

Traumatic Brain Injury Registry: Sharing the Pilot Study Experience to Foster a Multicenter Project on Traumatic Brain Injury Core Data

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Indian J Neurotrauma 2016;13:81–87.

Abstract

Background Trauma registry (TR) has been globally recognized as one of the vital tool in bridging the gap of information. The concept of TR has been extended to traumatic brain injuries (TBIs) in our study.

Objectives Present study was conducted to identify core variables necessary to collect data on the sociodemographics, clinical courses, interventions, and outcomes of TBIs and to develop an electronic data entry interface (including web-based data record interface).

Methods A predesigned pro forma with guidelines to complete the questionnaire was used to collect the data maintaining uniformity and reproducibility. The details of

Keywords

- ▶ traumatic brain injury
- ▶ registry
- ▶ data collection

received
September 5, 2015
accepted
June 26, 2016
published online
August 10, 2016

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DOI <http://dx.doi.org/10.1055/s-0036-1586486>.
ISSN 0973-0508.

TBI pilot study questionnaire and data collection procedure (which included emergency assessment, patient characterization, preclinical data, emergency room intervention details, intensive care unit management details, diagnosis, and follow-up) were structured indigenously.

Results A total of 402 patients were included in this study. The mean age was 37.34 ± 16.08 years (male 78.11% and female 21.89%) and fairly good amount of details were available for the majority of the variables. In addition to the previously described variables, many other variables are proposed to be added to the further study which include handedness (right/left/ambidexterity), primary caregiver—responsible for earning in family, management-related variables (hypothermia therapy, nutrition replacement, hyperventilation therapy, and seizure prophylaxis), and details of complications (hypotension episode, hypoxia episode, any infections, and deep vein thrombosis). Disability rating scale was being added to make data collection and follow-up more objective and comparable.

Conclusion We hope and believe that this study will provide a cost effective, yet comprehensive data collection system on different parameters encompassing TBIs including configuration of existing care in our country.

Introduction

In this new millennium, noncommunicable diseases are rapidly growing in the developing world including India adding to the existing burden of communicable diseases.^{1,2} Injuries have been accepted as major cause of mortality, morbidities, and disabilities with uncountable downstream economic loss.^{3,4} Yet, injury care in India is at a nascent stage of development and a nationwide survey encompassing various facilities has documented significant deficiencies in current trauma management systems.^{3–14} Accurate data are needed to evaluate clinical outcomes, therapeutic modalities, and quality of care in trauma.¹⁵ Reliable estimates of the burden of road traffic injuries are an essential input for rational priority setting and a national estimate of the burden of injuries should be built by collating information from all existing information sources by appropriately correcting for source-specific shortcomings.^{2,16} The available data in India have severe limitations as injury surveillance system needs reliable, accurate, and adequate data to improve road safety interventions.¹⁷ The present study was conducted to identify the core variables to collect data on the demographics, clinical course, management, and outcome of traumatic brain injuries (TBIs) and to develop an electronic data entry interface (including web-based data entry interface) in a resource-limited setting.

Materials and Methods

The current study is an exploratory study performed at the Narayana Medical College & Hospital, Nellore, Andhra Pradesh, India. Prospective data collection was done for all the diagnosed cases of TBI admitted during the study period (July 2014–December 2014), using a predesigned and pretested questionnaire. The data were collected in a

