Original Article

Feasibility and Data Quality of the National Spinal Cord Injury Registry of Iran (NSCIR-IR): A Pilot Study

Khatereh Naghdi[1], Zahra Azadmanjir PhD[2], Soheil Saadat MD PhD[1], Aidin Abedi MD[1], Sahar Koohi Habibi MSc[2], Pegah Derakhshan[1], Mahdi Safdarian MD[1], Shayan Abdollah Zadegan MD[1], Abbas Amirjamshidi MD[3], Mahdi Sharif-Alhoseini MD, PhD[1], Jalil Arab Kheradmand MD[4], Mahdi Mohammadzadeh MD[5], Kazem Zendehdel MD, PhD[6], Zahra Khazaeipour PhD[7], Seyed Mahmood Ramak Hashemi MD[8], Hooshang Saberi MD[7], Kourosh Karimi Yarandi MD[3], Seyed Ebrahim Ketabchi MD[3], Shahrokh Yousefzadeh-Chabok MD[9], Hamid Heidari MD[9], Arezo Sotodeh[10], Khalil Pestei MD[11], Zahra Ghodsi PhD[1], Farideh Sadeghian PhD[1], Vanessa Noonan MSc, PhD, PT[12], Edward C Benzel MD[13], Gerard Oreilly MD[14], Jens Chapman MD[15], Ellen Merete Hagen MD, PhD[16], Michael G Fehlings MD, PhD[17], Alexander R Vaccaro MD, PhD, M.B.A[18], Morteza Faghih Jooybari MD[19], Mohammad Reza Zarei MD[1], Mohammad Reza Zafarghandi MD[1], Payman Salamati MD[1], Saeed Nezareh MA[20], Moein Khormali[1], Mohsen Sadeghi-Naini MD[1], Seyed Behzad Jazayeri MD[1], Bizhan Aarabi MD, FRCSC[21], Vafa Rahimi-Movaghar MD•[1]

Abstract

Background: Spinal cord injury (SCI) is one of the most disabling consequences of trauma with unparalleled economic, social, and personal burden. Any attempt aimed at improving quality of care should be based on comprehensive and reliable data. This pilot investigation studied the feasibility of implementing the National Spinal Cord and Column Injury Registry of Iran (NSCIR-IR) and scrutinized the quality of the registered data.

Methods: From October 2015 to May 2016, over an 8-month period, 65 eligible trauma patients who were admitted to hospitals in three academic centers in mainland Iran were included in this pilot study. Certified registered nurses and neurosurgeons were in charge of data collection, quality verification, and registration.

Results: Sixty-five patients with vertebral column fracture dislocations were registered in the study, of whom 14 (21.5%) patients had evidence of SCI. Mechanisms of injury included mechanical falls in 30 patients (46.2%) and motor vehicle accidents in 29 (44.6%). The case identification rate i.e. clinical and radiographic confirmation of spine and SCI, ranged from 10.0% to 88.9% in different registry centers. The completion rate of all data items was 100%, except for five data elements in patients who could not provide clinical information because of their medical status. Consistency i.e. identification of the same elements by all the registrars, was 100% and accuracy of identification of the same pathology ranged from 66.6% to 100%.

Conclusions: Our pilot study showed both the feasibility and acceptable data quality of the NSCIR-IR. However, effective and successful implementation of NSCIR-IR data use requires some modifications such as presence of a dedicated registrar in each center, verification of data by a neurosurgeon, and continuous assessment of patients' neurological status and complications.

Key words: Nervous System, registries, spinal cord injuries, spinal fractures, trauma

Cite this article as: Naghdi K, Azadmanjir Z, Saadat S, Abedi A, Koohi Habibi S, Derakhshan P, et al. Feasibility and Data Quality of the National Spinal Cord Injury Registry of Iran (NSCIR-IR): A Pilot Study. *Arch Iran Med*. 2017; 20(8): 494 – 502.

