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The Italian spine trauma registry: design and rationale of a prospective nationwide multicenter study on surgically treated spinal trauma

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Abstract

Study Design: Prospective multicenter observational cohort study

Objectives: To describe the design, rationale, and methodology of the first nationwide Italian registry dedicated to surgically treated spinal trauma, enabling standardized data collection and long-term outcome assessment.

Setting: 48 neurosurgical centers across Italy

Methods: Adult patients undergoing surgical treatment for traumatic spinal injuries are prospectively enrolled from 2025 to 2034. Data are collected via a secure digital platform, including demographics, injury characteristics, neurological status, surgical timing and technique, perioperative management, complications, rehabilitation, and Patient Reported Outcome for Spine Trauma (PROST). Follow-up occurs at 3, 12, and 24 months. Statistical analyses will include descriptive statistics, regression, multivariate, and time-to-event models.

Results: This manuscript outlines the registry's design, data collection infrastructure, variables, outcomes, and planned analyses. The first-year enrollment included 673 patients, with the majority presenting lumbar injuries and preserved neurological function. Early surgery (<48 h) was most frequent in subaxial cervical injuries. Surgical approaches and discharge pathways are described.

Conclusion: TVMit represents the first nationwide Italian registry for surgically treated spinal trauma, integrating standardized multicenter data collection with longitudinal follow-up and patient-reported outcomes. It provides a platform to inform clinical decision-making, support guideline development, optimize trauma networks, and enable predictive modeling.

Introduction

Traumatic injuries of the spinal column and spinal cord remain among the most challenging emergencies in neurosurgery. Spinal cord injury (SCI) carries high morbidity and mortality, frequently resulting in permanent neurological deficits, long-term disability, and a substantial socioeconomic burden on patients, families, and healthcare systems [1,2]. Although advances in surgical techniques, neurocritical care, and rehabilitation have improved outcomes, several aspects of spinal trauma management, including timing of surgery, decompression strategies, and perioperative interventions, remain controversial [3,4]. These clinical uncertainties are compounded by the limited availability of high-quality, prospective, multicenter data, resulting in reliance on local practices or retrospective studies [3,8].

Over the past two decades, national and international spine registries have provided valuable insights into elective spinal surgery, implant performance, and perioperative complications [5–7]. However, trauma-specific registries remain scarce, and existing datasets often fail to capture detailed neurological

recovery, rehabilitation outcomes, or long-term functional reintegration [8,9]. Moreover, follow-up beyond hospital discharge is frequently incomplete, limiting understanding of recovery trajectories over time.

Italy, despite a well-developed neurosurgical network, currently lacks a nationwide coordinated registry dedicated specifically to surgically treated spinal trauma and spinal cord injury. The absence of standardized national data prevents benchmarking between centers, limits the evaluation of trauma system performance, and hinders the development of evidence-based guidelines tailored to real clinical practice [6,7].

To address these limitations, the Spine and Spinal Cord Surgery Department of the University Hospital of Udine, in collaboration with the Spine Section of the Italian Society of Neurosurgery (Società Italiana di Neurochirurgia, SINch), established the Italian National Registry for Surgical Spinal Trauma (TVMit). This nationwide, prospective initiative aims to systematically collect standardized, practice-based data on patients undergoing surgical treatment for traumatic spinal injuries, providing a robust foundation for clinical practice, research, and health policy development [5–7].

Alignment with the International Spinal Cord Injury (SCI) Core Data Set ensures methodological comparability with international registries, enabling cross-country analyses and contributing to global benchmarking and best practice development in spinal trauma care.

Methods

Study Design

The Italian Spine Trauma Registry (TVMit) is a prospective, multicenter, observational cohort study designed to provide a comprehensive, longitudinal evaluation of adult patients undergoing surgical treatment for traumatic spinal column and/or spinal cord injuries. This initiative is coordinated by the Spine and Spinal Cord Surgery Department of the University Hospital of Udine in collaboration with the Spine Section of the Italian Society of Neurosurgery (SINch). By involving 48 neurosurgical centers across Italy, the registry captures a broad spectrum of clinical practice, from highly specialized academic referral centers to regional hospitals, reflecting routine clinical variability in patient management.

