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AO SPINE Knowledge Forum Trauma

Understanding Decision Making as It Influences Treatment in Thoracolumbar Burst Fractures Without Neurological Deficit: Conceptual Framework and Methodology

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Abstract

Study Design: This paper presents a description of a conceptual framework and methodology that is applicable to the manuscripts that comprise this focus issue.

Objectives: Our goal is to present a conceptual framework which is relied upon to better understand the processes through which surgeons make therapeutic decisions around how to treat thoracolumbar burst fractures (TL) fractures.

Methods: We will describe the methodology used in the AO Spine TL A3/4 Study prospective observational study and how the radiographs collected for this study were utilized to study the relationships between various variables that factor into surgeon decision making.

Results: With 22 expert spine trauma surgeons analyzing the acute CT scans of 183 patients with TL fractures we were able to perform pairwise analyses, look at reliability and correlations between responses and develop frequency tables, and regression models to assess the relationships and interactions between variables. We also used machine learning to develop decision trees.

Conclusions: This paper outlines the overall methodological elements that are common to the subsequent papers in this focus issue.

Keywords

thoracolumbar, burst fractures, methodology, treatment recommendations

Introduction

Opinions of surgeons are divided regarding the role of surgery and non-surgical treatment for neurologically intact patients with thoraco-lumbar burst fractures (TL fractures).[1] With no consensus on optimal treatment for TL fractures there is wide variability in management of injuries that appear to be similar clinically and radiographically. Proponents of nonoperative management claim that all of these injuries can be managed nonoperatively.[2–4] Surgery is proposed to prevent deformity and speed recovery[1,2] Comparisons of surgical to non-surgical management of TL fractures have produced mixed results.[1,5–9]

The treatment of TL fractures is an example of 'clinical equipoise', which was defined by Freedman[10] in 1987 as "genuine uncertainty within the expert medical community–not necessarily on the part of the individual investigator–about the preferred treatment strategy". In the presence of equipoise, it is common in the surgical field to form "schools" based on convictions of clinical superiority among certain individual surgeons. In the treatment of TL fractures, both non-surgical and surgical schools have become well established in different centers or regions, with sufficient resources and clinical experience in support of both surgical and non-surgical interventional modalities. Surgeons in the surgical "schools" may be reluctant to treat patients in a non-surgical manner, whereas non-surgical "schools" may argue against the expense and invasiveness of surgery. With polarized opinions and sincere concern for patients receiving the most effective treatment, it has become difficult for surgeons to reach agreement on treatment strategies or to agree to randomization strategies.

Contributing to this clinical uncertainty is the very nature of TL fractures, which exhibit an infinite pattern of imaging characteristics in association with complex pathoanatomic disruption of the various components of the spinal column. This creates a scenario where categorizing these injuries in a way that would guide intervention is a complex task. Without agreement on the morphological characteristics that are relevant in determining the clinical trajectory of a specific injury, it is difficult to determine classification systems and to design studies to direct clinicians between surgical and nonoperative management. When classification systems exhibit low reliability and validity there is likely to be significant heterogeneity within each category of the classification and thus a resultant variability in the treatment of injuries between clinicians, between treatment centers and across various geographies.

The tremendous heterogeneity of TL fractures leads to difficulty in identifying those features of the injury that truly impact patient outcome and those that do not necessitate a specific mode of treatment to optimize the patients' outcome. Greater clarity in determining the features of a TL fracture that encourage a clinician to select a particular treatment approach is critical in achieving the goal of reduced variability in treatment while optimizing outcomes. Furthermore, there are likely to be specific characteristics related to training, geography and practice location of the clinician who decides on treatment that may influence the approach taken to manage these injuries.

It would seem to be beneficial to reduce the variability in treatment in an attempt to achieve optimal outcomes with minimal morbidity and risk. Understanding the surgeons' interpretation of radiographs, patient factors and use of classifications to guide treatment recommendations would be a necessary first step in achieving more consistent and optimal treatment for these injuries. The AO Spine thoracolumbar spine injury classification system is commonly used for the purpose of categorizing the morphology of an injury and guiding treatment.[11]

The goal of this paper is to describe the conceptual framework and methodology utilized in the subsequent papers in this focus issue. The conceptual framework utilizes an expert panel of spine surgeons to evaluate acute TL fracture CT scans and assess the morphology, classification and proposed treatment of these fractures. We endeavor to gain further understanding of the processes of therapeutic decision making for TL fractures. Specifically, our methodology will endeavor to analyze (1) radiographic imaging findings and elements of TL fracture morphology; (2) surgeon use of the AO Spine TL Classification and (3) physician and practice related factors and determine how these three elements lead the clinician to make certain treatment recommendations.