predesigned pro forma and all efforts were made to complete the questionnaire to maintain the uniformity and reproducibility. The details of TBI pilot study questionnaire and data collection procedure (which included emergency assessment, patient characterization, preclinical data, emergency room intervention details, intensive care unit [ICU] management details, diagnosis, and follow-up) have been described in our previous studies.^{9–12,18–20} Several variables are identified as an essential component for any trauma registry (TR) such as age, gender, residence, district hospital; date and time of injury and arrival; Glasgow coma scale score for head injuries (TBIs)²¹; category (blunt, burn, and penetrating); mechanism of injury; intent of trauma; pre-existing conditions; vital signs on arrival (blood pressure, heart rate, and respiratory rate); optimum investigations including roentgenogram, computed tomography (CT), laboratory tests, or ultrasound; procedures performed; date of first surgery; length of stay; discharge status (alive or dead); and Glasgow outcome scale²² were included in the pro forma (**►Supplementary Appendix I** and **►Supplementary Appendix II** [online only]).^{23–27} The data were collected by trained nursing personnel under the supervision of emergency and neurosurgery consultants. Based on paper-based pro forma, simultaneously, electronic data entry interface was developed in FileMaker Pro Advanced 13 (Copyright 1994–2015, FileMaker, Inc; Santa Clara, California, United States) and Web-based data entry interface was developed using Drupal CMS (<http://neuropractices.com/content/tbi-registry>). This helped in on-screen display, easy data entry, and proved useful in maintaining uniformity especially in case of data collection from multiple centers. The web-based data entry interface has restricted access and can only be accessible to registered users. All the measures were taken to mask the identity of the patients. Permission from

institutional ethics committee was sought for carrying out the study. Written informed consent was collected from the patients in compliance with regulations and guidelines following Helsinki declaration if they were conscious at the time of data collection. In other cases, legally authorized representatives were approached for consent, viz., from next of kin, or in case of minors or patients unable to give consent.

Statistical Analysis

A common analysis and reporting plan was prepared and analysis of data was done using StatsDirect version 3.0.150 (StatsDirect statistical software, StatsDirect Ltd., Cheshire, WA, England; 2015; <http://www.statsdirect.com>), generating simple frequencies for nonnumeric variables and simple averages for numeric variables.

Results

A total of 402 patients were included in the study. Mean age was 37.34 ± 16.08 years (male 78.11% and female 21.89%), majority was illiterate (46.52%) (►Table 1). Loss of consciousness (73.88%) with or without vomiting (48.51%) followed by bleeding from ear (39.55%) and nose (32.84%) was the common clinical presentations; rhinorrhea was not noted in this pilot study. In the analysis of body regions involved along with TBI, it was noted that injuries to the extremities (17.16%) were the most important comorbidities. However, injury to pelvic girdle was not associated with any of the cases in this series. In the

Table 1 Details of educational and employment status of the patients who sustained traumatic brain injury

Education and employment status	Frequency	%
Illiterate	187	46.5
Farmer	102	25.4
Primary	29	7.2
Unknown	14	3.5
House wife	12	3
Student	8	2
Employee in service	3	0.7
Unemployed	8	2
Self-employee	9	2.2
Retired employee	3	0.7
Graduate	3	0.7
Laborer	2	0.5
Secondary	11	2.7
Postgraduate	2	0.5
Total	393	97.8
Missing system	9	2.2
Total	402	100

conservative management apart from tetanus toxoid (70.90%), urinary catheter (61.69%) was the commonest intervention followed by administration of colloid (59.95%) and crystalloid (37.06%); 13.18% cases were put on ventilation; blood transfusion was needed by only two cases. Based on ICD-10, traumatic cerebral edema was the commonest diagnosis (35.32%) followed by concussion (30.10%) and traumatic subdural hemorrhage (18.66%) (►Table 2). After detail analysis, a revised variable list was obtained (►Supplementary Appendix I [online only]) and a revised paper pro forma and electronic data interface were designed (►Supplementary Appendix II [online only]). In addition to the previously described variables, many other variables are proposed to be added to the further study which include handedness (right/left/ambidexterity), primary caregiver—responsible for earning in family,^{24,27} management-related variables (hypothermia therapy, nutrition replacement, hyperventilation therapy, and seizure prophylaxis), and details of complications (hypotension episode, hypoxia episode, any infections, and deep vein thrombosis).^{23–26} Disability rating scale was being added to make data collection and follow-up more objective and comparable.²⁸