Enrollment is planned from January 2025 to December 2034, with interim analyses every three years to allow early identification of trends, facilitate timely feedback to participating centers, and support rapid dissemination of findings. Data are collected through a secure, centralized digital platform, designed to support standardized entry, real-time validation, and longitudinal follow-up. This infrastructure ensures consistent, high-quality data capture and allows integration of clinical, surgical, imaging, and patient-reported outcomes.

Prior to study initiation, the coordinating center undertook an extensive preparatory phase dedicated to the development of the full study protocol, regulatory documentation, data protection procedures, and standardized data collection tools required for ethical submission. The study protocol was submitted to

the Regional Centralized Ethics Committee (Comitato Etico Unico Regionale, CEUR), which conducted a formal review and granted approval following clarification of specific methodological and organizational aspects. After resolution of these comments, final authorization was obtained and the study was formally initiated.

Study Population

Inclusion criteria comprise adults (≥16 years) presenting with traumatic spinal column and/or spinal cord injuries who undergo surgical intervention, either urgent or delayed, at a participating center. Participants must be available for structured follow-up assessments; patients who die prior to postoperative evaluation are also included to ensure comprehensive assessment of perioperative mortality and outcome patterns.

Exclusion criteria include non-operative management, neoplastic fractures, insufficient baseline or perioperative data, and refusal or withdrawal of informed consent.

This comprehensive approach ensures that the registry captures the full spectrum of surgically treated patients, including those at high risk, thereby enhancing the generalizability and clinical relevance of the findings.

Data Collection

The registry collects detailed, standardized data across multiple domains to enable comprehensive analyses of patient characteristics, interventions, and outcomes.

Baseline variables include demographics, comorbidities, injury mechanism, anatomical level, and radiological severity, forming the basis for risk stratification and comparative analyses. Neurological status is assessed pre- and postoperatively using the ASIA Impairment Scale (AIS) and Medical Research Council (MRC) scale at baseline and predefined follow-up intervals, allowing longitudinal evaluation of motor and sensory recovery.

Surgical details include timing of intervention, surgical approach, and stabilization techniques, enabling comparison of operative strategies and functional outcomes. Perioperative variables include ICU admission, corticosteroid therapy, and rehabilitation planning to assess their influence on recovery.

Follow-up at 3, 12, and 24 months records neurological status, complications, reoperations, imaging findings, Patient Reported Outcome for Spine Trauma (PROST), functional independence, and return-to-work. Retention is supported through structured reminders, telemedicine consultations, and centralized coordination to ensure long-term follow-up.

Study Phases

The registry is implemented in four sequential but overlapping phases:

- Preparatory Phase (2022–2024): standardization of definitions, pilot testing of electronic forms, platform deployment, governance structure setup, and preparation and submission of regulatory documentation required to obtain approval from the Regional Centralized Ethics Committee (CEUR).
- Enrollment and Data Collection Phase (2025–2034): prospective recruitment, standardized data capture, and interim analyses every three years.
- Follow-Up Continuation Phase (2034–2036): completion of 24-month outcomes for all enrolled patients.
- Analysis and Dissemination Phase (2025–2036): comprehensive analyses, preparation of peer-reviewed publications, presentations at national and international conferences, and institutional reporting.

A schematic diagram (Fig. 1) illustrates the conceptual framework of the registry, the patient pathway, data flow, and feedback cycle from clinical care to benchmarking and guideline development.

Outcomes

The primary outcome is the proportion of patients achieving neurological improvement at 24 months, defined as at least a one-grade improvement on the ASIA Impairment Scale (AIS) or the Medical Research Council (MRC) scale. Secondary outcomes include neurological recovery at 3 and 12 months, perioperative complications and reoperation rates, functional independence, return to work, mortality, and the influence of surgical timing and perioperative management on clinical outcomes.