Authors' affiliations: [1]Sina Trauma and Surgery Research Center, Tehran University of Medical Sciences, Tehran, Iran. [2]Department of Health Information Management, School of Allied Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran. [3]Department of Neurosurgery, Sina Hospital, Tehran University of Medical Sciences, Tehran, Iran. [4]Ahya Neuroscience Research Center, Tehran, Iran. [5]Trauma Research Center, Kashan University of Medical Sciences, Kashan, Iran. [6]Cancer Research Center, Cancer Institute, Tehran University of Medical Sciences, Tehran, Iran. [7]Brain and Spinal Injuries Research Center (BASIR), Imam Khomeini Hospital, Tehran University of Medical Sciences, Tehran, Iran. [8]Department of Neurosurgery, Firoozgar General Hospital, Iran University of Medical Science, Tehran, Iran. [9]Guilan Road Trauma Research Center (GRTRC), Guilan University of Medical Sciences, Rasht, Iran. [10]Poursina Hospital, Guilan University of Medical Sciences, Rasht, Iran. [11]Department of Anesthesiology, Tehran University of Medical Sciences, Tehran, Iran. [12]Rick Hansen Institute, University of British Columbia, Vancouver, British Columbia, Canada. [13]Cleveland Clinic Foundation, Department of Neurosurgery, Cleveland, Ohio, United States of America. [14]Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia. [15]Swedish Neuroscience Institute, Swedish Medical Center, Seattle, Washington, USA. [16]Autonomic Unit, National Hospital for Neurology and Neurosurgery, Queen Square London, UK; Institute of Neurology, University College London, UK; Department of Neurology, Regional Hospital of Viborg, Viborg, Denmark; Department of Clinical Medicine Aarhus University, Aarhus, Denmark. [17]Toronto Western Hospital, University Health Network, Toronto, Ontario, Canada. [18]Department of Orthopaedic Surgery, the Rothman Institute, Thomas Jefferson University, Philadelphia, USA. [19]Department of Neurosurgery, Shariati Hospital, Tehran University of Medical Sciences, Tehran, Iran. [20]Cloudware Company, Ltd, Tehran, Iran. [21]Department of Neurosurgery, University of Maryland School of Medicine, Baltimore, Maryland, USA.

•Corresponding author and reprints: Vafa Rahimi-Movaghar MD, Professor of Neurosurgery, Department of Neurosurgery, Sina Trauma and Surgery Research Center, Sina Hospital, Tel: +98216675002 Fax: +982166757009, E-mail: v_rahimi@sina.tums.ac.ir; v_rahimi@yahoo.com

Accepted for publication: 20 July 2017

Introduction

Traumatic spinal cord injury (SCI) has significant personal, psychological, familial, and economic burdens on society.[1–4] According to Jazayeri *et al*., traumatic SCI has a global incidence of 3.6 to 195.4 patients per million.[1] Rahimi-Movaghar *et al.* reported the incidence of SCI in developing countries to be 25.5/million/year.[5] Although SCI has no definitive cure, quality management during pre-hospital resuscitation, critical care, and

rehabilitation are effective in overall improvement of the functional outcome of patients with SCI.[6–8] Recognition of pitfalls, validation of existing guidelines in developing countries through data registries, refinement of local policies and procedures and practice traditions may benefit patient care and improve outcome. According to Gliklich *et al*., a "patient registry is an organized system that uses observational methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure, which serves predetermined scientific, clinical, or policy purpose[s]".[9]

A top priority of the Iranian Government has been a well-established and reliable national SCI data registry aimed at better understanding the demographics, injury mechanisms, on-the-scene resuscitation, transfer, imaging evaluation, treatment and rehabilitation of patients with SCI, as well as its effect on health delivery and the national economy. A preliminary proposal for the design and methodology of a data registry (National Spinal Cord Injury Registry of Iran [NSCIR-IR]), supported by the Ministry of Health and Medical Education (MOHME), was introduced in August 2014, and this pilot study is the first attempt to validate the completeness, accuracy, and consistency of the data thus collected.

Materials and Methods

The NSCIR-IR is a not-for-profit hospital-based registry designed to register patient data prospectively. It was designed by a panel of national and international experts (Supplement 2). They were involved in the design, execution, data capture, quality control and production of the product.

Other contributing agencies included Ministry of Health and Medical Education, Welfare and other nongovernmental organizations. Three neurosurgical departments participated directly in the completion of the pilot study—the Sina and Firoozgar Neurosurgical Departments in Tehran and the Poursina Neurosurgical Department in Rasht.

Case definition

All patients with traumatic vertebral fractures/dislocations, with or without SCI, admitted to any neurosurgical or orthopedic service were eligible to be registered in NSCIR-IR (Table 2).

Minimum data set (MDS)

We adopted the MDS designed and developed by the International Spinal Cord Society (ISCoS) and accepted by the World Health Organization (WHO) in order to be able to exchange information with other academic centers internationally.[10–11] The registered MDS included prehospital resuscitation, acute care hospitalization, complications, and life-long follow-up of our patients.

There were 285 data elements in the data set, including 163 elements from the American Spinal Injury Association (ASIA) International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI). Acute case report forms (ACRFs) included categories pertaining to prehospitalization care, emergency department (ED) admission, demographics, injury mechanism, comorbidities and medical history, vertebral injury, ASIA motor score and ASIA impairment scale (AIS), surgical or nonoperative interventions, Glasgow Outcome Scale (GOS) score, and in-hospital complications (Supplement 1). Our expert panel confirmed the content validity of our Acute and Chronic Case Report Forms (CRFs). Follow-up of the patients was made possible through the Iranian Integrated Care Electronic Health Record. Chronic CRFs evaluated pain (11 data elements), pressure ulcers (16 data elements), and spasticity (12 data elements). For quality of life assessment, the validated Farsi version of the World Health Organization Quality of Life-BREF (WHOQOL-BREF) questionnaire was used.[12–13]

