelines in trauma centres and the wider healthcare system[23]

Financial incentives for meeting set standards and/or compliance with guidelines has been shown to be successful in facilitating the adoption of clinical guidelines. Following Shleifer's theory of yardstick competition[24] in 2010 the National Health Service in the United Kingdom implemented best practice tariffs, leading to significant improvements in trauma care, specifically hip fracture outcomes[25]. Whilst the reimbursement models and the cost

of care is heterogeneous between healthcare systems, such financial incentives may be considered by policy makers to promote application of standards in settings which are struggling to embed standards of care into routine practice[26]. Transparent, appropriate and timely reimbursement for the treatment of open lower limb injuries would further facilitate the adoption of clinical guidelines.

This study has several limitations, with some being derived from the methodology used for the INTELLECT study. Whilst LoS can be used as a proxy for burden of hospital resources[26,27], comprehensive analysis of the cost effectiveness of clinical guidelines in practice and to demonstrate the causal effect of guidelines, prospective detailed clinical data sets assessing guideline compliance alongside comprehensive direct and indirect costs per case are required. However, obtaining costs at this level would be challenging. The available pricing data in the literature stem from different national healthcare financing systems are not reliably comparable nor generalisable to other settings. A systematic review found direct hospital costs per patient ranged between €428 to €151,984 [10]. In our study we also found variation in the daily cost of LoS, across participating countries. This disparity may be explained by case-mix and complexity, caseload and its relationship with economies of scale, degree of competition, payment policy and ownership status[28].

The results presented here probably underestimate the potential savings of clinical guidelines for lower limb open fractures. Using only initial LoS stay as a proxy for resource use, other key drivers of cost, such as type of reconstruction, method of fracture fixation, intensive care stay, multiple surgical interventions are not included. The discrepancy would likely be even greater for patients who develop deep infection necessitating repeat admissions to hospital, long term intravenous antibiotic therapy and revision surgery.

Another inherent limitation of our study is that we used a pre-existing dataset derived from the INTELLECT study, without engaging with further data collection. The economic figures were obtained from the five countries contributing the largest number of cases to the INTELLECT study and our findings may not be representative of other countries. Two of the countries included in this study had national guideline in place at the time of data collection, the United Kingdom and the Netherlands[29]. However, presence of guidelines does not equate to adherence, and within the INTELLECT cohort it has not been demonstrated that it was the causal impact of the guidelines themselves that led to the improved outcomes and reduced LoS.

Conclusion

In healthcare settings in which national clinical guidelines are in place for the management of severe open lower limb fractures there are significant reductions in average LoS, which is associated with reduced rates of deep infection. Adaptation and adoption of lower limb guidelines in other trauma systems and countries would be a relatively low-cost, high-value-added intervention, requiring minimal input of new material resources, whilst improving clinical care, reducing unwarranted variation in clinical practice and reducing cost.

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Discussion

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Another inherent limitation of our study is that we used a pre-existing dataset derived from the INTELLECT study, without engaging with further data collection. The economic figures were obtained from the five countries contributing the largest number of cases to the INTELLECT study and our findings may not be representative of other countries. Two of the countries included in this study had national guideline in place at the time of data collection, the United Kingdom and the Netherlands[29]. However, presence of guidelines does not equate to adherence, and within the INTELLECT cohort it has not been demonstrated that it was the causal impact of the guidelines themselves that led to the improved outcomes and reduced LoS.

Conclusion

In healthcare settings in which national clinical guidelines are in place for the management of severe open lower limb fractures there are significant reductions in average LoS, which is associated with reduced rates of deep infection. Adaptation and adoption of lower limb guidelines in other trauma systems and countries would be a relatively low-cost, high-value-added intervention, requiring minimal input of new material resources, whilst improving clinical care, reducing unwarranted variation in clinical practice and reducing cost.

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Ethics statment

According to the HRA decision tool and The London School of Economics ethics committee this study did not required further ethical review, as the analysis was based on previously published research and the anonymity of the patients was maintained.

Table 1. Cohort data. N = 2641. LoS Length of Stay, IQR interquartile range.

Country or Region	Number of cases with LoS recorded	Median LoS (days)	IQR
High-income countries with guidelines (47%)			
United Kingdom	1026 (39%)	14	7-25
Netherlands	219 (8%)	13	5-24
High-income countries without guidelines (42%)			
Spain	389 (15%)	14	6-30
Chile	316 (12%)	9	4-26.5
Italy	97 (4%)	40	26-69
Australia	70 (3%)	20	14-29
Austria	68 (2%)	19	11.5-32.5
Taiwan	59 (2%)	12	7-22
Sweden	45 (2%)	13	7-37
Czechia	36 (1%)	16	11-27
South Korea	31 (1%)	46	31-83
Low and middle-income countries (11%)			
Mexico	113 (4%)	15	7-27
India	60 (2%)	12.5	9-19
Argentina	50 (2%)	25	9-78
Sudan	42 (2%)	15	7-27
Egypt	20 (1%)	22.5	17-34
Total	2641 (100%)	15	7-30

Table 2. Median Length of Stay (LoS) by country group.

	High income countries with guidelines (n 1242)	High-income countries no guidelines (n 1111)	LMICs with no guidelines (n 285)	p-value
Median LoS in days (IQR)	14 (7-25)*	17 (6-33)*	16 (9-32)	$p < 0.001$

Table 3. Median length of stay (LoS) by country group and presence or absence of deep infection.

	High income countries with guidelines (n 1241)	High income countries no guidelines (n 1109)	LMIC with no guidelines (n 285)
No deep infection (n) Median Los (IQR)	1140 14(6-24)	991 15 (6-31)	238 14 (8-29)
Deep infection (n) Median Los (IQR)	101 18 (11-32.5)	118 34 (19-67)	47 40 (20-90)

Table 4. Potential cost savings per 100 open lower limb fractures, by applying infection rates and LoS data from those with national guidelines.

	Spain (n 361)	Chile (n 316)	Italy (n 96)
Cost of overnight stay	400,00 €	131,10 €	900,00 €
Infection rate	7%	9%	18%
Cohort total	7900	6905	4915
Predicted with guidelines*			
Predicted cohort total LoS	5170	4566	1390
LoS reduction per 100 cases	756,2	740,2	3384
Cost saving in reduced LoS per 100 cases	302.480,00 €	97.040,22 €	3.045.600,00 €

Applying rates of infection of 8% and median Los: 14 no infection / 18 infection (as per countries with national guidelines)