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Analysing outcomes through orthopaedic trauma registry: A prospective cohort study

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ORIGINAL ARTICLE

Analysing outcomes through orthopaedic trauma registry - A prospective cohort study

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Abstract

Objective: To develop a registry for recording injury-specific data to identify gaps and improve care.

Methods: The prospective cohort study was conducted at Aga Khan University Hospital, Karachi, from June 2015 to July 2018 though enrollment of patients with limb trauma is continuing to date. Data on injuries and management related to Tibia shaft fractures was collected from medical records, and outcomes were assessed on follow-up visits. Internationally validated injury-specific scores were utilised for assessing functional, clinical and radiological outcomes. SPSS version 19 was used for data analysis.

Results: There were 763 patients with 825 limb injuries. Of the injuries, 310(37.6%) related to upper limbs and 515(62.4%) to the lower limbs. Management was surgical for 741(89.9%) and conservative for 84(10.1%) injuries. Overall, 12(1.57%) patients died, and in 7(0.91%) cases mortality was unrelated to trauma and its management. There were 105 patients with tibia shaft fractures. Of them, 88(83.8%) were males and 17(16.2%) were females. At one-year follow-up excellent-to-good results were 12(92%) for intramedullary nailing followed by 7(78%) for open reduction and internal fixation.

Conclusion: Registry data can be used to develop preventive strategies and to improve management protocols.

Keywords: Trauma, Database, Registry, Tibia shaft, Outcomes. (JPMA 69: S-7; 2019)

Introduction

Over the last few decades, several countries have developed national trauma registries and data systems that compile trauma data from hospitals and trauma care centres, and integrate nationwide data in their trauma databank. The first computerised trauma database was established in 1969 at the Cook County Hospital, Chicago.[1] Trauma data system provides a continuous monitoring tool for improving quality of care and patient outcomes. With the help of such systems, hospital trauma data can be retrieved to analyse effectiveness of current trauma care practices at multiple phases along with the care provided, and consequent patient outcomes.[2,3] Thus, literature shows that trauma registries have a positive impact on injury prevention, healthcare finances and outcomes.[4,5] The development of a trauma system model led to implementation of preventive programmes and changes in legislation, resulting in reduction of morbidity and mortality in trauma victims.[6,7] Moreover, trauma data system also reduces length of hospital stay and treatment-associated costs.[8,9] Two of these trauma data systems are the Victorian State Trauma Outcomes Registry (VSTS), and the American College of Surgeons' National Trauma Data Bank (NTDB).[10,11]

The VSTS gathers information about all major trauma patients from every hospital and healthcare facility in the state of Victoria. It provides high-quality trauma care data, including annual summary reports. After its introduction, there has been a decrease in trauma-specific death proportions for in-hospital deaths from the year 2010 to 2015. There has been increase in probability of experiencing good recovery from 28% in 2009-10 to 34% in 2013-14.[10]

The NTDB is one of the leading performance-improvement tools of trauma care in the United States. It collects trauma registry data from participating trauma centres annually

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and compiles information about traumatic injuries and outcomes. Data is aggregated and used to produce annual reports, hospital benchmark reports, and data quality reports.[11]

With considerable increase in trauma cases in Pakistan and subsequently increasing mortality and morbidity, it is essential to develop effective trauma care system in our country. Unfortunately at present, we lack such integrated quality care improvement system. Karachi Trauma Registry (KITR) is the first electronic trauma registry in Pakistan but it is limited to surveillance data such as mechanism of injuries, injury severity, length of stay in emergency department (ED) and survival probability.[12] Another effort, the City Trauma Registry, is in progress at two government-run trauma centres.[13] The Road Traffic Injury Research and Prevention Centre (RTIRPC) is a public health initiative in Karachi whose specific emphasis is on reducing road traffic accidents (RTAs) in the city. Data is mainly gathered from five major public and private hospitals in the city.[14] For successful initiation, implementation and sustainability of hospital-based trauma data systems, cost-effective software solutions and user-friendly process of data collection, such as use of mobile devices, could lead to efficient data capture in time- and resource-constrained situations.

The Musculoskeletal & Sports Medicine Service Line at Aga Khan University Hospital (AKUH), Karachi, has trauma care as one of its predominant functions. It was felt that the currently existing health information system does not capture sufficient injury-specific data, especially outcomes apart from in-hospital morbidity and mortality. Thus, the need for a robust data management system for injury, management and outcome information became evident.