Discussion

Success of a National Trauma Registry depend on the cooperative efforts; a short training to existing system of health workers can improve the scenario^{29–33} and needs to be cost effective also.³⁴ The burden from domestic and nondomestic injuries is increasing relentlessly worldwide, accounts for 16% and road traffic injuries as the 9th leading cause of the morbidity load globally; 5th in the developed world, whereas 10th in developing ones; most commonly affecting men in their productive age group.¹⁸ Major trauma accounts for approximately 10% of the world's deaths.^{3,35–39} Mortality from trauma in rural areas is increased because of delay in discovery of the victim or delay in accessing the trauma system.^{40,41} The prevalence of trauma as a public health hazard in low-resource settings globally has been severely neglected.⁴²

The majority of trauma research is epidemiological in nature and despite the extensive clinical trauma experience, literature shows limited clinical trauma research.⁴³ TR is a system of data collection that serves as a source of information for the evaluation of trauma care for a specific set of injured patients meeting well-defined inclusion criteria.^{34,44,45} TRs are an integral part of outcome assessment tool in many developed trauma systems^{45,46} and also have been recognized as one of the vital tool in filling the gap of injury information perpetually refining the internalization of injury care.⁴⁷ Yet, many countries with limited resources have been able to establish useful TRs.^{44,48,49} Initiation and continuation of a TR in any developing country is a challenging task, though it is feasible with the potential to develop a nationwide database.⁵⁰

TRs provide large longitudinal databases for analysis and policy improvement^{51,52} and can be used to successfully study the prehospital triage and survival of major trauma

Table 2 Details of clinical presentation, body regions involved, conservative management, and diagnosis (ICD-10) as a dichotomous variable

Clinical presentation	Yes	%	No	%
Loss of consciousness	297	73.88	105	26.12
Vomiting	195	48.51	207	51.49
Nausea	13	3.23	389	96.77
Ear bleed	159	39.55	243	60.45
Nasal bleed	132	32.84	270	67.16
Oral bleed	57	14.18	345	85.82
Headache	59	14.68	343	85.32
Seizures	29	7.21	373	92.79
Rhinorrhea	0	0.00	402	100.00
Otorrhea	5	1.24	397	98.76
Posttraumatic amnesia	22	5.47	380	94.53
Details of body regions involved				
Head	402	100.00	0	0.00
Neck	11	2.74	391	97.26
Thorax	5	1.24	397	98.76
Chest	16	3.98	386	96.02
Abdomen	1	0.25	401	99.75
Pelvic girdle	0	0.00	402	100.00
Extremities	69	17.16	333	82.84
Pelvic contents	0	0.00	402	100.00
Cervical spine body region	2	0.50	400	99.50
Thoracic spine body region	2	0.50	400	99.50
Lumbar spine body region	1	0.25	401	99.75
Details of conservative management				
Urinary catheter	248	61.69	154	38.31
Nasogastric tube	78	19.40	324	80.60
Tetanus toxoid	285	70.90	117	29.10
Crystalloid	149	37.06	253	62.94
Colloid	241	59.95	161	40.05
Blood transfusion	2	0.50	400	99.50
Cervical collar	16	3.98	386	96.02
Cervical traction	1	0.25	401	99.75
Bed rest	320	79.60	82	20.40
Steroids	3	0.75	399	99.25
Ventilation	53	13.18	349	86.82
Details of diagnosis (based on ICD-10)				
S02.0 Fracture of vault of skull	20	4.98	382	95.02
S02.1 Fracture of base of skull	24	5.97	378	94.03
S02.3 Fracture of the orbital floor	14	3.48	388	96.52
S02.7 Multiple fractures involving skull and facial bones	6	1.49	396	98.51

Table 2 (Continued)