This comprehensive outcome framework enables evaluation of both functional recovery and safety across diverse patient populations.

Statistical Methods and Control of Confounding Factors

Continuous variables will be summarized as means ± standard deviations or medians with interquartile ranges, and categorical variables as frequencies. Normality will be assessed using the Shapiro–Wilk test. Group comparisons will be performed using the chi-square or Fisher's exact test for categorical variables and the independent samples t-test or Wilcoxon–Mann–Whitney test for continuous variables, as appropriate. Univariable and multivariable logistic regression analyses will identify factors associated with clinically relevant neurological or functional improvement at T3, T12, and T24. Statistical significance will be set at $p < 0.05$. Analyses will be conducted using SAS Enterprise Guide 7.1, with alternative models applied if required by data distribution or regression assumptions.

Governance, Ethics, and Data Protection

To enhance the global relevance of findings, the registry aligns with the International SCI Core Data Set [8, 9], allowing standardized reporting of AIS conversion, complication rates, functional recovery, and mortality. This framework supports cross-country benchmarking, international collaboration, and identification of best practices in spinal trauma care.

The registry ensures data quality through continuous local verification and centralized oversight by the Principal Investigator, supported by regular audits and standardized assessment protocols to maintain consistency across centers. Communication among investigators is facilitated through a dedicated group platform. The registry complies with General Data Protection Regulations (GDPR), with pseudo-anonymized data securely stored and accessible only to authorized personnel. Written informed consent is obtained from all participants, and participation does not modify standard clinical care.

Funding

This is a physician-initiated and investigator-led study conducted without external funding. It is supported by the professional commitment of participating centers and embedded within routine clinical practice.

First-year population characteristics

During the first year, 673 patients were enrolled (Tables 1 and 2).

Lumbar injuries (L1–L5) were the most frequent (46.2%), followed by thoracic (T1–T12, 30.6%), subaxial cervical (C3–C7, 15.0%), and upper cervical (C0–C2, 8.0%) levels. Overall, most patients presented with preserved neurological function (AIS E); however, patients with subaxial cervical injuries (C3–C7) showed a higher proportion of severe neurological impairment (AIS A–B, 25.7%) compared with thoracic (12.1%), lumbar (2.9%), and upper cervical injuries (1.9%).

Regarding surgical timing, early intervention within 48 hours was more frequent in subaxial cervical injuries (46.5%) compared with upper cervical (9.3%), thoracic (16.5%), and lumbar cases (19.6%). Planned procedures, performed after 72 hours, were more common in thoracic (73.8%) and lumbar injuries (68.8%), as well as in upper cervical trauma (74.1%), whereas they accounted for 38.6% of subaxial cervical cases.

The posterior approach was predominant in upper cervical (85.2%), thoracic (91.3%), and lumbar injuries (88.1%). In contrast, in subaxial cervical trauma, anterior (41.6%), posterior (29.7%), and combined approaches (28.7%) were distributed in nearly equivalent proportions.

Most patients were discharged home, while a minority required rehabilitation or extended care facilities.

Discussion

A principal strength of TVMit is its prospective, nationwide, multicenter design, which enhances both methodological rigor and external validity. In spinal cord injury (SCI), much of the existing evidence derives from retrospective cohorts or single-center experiences, frequently limited by incomplete data capture, selection bias, and heterogeneous follow-up intervals [1–3]. Prospective registries have been recognized as essential tools in conditions where randomized controlled trials are challenging due to ethical constraints and injury heterogeneity [4]. By enrolling patients consecutively across 48 centers,

TVMit reduces referral bias and reflects contemporary surgical practice, thereby improving generalizability while preserving standardized data collection.