Registry process

Registry data capture training for the nursing personnel was either face-to-face or online. Electronic data collection was performed by the designed web-based system for our registry. The web-based application was compatible with the workflow of registry. The case report forms were implemented into the system and registrars in each local registry center had access to the system for data entry. They created a record for each new patient and entered the required data in case report forms. Each patient has a unique identifier. Therefore, one record is created for each patient in the system and is completed in all future follow-up episodes. After data entry and submission of patient record in the system by registrars, quality reviewers checked data in terms of completeness, consistency and accuracy. If there were a defect or a problem for each data element, it would be specified with a label and comment by quality reviewer. Then, the record would be returned electronically to the corresponding registrar to edit. Otherwise, submitted data was verified by quality reviewer.

Three trained reviewers were assigned to re-check data for accuracy, completeness, consistency, and quality. Two independent observers (a trained nurse and a neurosurgeon) assessed the medical images (X-ray, CT scan, and MRI) to determine injury morphology based on the AOSpine spinal fractures classification system and SCI severity. The accuracy of the NSCIR-IR patient identification data was crosschecked with the patients' identification records, medical images, and hospital charts. Uploaded online data were also checked for missing, incomplete, and inaccurate data. Feedback programs embedded in the software contributed to online teaching of the appropriate personnel.[14] We followed two methods to assure consistency: 1) the software alerted and rejected all the entries which were not consistent with predefined rules. For example, surgery cannot happen before the accident; therefore, if there were a conflict in the hierarchy of dates, the computer would not accept the data. 2) In addition, after data submission and before the completion of registration, our expert reviewers checked the entered data to ensure that there was no other inconsistency that could not be identified or prevented by software.

Coverage assessment

The coverage of the registry was estimated using the following formula:

$$[N(R+ H+) + N(R+ H-)] / [N(R+ H+) + N(R+ H-) + N(R- H+) + N(R- H-)]$$

Where N(R+ H+) is the number of cases identified by both NSCIR-IR and hospitals, N(R+ H-) is the number of cases identified by NSCIR-IR but not identified by hospitals, N(R- H+) is the number of cases identified by hospitals but not by NSCIR-IR, and N(R- H-) represents the number of cases that are identified by neither hospital nor NSCIR-IR. N(R- H-) was estimated using the following formula:

$$N(R- H-) = [N(R+ H-) * N(R- H+)] / N(R+ H+).$$

Table 1. Eligibility Criteria for Pilot Phase of the National Spinal Cord and Column Injury Registry of Iran (NSCIR-IR).

Criteria		Definition
Inclusion criteria		
1.	Acute trauma	Less than 30 days from the incident
2.	Spinal fracture or dislocation or	Fractures or dislocations of the occipital condyle (C0), cervical, thoracic, lumbar, sacral or coccygeal vertebrae including osteoporotic fractures due to falling or slipping.
	Spinal cord injury	Injury to the spinal cord, including the cauda equina, resulting in motor dysfunction, sensory dysfunction, and at least one of the three followings: Urinary incontinence, stool incontinence, sexual dysfunction.
Exclusion criteria		
1.	Pathologic spinal fracture	Spinal fracture due to tumor, infection or other non-traumatic conditions.
2.	Non-traumatic spinal cord injury	Spinal cord injury due to tumor, infection, ischemia or other non-traumatic conditions.
3.	Spinal column degeneration	Spinal column degeneration without fracture, confirmed by CT or MRI, in elderly patients admitted due to pain following falling or negligible trauma.

Table 2. Demographic Characteristics of Registered Patients.

Characteristics	Men (n = 47) 72.3%	Women (n = 18) 27.7%	Total (n = 65) 100%
Age (mean ± SD) (years)	36.23 ± 16.97	49.00 ± 20.02	39.77 ± 18.62
Education (n) %			
Illiterate	(11) 16.9	(5)7.7	(16) 24.6
Primary school	(7) 10.8	(2) 3.1	(9) 13.9
Secondary school	(13) 20.0	(4) 6.1	(17) 26.1
Diploma	(10) 15.4	(5) 7.7	(15) 23.1
Associate degree	0	(1) 1.5	(1) 1.5
Bachelor	(2) 3.1	0	(2) 3.1
Unspecified	(4) 6.2	(1) 1.5	(5) 7.7
Marital Status (n) %			
Single	(20) 30.8	(1) 1.5	(21) 32.3
Married	(27) 41.5	(13) 20.0	(40) 61.5
Widow	0	(3) 4.6	(3) 4.6
Divorced	0	(1) 1.5	(1) 1.5
Nationality (n) %			
Iranian	(40) 61.5	(17) 26.2	(57) 87/7
Afghan	(7) 10.8	(1) 1.5	(8) 12/3

Ethical considerations

The Ethics Committee of the Sina Trauma and Surgery Research Center, Tehran University of Medical Sciences, which is the coordinating unit of the NSCIR-IR, approved this study. In all cases, patients gave their oral informed consent. We used an opt-in informed consent that includes consent for other future registry roles, such as follow-up contacts and research registration project.