The main goal of the project was, and remains, to develop a reliable and secure data capture and management system that enables timely access to injury-specific information about the trauma itself, the patient care process and the outcomes. The project intends to establish a practice of objective and reliable assessment of outcomes with organised documentation. This will enable periodic reports for comparison with international benchmarks, leading to exploration of possible areas for improvement in the infrastructure, processes and outcomes. Our trauma data system will provide a continuous monitoring tool for trauma care and may thus lead to continuous quantifiable quality care improvement. The scope of this project is to compile patient- and injury-specific data from the hospital information system, and then add functional, clinical and radiological outcome data after their treatment. The current study was planned to share our experience related to the project, with particular focus of tibia shaft fractures.

Patients and Method

The prospective cohort study was conducted at Aga Khan University Hospital (AKUH), Karachi, from June 2015 to July 2018 though enrollment of patients with limb trauma and is continuing to date. Approval was obtained from the institutional ethics review committee and the study was registered at the Research Registry with unique identification number (UIN) 3467 and 3466. All patients with upper or lower limb trauma presenting to the hospital were included. Patients with pathological fractures were excluded. The subjects were enrolled from the orthopaedic in-patient and out-patient units. Written informed consent was obtained from patients or guardians. Consenting patients were enrolled and UIN was assigned. From the medical records, demographic data, injury-related information, treatment-related information, including surgical procedures, and data about in-hospital morbidity and mortality was collected. After discharge, patients were actively tracked for follow-up visits using the hospital's Health Information Management System (HIMS). In the follow-up visits, patients were assessed for outcomes at approximately 2 weeks, 6 weeks, 3, 6 and 12 months after their initial visit. Relevant validated scoring systems were used according to the injured limb/segment. At different follow-up time points, Johner and Wruh's criteria[15] was used to assess the clinical and functional outcome of tibia shaft fractures. Data was maintained and analysed on SPSS version 19. Reports about injury patterns, treatment and outcomes were produced at 6 and 12 months.

Results

Of the 763 patients enrolled, upper limb injuries were sustained by 248(32.5%), lower limb injuries by 453(59.4%) and both upper and lower limb injuries by 62(8.1%) patients. Of the injuries, 310(37.6%) related to upper limbs and 515(62.4%) to the lower limbs. There were 82(26.5%) open and 228(73.5%) closed fractures in the upper limb, and 126(24.5%) open and 389(75.5%) closed fractures in the lower limb. Of the total 825 limb injuries, 617(74.8%) were closed fractures while 208(25.2%) were open

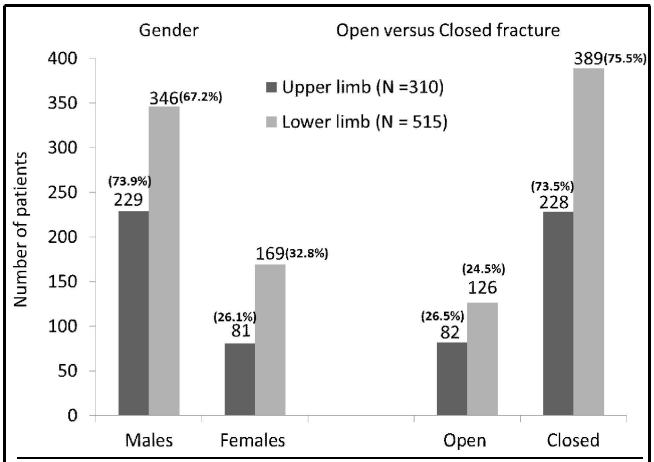

Figure-1: Open versus closed fractures and gender distribution according to anatomical site.

fractures. Among cases of upper limb fractures, 229(73.9%) were males and 81(26.1%) were females. In lower limb fractures, 346(67.2%) were males and 169(32.8%) were females (Figure 1).

RTAs were the leading cause of injuries 160(51.6%) in upper limb and 236(45.8%) in lower limb. Fall was the second leading cause, 116(37.4%) in upper and 229(44.5%) in lower limb, followed by firearm injuries 12(3.8%) in upper and 12(2.3%) in lower limb. Other mechanisms of injury were blast trauma, blunt trauma, twisting injuries, assault, machine injuries and firecracker accounting for 22(7.1%) in upper and 38(7.3%) in lower limb. Follow-up was completed on 438(53.1%) cases at 3 months. Clinical, functional and radiological outcomes were assessed at the follow-up in 354 of 438(80.8%) cases. Follow-up is still due for 171(20.72%) cases, while 195(23.63%) have been lost to follow-up. Due to complete recovery, visits were ended in 10(1.21%) patients while 7(0.85%) patients expired at 3 months and among them, 2(0.24%) patients had both upper and lower limbs involved. Besides, 2(0.24%) cases were excluded due to limb amputation.