Another major strength is the focus on surgically treated spinal trauma, allowing detailed evaluation of operative strategies in a population where decision-making remains controversial. Although early decompression is widely advocated following the STASCIS study [5] and subsequent meta-analyses [6], important uncertainties persist regarding optimal timing thresholds, patient selection in incomplete injuries, and the influence of surgical approach. Furthermore, debates continue regarding the role of adjunctive therapies such as high-dose methylprednisolone, whose benefit-risk profile remains contested despite historical NASCIS trials [10, 11,12]. A prospective national registry capturing granular surgical and perioperative data offers a unique opportunity to evaluate these issues in a routine clinical setting beyond the constraints of randomized protocols.

The integration of standardized neurological assessment with Patient Reported Outcome for Spine Trauma (PROST) [13, 14] represents a further methodological advancement. Neurological grading using the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) and AIS remains fundamental for impairment quantification [15]. However, neurological recovery does not fully correlate with functional independence or quality of life [16]. Contemporary SCI research increasingly emphasizes multidimensional outcome frameworks that incorporate autonomy, participation, and psychosocial recovery [17]. By combining objective neurological scales with patient-centered outcomes (PROST), TVMit aligns with value-based healthcare principles and provides a more comprehensive evaluation of long-term recovery.

The longitudinal follow-up structure (3, 12, and 24 months) constitutes another critical strength. Neurological and functional recovery after SCI is dynamic, with early improvements often occurring within the first months and later gains associated with rehabilitation and neuroplastic adaptation [18,19,20]. Many existing studies report short-term outcomes, limiting understanding of sustained functional trajectories. Serial assessments enable characterization of recovery patterns, differentiation between transient and durable improvements, and identification of early prognostic indicators. Such longitudinal data are essential for developing robust outcome prediction models and refining patient counseling strategies.

From an analytical perspective, TVMit provides a foundation for predictive modeling and data-driven clinical decision support. Recent work has demonstrated the potential of multivariable and machine-learning models to predict neurological and functional outcomes after SCI using clinical and imaging variables [21,22]. However, the reliability of such models depends heavily on large, high-quality prospective datasets. The structured architecture of TVMit — incorporating baseline injury characteristics, surgical parameters, complications, and longitudinal outcomes — creates a suitable infrastructure for precision-medicine approaches in spinal trauma care.

TVMit also strengthens the national and international research landscape. Established registries such as the Rick Hansen Spinal Cord Injury Registry (RHSCIR) [23] and the European Multicenter Study about

Spinal Cord Injury (EMSCI) [24] have demonstrated the scientific value of harmonized data collection and multicenter collaboration. By adopting standardized outcome measures and prospective methodology, TVMit positions Italy within this international framework, enabling cross-country benchmarking and contributing to the global harmonization of SCI research.

Finally, the registry has significant implications for health system governance and quality improvement [25]. Nationwide benchmarking allows identification of practice variation in surgical timing, approach selection, complication rates, and rehabilitation referral patterns. Reducing unwarranted variation is a recognized pathway toward improving healthcare quality and cost-effectiveness [26]. In this context, TVMit functions not only as a research instrument but also as a structured quality-assurance platform capable of informing national guidelines and optimizing resource allocation. Collectively, these strengths - prospective design, surgical specificity, multidimensional outcome integration, longitudinal follow-up, analytical scalability, and system-level impact - position TVMit as a transformative initiative in spinal trauma research. By bridging clinical practice, epidemiology, and predictive analytics, the registry has the potential to advance evidence generation and support more individualized, data-driven care for patients with spinal cord injury.

Nevertheless, registry-based studies inherently carry potential methodological limitations.

Selection bias may occur because only surgically treated patients admitted to neurosurgical centers are included, potentially underrepresenting milder injuries or patients managed conservatively. However, this design reflects the registry's specific aim of evaluating surgical decision-making and operative outcomes in spinal trauma [27].