Results

Baseline characteristics of patients

Sixty-five patients were enrolled and their data were electronically captured in this 8-month pilot phase of the NSCIR-IR registry: Sina Medical Center, 27 patients; Firoozgar, 24 patients; and Poursina, 14 patients. Fourteen of the 65 (21.5%) had evidence of SCI (Tables 2 and 3). Nearly 60% (58.5%) of registered patients were residents of Tehran or Rasht, where registry headquarters are located; however, the nearly 40% remaining were transferred from distant provinces such as Azerbaijan, Esfahan, or Khorasan (Table 2). Tables 4, 3, and 5 depict injury mechanism, geographic region of vertebral column involved, and injury morphology.

Selected indices of quality of care

Table 6 shows the indices of quality of care recorded in the study.

Effort expended on completion of acute case report forms and quality control

Completion of ACRFs and maintenance of a database registry are labor intensive and require continuous vigilance. Patient identification, registration, and completion of ACRFs took 28 (SD 10) minutes. In addition, another 15 minutes was spent by a trained reviewer to ensure quality control. Overall, for a single patient, the process took 2 weeks from initiation until confirmation of ACRFs by a reviewer. A review of Hospital Information Systems at Sina and Firoozgar identified two challenges: 1) precise screening of patients that took into consideration inclusion and exclusion

Table 3. Distribution of patients based on ASIA impairment scale and Levels of spinal trauma.

	Number	Percentage
ASIA impairment scale		
-AIS grade A	10	15.4
-AIS grade B	0	0
-AIS grade C	0	0
-AIS grade D	4	6.1
-AIS grade E	51	78.5
Level of spinal fractures		
-Cervical	30	(31.3%)
-Thoracic	25	(26%)
-Lumbar	40	(41.7%)
-Sacral	1	(1%)

Table 4. Distribution of Patients Based on Injury Etiology.

Cause of injury	**Men (*n* = 47) 72.3 %**	**Women (*n* = 18) 27.7 %**	**Total (*n* = 65) 100 %**
Mechanical fall	(23) 35.4	(7) 10.8	(30) 46.2
Traffic crashes	(21) 32.3	(8) 12.3	(29) 44.6
Type of Accident			
Collision	15() 51.7	(6) 20.7	(21) 72.4
Overturning	(6) 20.7	(2) 6.9	(8) 27.6
Position of the person injured			
Pedestrian	(4) 13.8	(3) 10.3	(7) 24.1
Motorcycle	(10) 34.5	(1)3.4	(11) 37.9
Car	(5) 17.2	(4)13.8	(9) 31.0
Bus	(1) 3.4	0	(1) 3.4
Bicycle	(1) 3.4	0	(1) 3.4
Suicide	0	(1) 1.5	(1) 1.5
Violence, other assault	(1) 1.55	(1) 1.55	(2) 3.1
Sport	(1) 1.5	0	(1) 1.5
Other cause of injury	(1) 1.55	(1) 1.55	(2) 3.1

Table 5. Frequency and Percentage of Spinal Fracture Types in Registered Patients.

Type of spinal fractures	**N (%)**
Subaxial Cervical	
A: Compression injuries	**13 (49.9)**
A0	3 (11.5)
A1	3 (11.5)
A2	2 (7.7)
A3	4 (15.4)
A4	1 (3.8)
B: Distraction injuries	**0**
BL: Bilateral injuries	**0**
C: Translation injuries	**10 (38.5)**
F: Facet injuries	**3 (11.49)**
F1	1 (3.83)
F2	1 (3.83)
F4	1 (3.83)
Thoracolumbar	
A: Compression injuries	**65 (90.2)***
A0	6 (8.3)
A1	13 (18.1)
A2	2 (2.8)
A3	24 (33.3)
A4	20 (27.7)
B: Distraction injuries	**3 (4.2)**
B1	2 (2.8)
B2	1 (1.4)
C: Translation injuries	**4 (5.5)**

*There are patients with fracture in more than one spinal vertebra and multiple type of fracture. The type of A was common in the majority of patients.

Table 6. Recorded Care Indices in the Pilot Project.

Care Index	Number	Percentage
EMT Transfer	40	61.5
Scene Time (min)	7.5 ± 5	-
Immobilization	38	95
Availability of ED arrival time	55	84.6
Direct admission	10	15.4
ED length of stay (mean in hours)	7.92	-
Patients with surgical decompression	46	70.8
Time lapse (median) from injury to decompression in days (available in 44 patients)	6.9	-
Time lapse (median) from admission to decompression in days	4.4	-
Pressure Ulcers were recorded in patients	5	7.7
Patients who required pain management	13	20
Need for ventilator support	8	12.3
Recorded GOS score	47	72.3
Length of hospital stay (median in days)	10	

Table 7. Data completion rate, effort consistency, and data accuracy in registry centers.