From the remaining 804 cases, follow-up examination was completed on 280(34.82%) cases at 6 months in which outcomes were assessed in 233of 280(83.2%). Follow-up visit is still due for 253(31.46%) cases, while 254(31.6%) have been lost to follow-up. Due to complete recovery, visits were ended in 14(1.74%) patients at 6 months, while 3(0.37%) patients expired at the 6-month follow-up. From the remaining 788 cases, follow-up examination was completed on 135(17.13%) cases at 12 months in

Table: Tibia shaft fractures characteristics and Surgical Procedures performed.

Total cases	105 patients 05 bilateral tibia shaft fractures (Total 110 cases)
Gender	Male - 88 (83.8%) Female - 17 (16.2%)
Mechanism of injury	RTA - 73(69.5%), Fall - 16(15.2%), Blast - 6(5.7%), Blunt - 5(4.76%), Fire arm injury - 3(2.85%), Assault - 2(1.9%)
Operated	101(96.2%)
Non-operated	4(3.8%)
Surgical Procedures	
ORIF	27(24.54%)
IM nailing	45(40.9%)
External fixator	24(21.8%)
ORIF + IM nailing	06(5.45%)
CRIF + IM nailing	05(4.54%)
Other	03(2.72%)
Revision Surgeries	
External fixator to IM nailing	02(1.8%)
IM nailing to External fixator	01(0.9%)
External fixator to MIPPO plate	01(0.9%)
External fixator to ORIF	01(0.9%)

RTA: Road traffic accident, IM: Intramedullary nailing, ORIF: Open reduction and internal fixation, MIPPO: Minimally invasive percutaneous plate osteosynthesis.

which outcomes were assessed in 115 of 135(85.2%). Follow-up visit is still due for 324(41.11%) cases, while 318(40.36%) have been lost to follow-up. Due to complete recovery, visits were ended in 9(1.14%) cases after 6 months but before 12 months, while 2(0.25%) patients expired at the 12-month follow-up.

Overall, 5 patients expired due to surgical sepsis, while 7 patients died due to non-surgical reasons. Management outcomes data is available for all fractures, but, in line with the focus of the study, only tibial shaft fractures are presented in this regard. Of the 105 such patients, 88(83.8%) were males and 17(16.2%) were females. Of them, 5 patients had bilateral fractures. RTAs was the leading cause of tibia shaft fractures with 73(69.5%) patients followed by fall 16(15.2%). Other mechanisms of injury were blast trauma, blunt trauma, firearm injury and assault accounting together for 16(15.2%) patients.

The main surgical procedures comprised fracture-specific interventions, such as intramedullary (IM) nailing in 45(41%) cases, open reduction and internal fixation (ORIF) in 33(30%) cases with or without IM nailing, and external fixation in 24(21.8%) cases. With progress in bone healing, revision surgeries were performed in 5(4.5%) cases like external fixator being replaced by IM nailing (Table).

At 6-month follow-up, outcomes of 44(40%) cases of tibial

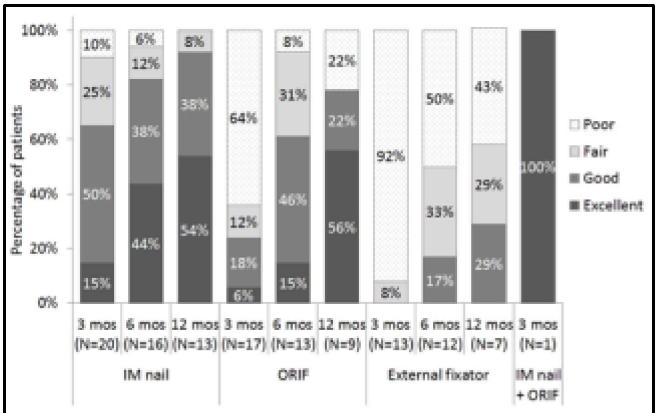

Figure-2: Tibia shaft Surgical procedures and outcomes.

fractures were recorded (Figure 2). Among 16 cases that underwent IM nailing, 7(44%) had excellent, 6(37.5%) good, 2(12.5%) fair and 1(6%) poor outcomes. Among 13 cases that underwent ORIF, 2(15%) had excellent, 6(46%) good, 4(31%) fair and 1(8%) poor outcomes. Among 12 cases with external fixation, 2(17%) had good, 4(33%) fair and 6(50%) poor outcomes. There was no excellent outcome at 6-month follow-up. One patient treated with IM nailing combined with ORIF had excellent outcome at 3 months, but was subsequently lost to follow-up.