Inter-center heterogeneity in surgical techniques, perioperative protocols, and rehabilitation pathways represents another limitation. Rather than a weakness, this variability also constitutes a strength of real-world registries, as it allows comparative effectiveness analyses across different clinical strategies. To mitigate this issue, standardized variable definitions, mandatory investigator training, and predefined outcome measures are implemented across all centers.

Missing data and loss to follow-up are recognized challenges in longitudinal registries. Multiple mitigation strategies have been incorporated, including reminders, centralized follow-up coordination, and telemedicine visits. In addition, real-time validation checks and centralized discrepancy queries aim to ensure data completeness and reliability.

Variability in neurological grading between evaluators and in fracture classification may introduce misclassification bias, affecting data consistency as well as the reproducibility of the study findings.

Finally, as an observational study, causal relationships between treatments and outcomes cannot be definitively established. However, multivariate analyses and large sample size will allow identification of independent predictors and generation of robust hypotheses for future clinical trials [28].

Conclusion

The Italian Spine Trauma Registry (TVMit) is the first nationwide prospective multicenter initiative in Italy dedicated to surgically treated spinal trauma and spinal cord injury. By combining standardized neurological assessments, longitudinal follow-up, and patient-centered outcomes, the registry provides a structured platform for real-world evidence generation.

Beyond descriptive epidemiology, TVMit enables benchmarking across centers, evaluation of clinical strategies, and identification of predictors of recovery and complications. Through alignment with international data standards, the registry also supports global collaboration and comparative analyses.

Ultimately, TVMit aims to inform clinical decision-making, improve quality of care, and guide health policy in spinal trauma management.

Declarations

Sponsorship: Physician-initiated and investigator-led study, supported by the Italian Society of Neurosurgery (SINch) and embedded in routine clinical practice.

CONFLICT OF INTEREST

The authors declare no conflicts of interest related to this work.

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Tables

Table 1. Baseline characteristics of the study population during the first year of enrollment (n = 673)

Variable		n	%
Age	Median (years)	60	
	Range (min–max)	16–88	
Sex	Male	402	59.7%
	Female	271	40.3%
Mechanism of Injury	Road traffic accident	198	29.4%
	Domestic accident	218	32.4%
	Fall from height	143	21.2%
	Sports injury	38	5.6%
	Suicide attempt	16	2.4%
	Other	60	8.9%
Polytrauma	No	452	67.2%
	Yes	221	32.8%
ICU Admission	No	564	83.8%
	Yes	109	16.2%
Spinal Level	C0–C2	54	8.0%
	C3–C7	101	15.0%
	T1–T12	206	30.6%
	L1–L5	311	46.2%
	Sacrum	1	0.1%

Table 2. Clinical, surgical, and discharge characteristics by spinal level in the study population during the first year of enrollment (n = 673).

		C0–C2 (n=54)	C3–C7 (n=101)	T1–T12 (n=206)	L1–L5 (n=311)	Sacrum (n=1)
AIS Grade	AIS A		15	23	5	
	AIS B	1	11	2	4	
	AIS C	2	15	8	10	
	AIS D	3	18	13	23	
	AIS E	48	42	160	269	1
NASCIS	Yes	3	21	11	7	
	No	51	80	195	304	1
Surg. Timing	0–24 hours	1	30	18	21	
	25–48 hours	4	17	16	40	
	49–72 hours	9	15	20	36	
	Planned (>72h)	40	39	152	214	1
Surg. Approach	Anterior	7	42		2	
	Posterior	46	30	188	274	1
	Combined		29	1	5	
	Other	1		17	30	
Discharge	Home	41	35	145	228	1
	Rehab. facility	7	37	42	53	
	Nursing home	3	2	1	4	
	To other ward	1	14	13	21	
	Other	1	9	5	5	
	Deceased	1	4			