Hospital	Case Identification Rate	Data Completion Rate																	Effort Consistency	Data Accuracy
		Demographic data			Clinical Data															
		Age	Gender	InJ Mec	% Intubated	ED B/P	ED Sats	Multiple Trauma	ASIA motor sc	Cer/Th/ Lumbar	CT	MRI	AO calss	Surgery	Inj to Surg	Crit Care	Pneumonia	DVT	PE	Death	H Leng. Stay		
Sina (27 patients)	**60.0%**	27/27 (100%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	3/27 (11.1%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	26/27 (96.3%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	27/27 (100%)	100%	100%
Firoozgar (24 patients)	**88.9 %**	24/24 (100%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	12/24 (50%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	17/24(70.8%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	24/24 (100%)	100%	100%
Poursina (14 patients)	**10.0%**	14/14(100%)	14/14(100%)	14/14(100%)	14/14(100%)	14/14(100%)	12/14 (85.7%)	14/14(100%)	14/14(100%)	14/14(100%)	14/14(100%)	12/14(85.7%)	14/14(100%)	14/14(100%)	14/14(100%)	14/14(100%)	14/14(100%)	14/14(100%)	14/14(100%)	14/14(100%)	14/14(100%)	From NA** to 100%	100%
Mean for all of hospitals (65 patients)	**30.7%**	65/65 (100%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	27/65 (41.5%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	63/65 (96.9%)	51/65 (78.5%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	65/65 (100%)	66.6% -100 %	100%

criteria; and 2) erroneous primary diagnoses. For example, among 87 patients screened in Tehran, only 37 were included in the registry: 50 of the patients were not eligible for different reasons such as non-traumatic cases and those who were among excluded patients. The exact rate of patient capture was 70.8%, and the rate of missing eligible patients was 29.2%. Analysis of the health information system data from Poursina indicated that 70 patients might have been candidates for screening. However, only 14 patients were captured for the database, a missed opportunity rate of 90.0% (Table 7). The discrepancy between identified patients and eligible patients were missing cases due to the following reasons: 1) High-volume patient load; 2) Small number of registrars; 3) Wrong admission diagnosis; 4) Patients not identified by study Medical Centers and the NSCIR-IR registrars.

Although software programming has been designed to pick up incomplete data fields, sometimes ACRFs could not be completed

because of missing data. For example, some spine injuries were encountered in unconscious patients without identifiers or paraclinical studies, such as oxygen saturation, which were not recorded by the nursing personnel.

Discussion

A well-functioning trauma registry that is feasible to execute and has a high degree of validity, reliability, and fidelity is a core requirement for healthcare delivery to trauma victims, an element of the healthcare system that accounts for a large proportion of country's economy.[15] Analysis of the results from our pilot study indicated that the NSCIR-IR registry was easy to work with, valid in data completion, consistently used by different registrars, and had a high degree of accuracy. Its reliability is important to Iran's healthcare delivery, recognizing regions with high rate of trauma, and appropriately allocating funding for research and patient services.

As shown in Table 9, the weakest fields in the registry were case identification rate, completion of diagnostic imaging (CT and MRI), and follow-up information. Clearly, these three fields are most valuable for highly specialized registries and, not surprisingly, are incomplete in many functioning registries such as the North American Clinical Trials Network (NACTN) and Rich Hansen registries[16]. One way to remedy these deficiencies is to provide and support adequately educated and dedicated registrars and personnel who will verify the consistency and accuracy of data and persist in case identification. Their review of emergency medical technician (EMT) and ED files, radiology reports, operative notes, and hard copies of ICU flow-sheets and hospital and rehabilitation charts will assure the registry's suitability for high valued longitudinal studies.

A top priority is to identify patients who might have been missed within a conglomerate of health services where the patient volume is high. For example, it would be beneficial to add EMT, orthopedic and general surgery services to the areas of the hospital covered by the registrars. It is of value to have easy access to electronic radiology and MRI reports in order to find missed patients and include patients with multiple trauma in the screening process.[17–20] We need to realize that many patients with multiple trauma have distracting issues such as pain from long bone fractures or exigencies of internal organ injuries, which might undermine the diagnosis of spine fractures. Appropriate identifiers are of immense value, since correct identification (name, medical record number, telephone number, address, passport number) facilitates follow-up of the patients.

According to WHO guidelines and other resources, one source of confusion and loss of trust is registering inaccurate data by registrars or evaluators.[21] In similar registries, a simple demographic field such as age had a 61% to 100% range of inaccuracy.[22] Identifiers such as education documents, passports, or national identity cards can help solve some of these inadequacies. For example, many of the Afghan citizens treated in Iran had no valid passports or identity documents. "Metropolitan cultures" is problematic in having a high risk of missing demographics and losing a chance to follow the patients accurately. The success of a trauma registry will be impossible without appropriately completed EMT records, ED files, critical care flow sheets, hospital master files, and rehabilitation data.