Methods

Research Questions

In general, the characteristics of TL fractures that determine inclusion in a specific category of classification can broadly be reduced to injury patterns to the anterior vertebral structures (disc and vertebral body and endplates) and injuries to the dorsal bony elements and posterior ligamentous complex (PLC). Given this, our first objective was to determine to what degree various patterns of injury contribute to inclusion in specific categories of the AO Spine thoracolumbar spine injury classification system and how reliable this process of classifying these fractures is in the hands of a panel of spine trauma experts. We also sought to assess which elements of the anterior and posterior column injury pattern and the resultant AO Spine thoracolumbar spine injury classification category contributed most to the clinicians' decisions to select either surgical or non-surgical treatment. Additionally, we analyzed which factors related to the surgeon's environment, practice and geographical location influence the decision to treat patients' surgically.

Finally, in paper 9 we endeavored to use these elements of the expert panel members assessment of radiographic parameters to create a predictive model that would provide an algorithm (using decision tree) of the elements related to surgical or non-operative decision making.

Data Sources

The methodology proposed here was made possible by the confluence of two opportunities. First of all, within the Spine TL A3/4 study [Clinical Trials.gov Identifier NCT02827214[12]], we collected the preoperative CT scan images of 183 patients with TL fractures that were recruited into this prospective observational study.

The second opportunity was the AO Spine Knowledge Forum Trauma (AOSKFT) which is composed of spine trauma thought leaders from around the world. We identified a group of 22 spine trauma experts from the AOSKFT to create a panel of experts who would be able to classify, analyze, and make treatment recommendations on the images from the 183 radiographic records from patients included in the Spine TL A3/4 study. The investigations based upon this panel of experts assessment of the radiographs of the 183 TL fracture records was performed with all investigators and participants agnostic to the actual real-world treatment the patients received and also agnostic to the outcome results of the Spine TL A3/4 study itself and comprises a series of investigations in this special issue of the Global Spine Journal that we refer to as "the Equipoise TL Fracture Study".

Patient Characteristics and Study Parameters of the Spine TL A3/4 Study

The AOSKFT completed recruitment for a prospective observational study of TL fractures; the Spine TL A3/4 study.[12] This study was designed and conducted by the Knowledge Forum Trauma of the AO Spine, an expert driven research study working group supported by the non-profit AO Foundation. The purpose and the design of the study was agreed upon by the steering committee of the Knowledge Forum and a CIP (Clinical Investigation Plan) was composed defining the study design, inclusion and exclusion criteria, the aims of the study and primary and secondary outcome measures. This was done in collaboration with AO ITC CE (AO Innovation Translation Center Clinical Evidence).

Participating study centres were selected based upon their access to sufficient cases regularly treated in the center, facilities for adequate imaging and follow up of the patients, proven capacity to conduct prospective studies, established IRB procedures, geographical diversity and diversity in treatment preferences.

From this study, we had available the baseline CT scans and plain radiographs of 183 patients who were recruited to participate in this study. All patients were neurologically intact and had injuries between T11 and L2 that met the inclusion criteria of:

- Skeletally mature, age 18 to 65 years old inclusive.
- Diagnosis of AO Spine type A3 and A4 fractures on a CT scan with or without a suspected PLC injury from T11 to L2. Fractures may have an associated (suspected) B injury but must have an A3 or A4 vertebral body fracture. This was to prevent selective exclusion knowing that distinction between A and B is not always reliable.
- TLICS Score between 2 and 5[13,14]
- Acute fracture – diagnosis and treatment within 10 days of injury.
- Ability to understand the content of the patient information/informed consent form.
- Willingness and ability to participate in the clinical investigation including imaging and follow-up procedures.

- Signed and dated Institutional Review Boards/Ethics Committees-approved written informed consent according to local legislations and applicable guidelines.