At 12-month follow-up visits, outcomes of 32(29.1%) cases were recorded. Among 13 cases that underwent IM nailing, 7(54%) had excellent, 5(38%) good and 1(8%) fair outcomes. There was no poor outcome. Among 9 cases undergoing ORIF, 5(56%) had excellent, 2(22%) good and 2(22%) poor outcomes. Among 7 cases that underwent external fixation, 2(28.5%) had good, 2(28.5%) fair and 3(43%) poor outcomes, but there was no excellent outcome. In the external fixator group, all patients had open fractures and 4 cases had polytrauma with severe injuries to lower limbs. Outcomes were recorded in3of 5(60%) cases who underwent revision surgical procedures. In 1 of them, external fixation was revised with IM nailing, and outcome was noted at 6 and 12 months. In 1case, external fixation was revised with minimally invasive percutaneous plate osteosynthesis (MIPPO), and fair outcome at 6 months and good at 12 months was noted. In the last 1 patient, external fixation was revised with ORIF with plate, and at 6 and 12 months, good outcome was observed.

Discussion

It is challenging for a low-middle income country (LMIC) to initiate a trauma registry when there are limited resources allocated to healthcare and related costs. However, considering the increasing burden of trauma from violence and disasters, and the related mortality and morbidity in our country, sustained improvement in trauma care is of utmost importance and that requires data. We have demonstrated the feasibility of a small-scale comprehensive orthopaedic trauma registry in our 542-bed tertiary care hospital in Karachi to provide injury-specific data.

The study presented the outcomes of tibial shaft fractures as an example of the utility of injury-specific data collection, while data about outcomes of other fractures of the upper and lower limb remains to be analysed and discussed with the care providers. Our results showed that IM nailing is the procedure producing best clinical and functional outcomes, followed by ORIF. An important fact that should not be overlooked is that the results of a surgical procedure should be seen in consideration of multiple factors in clinical decision-making such as associated co-morbids, fracture type, proximity to joint, nature of soft tissue injuries, associated injuries such as polytrauma, anaesthetic risks and various patient factors. When the poor outcomes were examined in depth, it was found that 1 patient who had undergone ORIF was mentally retarded and unable to follow the rehabilitation instructions, while 1 who had undergone external fixation had multiple fractures in both lower limbs, and another had bilateral tibia shaft fractures and one side required amputation.

Illustration of outcomes of tibia shaft fracture in this study has provided an insight for identifying the preferred surgical option with best outcome. Notably, there was no poor outcome at 6-month follow-up in the IM nailing group, suggesting that this should be the procedure of choice in general, while ORIF would be the second best option.

Several limitations and challenges were identified during the execution of this trauma registry project. Availability of funds for the development of the registry software necessitated use of conventional database software SPSS version 19. Although data entry and analysis can be performed on this software, it is a tedious process because it has not been customised to simplify data entry and

report-generation. Lack of sufficient human resource led to shortfalls in completing data collection when patients arrive at odd hours and on weekends, and lack of documentation of pre-hospital information and complications in the medical records placed additional burden on the data collection officer. As we work to overcome these challenges, we also plan on expansion of the registry to other institutions and eventually across the country, but that would require negotiating through institutional and national confidentiality guidelines and regulations.

The data available can be utilised for audit, quality care improvement, research, publications and international benchmarking. We envision developing and transitioning onto a registry-specific software solution which can be used not only at our institution but also at other institutions as it would be configurable according to specific institutional needs; be accessible to authorised users through a web-browser from any computer / smartphone connected to the internet; provide data security and secure access to users; be integrated with the hospital electronic medical record (EMR) systems to facilitate workflow; and permit exporting data for submission to external / international databases / registries for benchmarking of outcomes.

Conclusion

The use of injury specific-outcome assessments through our elaborate data collection and analysis methodology system enables identification of areas in trauma care in need of improvement, and provides indications for the potential of reducing trauma-related morbidity and mortality. Once a dedicated software solution is developed, nationwide extension of this data system can be envisioned to see improvements in trauma care across the country. Commitment, funding and manpower need to be ensured for sustainability of such projects.

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Conflict of Interest: None.

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