Without question, even the best registrars cannot complete inclusion criteria if the field data are missing from the patient files. For example, only 41.5% of the oxygen saturation data were completed, partly because the hospital charts lacked such data. Another distressing issue for most of the clinical researchers is that most registries lack appropriate documentation of timing of events and services, e.g., timing of accidents at the scene and then arrival at the ED, timing of the imaging studies and surgical intervention, and the duration of follow-up. Many such periods are of immense importance in clinical outcome studies. The mean time from accident to surgery in our registry was 158 hours. If this is a national norm, we are compelled to compare our data with the STASCIS data[23] to see if the timing of decompression affects outcome between the two cultures of Iran and North America. It is almost universally true that critical care data are good, but not so much the follow-up information.[24]

Almost 100% of the pilot study patients had information about major complications such as pain, pressure ulcers, and death. The value of the registry will increase as the registry becomes more inclusive of appropriate complications with relevance to outcome. The extent of completeness of registered complications in a recent study was 93%.[22] Registration of all the complications is almost impossible because the task is so labor intensive and thus financially expensive.

In our study, the consistency of data was reported to be 100%. Data consistency in two other recent studies was 98.7% and 99.6%, where the inconsistency was related to transport mode, time values for the patients' trauma, diagnostic and therapeutic procedures, and length of hospital stay.[22,25] Verification of data by our neurosurgeons was the key to the success of this registry. In our study, the in-patient SCI mortality rate was 7.7%. In a systematic review, the in-patient mortality for SCI patients was 24.1% (95% confidence interval [CI]: 14.1–38.0) for Africa, 7.6% (95% CI: 6.3–9.0) for the Americas, 7.0% (95% CI: 1.5–27.4) for Europe, and 2.1% (95% CI: 0.9–5.0) for Western Pacific.[26] Recent studies indicated that the accuracies of demographic variables, GCS score, and lengths of hospital stay were more than 95%.[27–29]

Although our registrars collected data from hard copy patient files and, in some cases, face-to-face interviews, we must caution that data verification was cumbersome and occasionally impossible. Verification of accurate patient data, including past medical history, social history, and present illness, requires repeated, time-consuming efforts by the registrars and neurosurgeons.

Analysis of results from the NSCIR-IR pilot study indicates that the registry needs the following modifications: (i) Reinforcement of cooperation and coordination between NSCIR-IR headquarters staff and nurse registrars across the country; (ii) Assignment of a dedicated registrar in high-volume hospitals; (iii) Inclusion of GOS score, ASIA motor score, and ASIA Impairment Scale (AIS) in clinical evaluations routinely performed at admission and at 6-week, 3-month, 6-month, and 12-month follow-up.[27,30]

Disclaimer

The preliminary results of this study were presented at the 5th Symposium of World Federation of Neurosurgical Societies (WFNS), Tehran, Iran, 2016. This pilot study is original, has not been published elsewhere, and is not under consideration for publication elsewhere.

Funding Support

The Deputy of Research and Technology, Ministry of Health and Medical Education of Iran, provided funding and resources for the implementation of the NSCIR-IR.

Acknowledgments

We acknowledge the Deputy of Research and Technology, Ministry of Health and Medical Education of Iran support for the NSCIR-IR. We thank our collaborators in Guilan Road Trauma Research Center (GRTRC), Guilan University of Medical Sciences, neurosurgery departments of Sina and Firoozgar hospitals who contributed to the pilot study. In addition, we thank all persons who provided insight and expertise that greatly assisted the research.

Author contributions

BA, SBJ, SS, and AA wrote the draft of paper and contributed in project implementation. KN and AS contributed in patient registration, analyzed data, and revised the paper. VRM and ZA designed and implemented the project from idea to deployment and also made major revisions to the paper. SAZ, SKH, PD, ZK, HS, AAJ, MSH, KKY, SEK, SYC, HH, KP, ZG, FS, VN, ECB, GO, MD, JC, EMH, MGF, ARV, MFJ, MRZar, MRZaf, PS, SN, MK, and MSN contributed in draft preparation and revision of the manuscript. PD contributed to data analysis and paper revision. MS contributed to the review of registry data quality and revision of drafts of the paper. JAK, MM, KZ, and SMRH were members of the expert panel and contributed to the paper's revision.