Excluded, were patients with:

- Severe systemic disease that would exclude the patient from surgery.
- Recent history of substance abuse (i.e. recreational drugs, alcohol) that would preclude reliable assessment.
- Pregnancy or women planning to conceive within the study period.
- Prisoner
- Participation in any medical device or medicinal product study within the previous month that could influence in opinion of the PI the results of the present study.
- Any neurological deficit associated with the fracture (N0).
- Spontaneous or low energy fractures due to pathologic processes (e.g. osteoporosis) or neoplasia.
- Head injuries causing inability to cooperate during hospital admission.
- Open or penetrating spinal lesion due to gun, stab, or projectile.
- Prior spinal surgeries in thoracic or lumbar spine.
- Additional musculoskeletal, head or other injuries which would preclude rapid mobilization.
- Multiple trauma or ISS > 16.
- Other co-morbidities precluding the patient to be considered as a surgical or non-surgical candidate such as: burns, dementia, BMI > 40, connective tissue disease, hemiplegia, diabetes with end-organ damage, leukemia, lymphoma, metastatic solid tumor and AIDS.

The surgical/non-surgical procedure(s)/study procedure(s) were per standard of care at each institution. The choice of treatment was at the discretion of the treating surgeon at the participating institution. The treatment selected by the treating surgeon in the Spine TL A3/4 study was not known to the expert assessors in the Equipoise study however the actual 'real world treatment' was available to be analyzed as a part of the Equipoise study analyses after the expert assessors had completed their assessments.

Non-surgical treatment is defined as bed rest if deemed necessary by the treating surgeon with or without following immobilization with any of the following techniques:

- Custom-molded or prefabricated total body contact thoracolumbosacral orthosis (TLSO)
- Thermoplastic removable brace
- Jewett hyperextension braces
- Anterior hyperextension brace (ASH)
- Taylor-Knight brace
- Plaster of Paris (POP)
- Other (any other non-surgical supportive measures, such as pain medication, physiotherapy, observation only with or without prescribed bed rest period etc.)

Surgical Treatment included any of the following approaches as chosen by the treating surgeon:

- Open short segment surgical fixation (1 level above and below the fracture level) with or without posterior decompression
- Open long segment posterior fixation (2 or more levels above, 2 or more levels below) with or without posterior decompression
- Posterior short or long fixation with posterolateral corpectomy and reconstruction
- Anterior alone instrumentation
- Combined AP instrumentation
- Percutaneous posterior fixation combined with anterior instrumentation
- Percutaneous posterior fixation with or without vertebroplasty

Enrollment of Participants

The 22 participating Spine Trauma experts were recruited from within the membership of the AOSKFT. Membership in the AOSKFT is proposed upon review of each surgeon's curriculum vitae and must include a demonstrated clinical and academic interest in spine trauma care. The expert panel included surgeons that were representative of a variety of geographic regions and reflected a heterogeneity in training backgrounds as well as patterns of clinical practice. The expert panel represented North/South America, Europe, and Asia (including India). All members of the expert panel had extensive experience in managing TL fractures. Eight Expert Panel members represented sites that recruited patients to the Spine TL A3/4 study.

In the Spine TL A3/4 study, imaging was performed at time intervals reflecting local standard of care. A baseline CT scan was mandatory, while baseline plain radiographs were optional. MRI was optional and was collected if performed due to clinical indication. These radiographic images on the patient were available and used for the analyses included in this focus issue. DICOM images which could be viewed as axial, sagittal and coronal reformatted images were provided to the Expert Panel assessors.

Focus Issue Methodology

A total of 22 members of the AOSKFT were provided DICOM images of the CT Scan, and plain radiographs from the time of injury prior to treatment decision. The expert trauma clinicians were agnostic to the actual treatment that the patient received within the Spine TL A3/4 study and were also agnostic to any preliminary results of the Spine TL A3/4 study results. The expert trauma clinicians were asked about several radiographic characteristics of each injury and then were asked to

classify each injury based on the AO Spine Thoracolumbar Injury Classification System. Finally, they were asked to recommend treatment – either surgical or non-operative, and type of treatment.

For each of the 183 cases with radiographs, each expert assessor was asked to complete the questionnaire in Figure 1.

For radiographic features of the injury such as vertebral body comminution, each expert was asked to grade the degree of comminution from 0 to 100 with 0 representing intact vertebral body and 100 representing complete disruption. For Posterior ligamentous complex (PLC), each expert was asked to quantify how certain they were about the PLC being disrupted from 0 to 100 with 0 reflecting a completely intact PLC and 100 representing complete disruption.