Clinical presentation	Yes	%	No	%
S02.8 Fractures of other skull and facial bones	15	3.73	387	96.27
S02.9 Fracture of skull and facial bones, part unspecified	1	0.25	401	99.75
S06.0 Concussion	121	30.10	281	69.90
S06.1 Traumatic cerebral edema	142	35.32	260	64.68
S06.2 Diffuse brain injury	10	2.49	392	97.51
S06.3 Focal brain injury	2	0.50	400	99.50
S06.4 Epidural hemorrhage	45	11.19	357	88.81
S06.5 Traumatic subdural hemorrhage	75	18.66	327	81.34
S06.6 Traumatic subarachnoid hemorrhage	37	9.20	365	90.80

patients.⁵³ Global evidence supports an improved trauma care through the use of functionally active and well-organized TRs to improve the management and outcome of trauma patients.^{45,46,54-56} Besides demographic information, TRs provide information risk factors and outcomes of injury in terms of death and disability with details of various levels of care system (emergency medical services, emergency department, operating room, ICU, ward, rehabilitation units, etc.)^{44,56} In the absence of accurate routine medical record data or well-designed injury surveillance systems, it is a challenge to understand the problems and risk factors for types of trauma, design appropriate interventions to prevent and treat trauma, monitor the effectiveness of interventions, and provide information to policy makers.⁵⁷⁻⁵⁹

For successful establishment of a multicenter TR, user friendly data entry system and continuous data analysis are needed.⁵¹ The use of the common trauma template has been shown feasible across international registries for the majority of the data variables,⁶⁰ though the datasets of existing TRs frequently lack compatible definitions of common data variables.⁶¹⁻⁶⁵ Further, uniformity in the outcome variables and injury scoring systems across international trauma institutions is mandatory to obviate challenges to compare quality of the health care systems.⁶⁰ Successful TRs will be resource and setting specific in design to improve trauma care and outcomes, prevention programs are developed, and capacity-building goals realized.⁴⁸ Analysis of a TR as early as 6 months can lead to useful information which has long-term effects on the progress of trauma research and prevention.⁵⁰ The German Society for Trauma Surgery has contributed outcome analysis in relation to the injury pattern.⁶⁶ TRs in developing settings are plausible tools for injury surveillance. Since "multiple injuries" is not a homogeneous diagnosis, TRs collect prospective data from bigger hinterland to provide valid

data.^{67,68} Regional registries will also ensure auditing enhancing policy making for injury prevention and improving the quality of patient-centered care as no standard definition exist for documenting, reporting, and comparing data from severely injured trauma victims.^{69,70}

Strengths of the Study

The study provides operationalization approach in establishing trauma-based registry in India using web-based interface for recording essential epidemiological and clinical profile of patients with TBI in uniform manner. This is essential as properly documented information in the medical record is important to understand the mechanisms of injury, the clinical characteristics, and to postulate how many deaths were preventable. To the horizon of our knowledge, this study is the debut one that systematically collected data on indigenously mastered registry in India. Furthermore, team-based approach was used with paramedics managing most of the demographic, clinical, and investigation variable with expert consultation for data regarding CT scan, electrocardiogram, and follow-up of patient. This is notable as the emergency physicians if sensitized may use similar approach to generate countrywide robust TBI data.

Limitations of the Study

The findings of this study are subject to some limitations. Some epidemiological and clinical information may have been underreported due to the lack of proper documentation on the medical records; examples of missing information include: alcohol use, type of road where the injury occurred, pedestrian status, occupancy in a vehicle status, and type of vehicle. There were discrepancy and duplication of data at many of the places. Our study also does not account for patients who sought care in other nearby health care facilities, died on site, died after the first 24 hours, or those who survived their injuries; therefore, the results of this study should be interpreted with caution as they may not be representative of all cases of TBI in our hinterland.

Future Directions of the Study

Fairly good amount of details were available for the majority of the variables that enthused for the next phase of the study. This information can be used to develop preventive interventions, emergency medical response services, and clinical guidelines and to educate decision makers about the preventability of this public health problem.

Conclusion

TR has been globally recognized as one of the vital tool in bridging the gap of information. This can help enhance quality of injury care by identifying gaps in the trauma management system and find out opportunities of

improvements. In absence of any national database, the policy makers could not be well sensitized regarding the socioeconomic and health impact of injury. We hope and believe that this study will provide a cost effective, yet comprehensive data collection system on different parameters encompassing TBIs including configuration of present scenario of prehospital care in our country.

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