References

1. Jazayeri SB, Beygi S, Shokraneh F, Hagen EM, Rahimi-Movaghar V. Incidence of traumatic spinal cord injury worldwide: a systematic review. Eur Spine J. 2015; 24(5): 905 – 918.
2. Munce SE, Wodchis W, Guilcher SJ, Couris C, Verrier M, Fung K, et al. Direct costs of adult traumatic spinal cord injury in Ontario. Spinal Cord. 2013; 51(1): 64 – 69.
3. Craig A, Tran Y, Middleton J. Psychological morbidity and spinal cord injury: a systematic review. Spinal Cord. 2009; 47(2): 108 – 14.
4. Pollard C, Kennedy P. A longitudinal analysis of emotional impact, coping strategies and post-traumatic psychological growth following spinal cord injury: A 10-year review. Br J Health Psychol. 2007; 12(Pt 3): 347 – 362.
5. Rahimi-Movaghar V, Sayyah MK, Akbari H, Khorramirouz R, Rasouli MR, Moradi-Lakeh M, et al. Epidemiology of traumatic spinal cord injury in developing countries: a systematic review. Neuroepidemiology. 2013; 4(2): 65 – 85.
6. Guertin PA. New avenues for reducing intensive care needs in patients with chronic spinal cord injury. World J Crit Care Med. 2016; 5(4): 201 – 203.
7. Oosterwold JT, Sagel DC, van Grunsven PM, Holla M, de Man-van Ginkel J, Berben S. The characteristics and pre-hospital management of blunt trauma patients with suspected spinal column injuries: a retrospective observational study. Eur J Trauma Emerg Surg. 2017; 43(4): 513 – 524.
8. Rinkaewkan P, Kuptniratsaikul V. The effectiveness of inpatients rehabilitation for spinal cord patients in Siriraj hospital. Spinal Cord. 2015; 53(8): 591 – 597.
9. Gliklich RE, Dreyer NA, Leavy MB. *Registries for Evaluating Patient Outcomes: A User's Guide*. 3rd ed. USA: Agency for Healthcare Research and Quality; 2014; 1
10. World Health Organization, International Spinal Cord Society. *International Perspectives on Spinal Cord Injury*. Geneva, Switzerland: World Health Organization Press; 2013: 30 – 33.
11. Biering-Sørensen F, Charlifue S, Devivo M, Noonan V, Post M, Stripling T, et al. International spinal cord injury data sets. Spinal Cord. 2006; 44(9): 530 – 534.
12. World Health Organization. *WHOQOL-BREF: Introduction, Administration, Scoring and Generic Version of the Assessment*. field trial version. Geneva, Switzerland: World Health Organization; 1996: 5 – 18.
13. Nejat S, Montazeri A, Holakouie NK, Mohammad K. The World Health Organization Quality of Life (WHOQOL-BREF) questionnaire: Translation and validation study of the Iranian version. J of School of Public Health and Institute of Public Health Research. 2006; 4: 1 – 12.
14. Azadmanjir Z, Nezareh S, Aarabi B, Zendehdel K, Abdolazimi AM, Jafarpour M, et al. Dynamism of Electronic National Spinal Cord Injury Registry of Iran; Experiences on Developing a Web-Based System. The 5th Symposium of World Federation of Neurosurgical Societies ; Tehran, Iran. 17–22 April 2016. Abstracts ID: 169 P: 7. Available from: URL: http://iranwfns2016.com/MckUpload/file/poster_presentation7.pdf
15. Kyu HH, Pinho C, Wagner JA, Brown JC, Bertozzi-Villa A, Charlson FJ, et al. Global and National Burden of Diseases and Injuries Among Children and Adolescents Between 1990 and 2013: Findings From the Global Burden of Disease 2013 Study. JAMA Pediatr. 2016; 170(3): 267 – 287.
16. Grossman RG, Toups EG, Frankowski RF, Burau KD, Howley S. North American Clinical Trials Network for the Treatment of Spinal Cord Injury: goals and progress. J Neurosurg Spine. 2012;17(1 Suppl): 6 – 10.
17. Mancini DJ, Burchard KW, Pekala JS. Optimal thoracic and lumbar spine imaging for trauma: are thoracic and lumbar spine reformats always indicated? J Trauma Acute Care Surg. 2010; 69(1): 119 – 21.
18. Frankel HL, Rozycki GS, Ochsner MG, Harviel JD, Champion HR. Indications for obtaining surveillance thoracic and lumbar spine radiographs. J Trauma Acute Care Surg. 1994; 37(4): 673 – 676.
19. Durham RM, Luchtefeld WB, Wibbenmeyer L, Maxwell P, Shapiro MJ, Mazuski JE. Evaluation of the thoracic and lumbar spine after blunt trauma. Am J Surg. 1995; 170(6): 681 – 684; discussion 4 – 5.
20. Sheridan R, Peralta R, Rhea J, Ptak T, Novelline R. Reformatted visceral protocol helical computed tomographic scanning allows conventional radiographs of the thoracic and lumbar spine to be eliminated in the evaluation of blunt trauma patients. J Trauma . 2003; 55(4): 665 – 669.
21. World Health Organization. Improving data quality: a guide for developing countries: Manila: WHO Regional Office for the Western Pacific; Geneva, 2003: 60 – 61.
22. Porgo TV, Moore L, Tardif PA. Evidence of data quality in trauma registries: A systematic review. J Trauma Acute Care Surg. 2016; 80(4): 648 – 658.
23. Fehlings MG, Vaccaro A, Wilson JR, Singh A, D WC, Harrop JS, et al. Early versus delayed decompression for traumatic cervical spinal cord injury: results of the Surgical Timing in Acute Spinal Cord Injury Study (STASCIS). PloS one. 2012; 7(2): e32037.
24. Spinal Cord Injury (SCI) Facts and Figures at a Glance. J Spinal Cord Med. 2016; 39(4): 243 – 244.
25. Hlaing T, Hollister L, Aaland M. Trauma registry data validation: essential for quality trauma care. J Trauma. 2006; 61(6): 1400 – 1407
26. Chamberlain JD, Meier S, Mader L, von Groote PM, Brinkhof MW. Mortality and longevity after a spinal cord injury: systematic review and meta-analysis. Neuroepidemiology. 2015; 44(3): 182 – 198.
27. Datta I, Findlay C, Kortbeek JB, Hameed SM. Evaluation of a regional trauma registry. Can J Surg. 2007; 50(3): 210 – 213.
28. Newgard CD. The Validity of Using Multiple Imputation for Missing Out-of-hospital Data in a State Trauma Registry. Acad Emerg Med. 2006; 13(3): 314 – 324.
29. McKenzie K, Walker S, Besenyei A, Aitken LM, Allison B. Assessing the concordance of trauma registry data and hospital records. HIM J. 2005; 34(1): 3 – 7.
30. Thibault-Halman G, Rivers CS, Bailey CS, Tsai EC, Drew B, Noonan VK, et al. Predicting recruitment feasibility for acute spinal cord injury clinical trials in Canada using national registry data. J Neurotrauma . 2017; 34(3): 599 – 606.