Figures

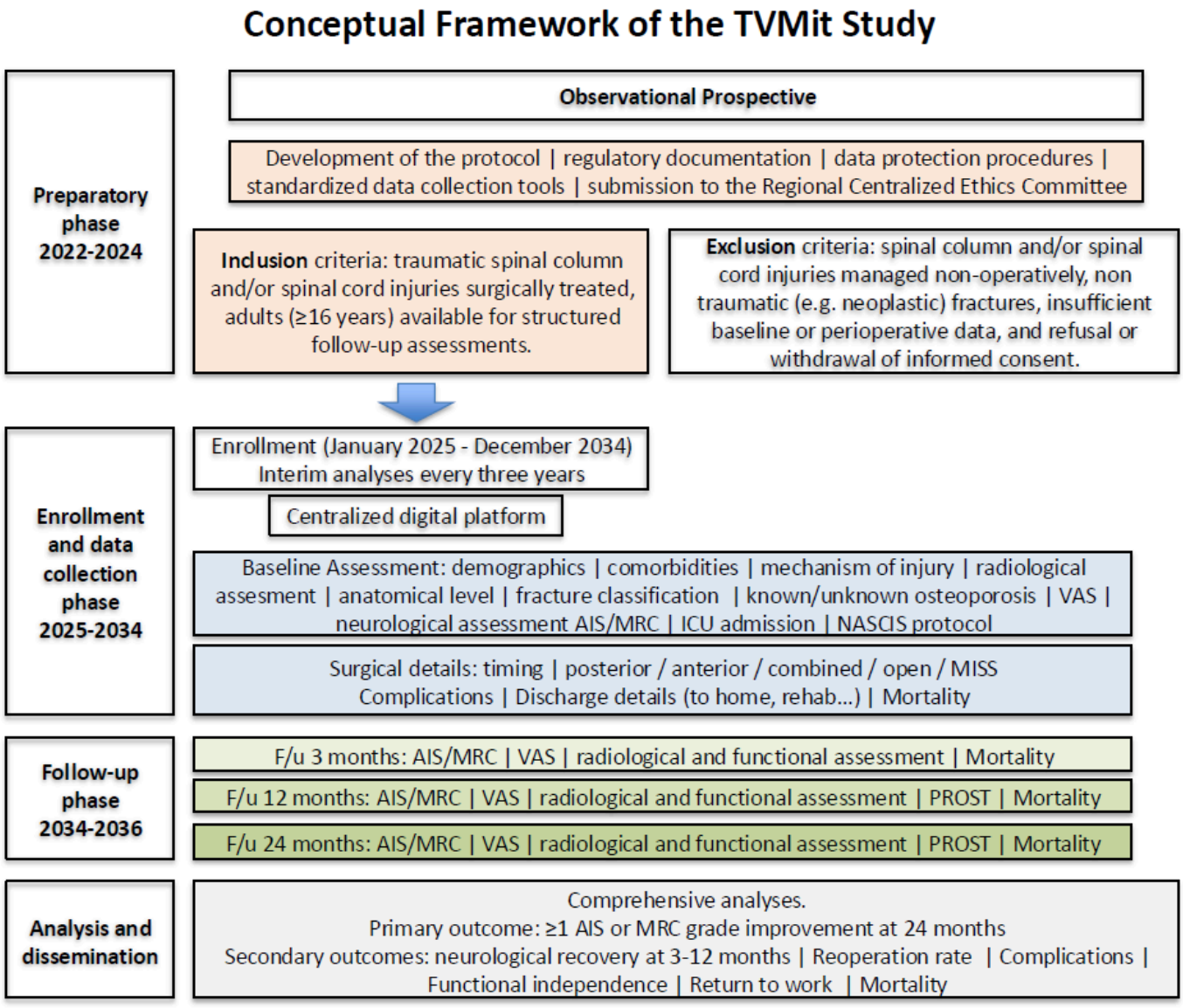


Figure 1

Conceptual framework of the Italian Spine Trauma Registry (TVMit), illustrating the patient pathway, data flow, and feedback cycle from clinical care to benchmarking and guideline development.