Supplement 1. NSCIR-IR Minimum Data Set – acute phase.

Category	Data Items
Identifiers and Demographic data	Hospital ID Patient ID National ID File Number Admission ID Passport ID Name Sex Age Birth date Marital status Education Job Nationality Province City Address Telephone
Admission	triage admission date triage admission time Emergency exit date Emergency exit time Ward admission Date Ward admission Time
Injury incident based on ICD codes	Timing to trauma Cause of trauma Position of the injured person Position seat (in traffic accidents) Type of accident Accident with Activity Place of trauma occurrence External cause of injury (ICD-10 codes) Safety devices Province event County event City event
Pre-hospital	Time and data related to EMS GCS at the scene of accident GCS in transit GCS at the time of delivery to the hospital Cardiac arrest CPR Intubation Immobilization
Emergency Department	Airway Primary respiratory assistance services SpO2 Pulse rate Respiration rate Blood Pressure Glasgow Coma Scale(GCS): ● Eye response ● Verbal response ● Motor response Mode of separation: ● Recovery ● Admission in the ward or ICU ● Transfer to the operating room ● Self-consent ● Referral ● Death
Co-morbidities and medical history	Cardiovascular disease Respiratory disease Smoking Other diseases

Co-existing injuries	Traumatic brain injury (TBI) Burn Fracture of extremities Injury or bleeding in internal organs
Neurological assessments based on standards neurological classification of SCI ASIA impairment scale	Motor Sensory: ● Pin Prick Score ● Light Touch Score Complete or Incomplete ASIA Impairment Scale (AIS)
Vertebra injury characteristics	Trauma type Number of injured vertebra Level of vertebra damaged Fractures type based on spinal fractures classification system – AOSpine Locket facet
Type of Spinal cord injury (SCI)	Type of (SCI)
Interventions	Non-surgical or Traction Timing to traction Traction weight Surgical intervention Timing to surgery Surgical approach Fusion-stabilization Corticosteroid administration
Complications	Complications: ● CSF fluid out of the wound ● Pressure ulcer ● Fever Cause of fever Ventilator use Total days of ventilator use Spasticity based on modified Ashworth scale Pain assessment using visual analogue scale (VAS) Urinary incontinence Bowel incontinence
Outcome	Duration of hospitalization in ICU Discharge date External immobilization Glasgow outcome score (GOS)

Supplement 2. Specialty and number of team members.

Specialty	National	International	Total
Anesthesiology	2	0	2
Biostatistics	2	0	2
Emergency Medicine	1	1	2
Epidemiology	1	1	2
General Practitioner	6	0	6
General Surgery	3	0	3
Health Information Management	1	0	1
Information Technology	3	0	3
Medical Rehabilitation	1	1	2
Neurosurgery	11	4	15
Nursing	1	0	1
Orthopedics	1	1	2
Psychiatry	2	0	2
Community Medicine	2	0	2
Total	**37**	**8**	**45**