When recommending either surgical or non-operative treatment, the experts were similarly asked to grade their certainty of the need for specific treatment with 0 representing high certainty that non-operative management is necessary while 100% represented absolute certainty that surgical treatment should be recommended.

Questionnaire to 22 Expert Reviewers to Identify Influence of Surgeon Factors

To assess the influence of non-clinical factors on decision making in thoracolumbar burst fractures, a survey was sent to all 22 expert reviewers and site Principal investigators (N = 14) of the Spine TL A3/4 study. From the 14 site investigators, 8 participated in the expert review panel. Therefore, the survey was sent to 28 participants in total with 26 participants returning the completed survey. Two participants did not complete the survey. The survey was constructed using REDCapTM (Version 6.5.4) and was divided into 2 sections to help understand: (1) what practice environment and training background factors led to choosing either surgical or nonoperative management, and (2) what radiographic factors influence treatment decision. All partial or complete responses were included in the analysis.

Statistical Analyses

Frequency tables were produced for the distribution of each injury type for each member of the expert panel. Fleiss Multi-rater Kappa scores were produced for analyzing the agreement of all expert panel raters for both injury classification and treatment. Inter class correlation coefficients (ICC) were produced as a measure of reliability whenever data were continuous or ordinal. Cross tabulation comparing various factors in reference to surgical or non-surgical treatment was analyzed with a Pearson Chi-Square test. T-test and Analysis of Variance (ANOVA) were used for comparing groups. For not normally distributed data Mann-Whitney U Tests and Levene's Test for Equality of Variances was used.

Regression models were performed to assess the influence of variables on recommending surgical treatment. A receiver

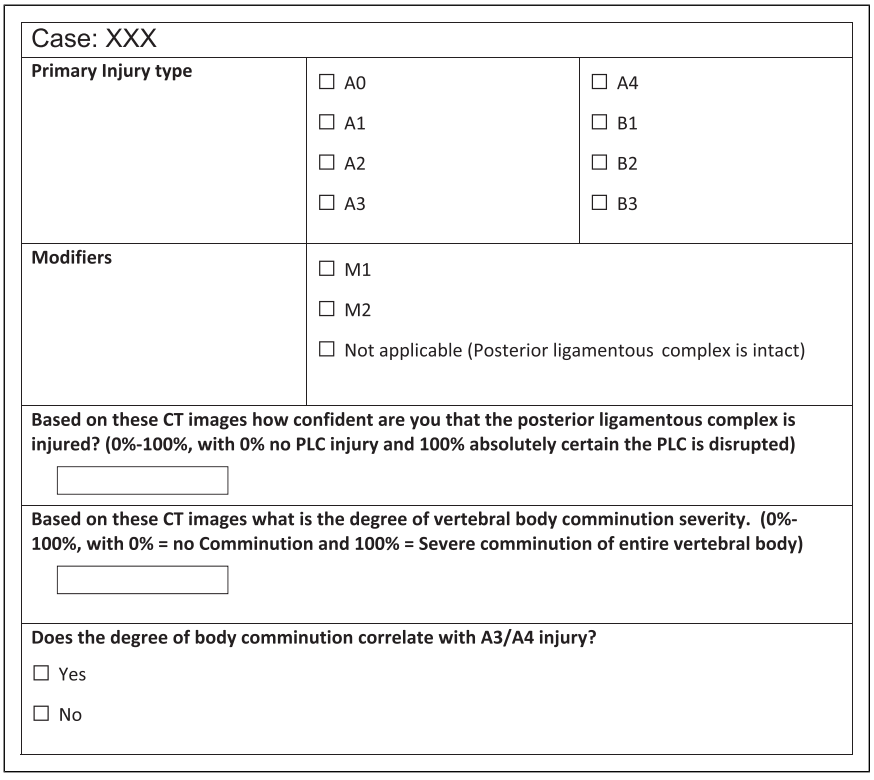

Figure 1. Radiographic evaluation and treatment decision questionnaire.

Assuming normal neurology and no other co-morbidities or injuries and based on these CT images, what treatment are you most likely to recommend?

Case: XXX

Please specify your treatment recommendation for this patient	☐ Surgical ☐ Non-surgical
If you have selected non-surgical, please specify the recommended **non-surgical** intervention for this patient	Bed rest followed by Immobilization with: ☐ Custom-molded or prefabricated total body contact thoracolumbosacral orthosis (TLSO) ☐ Thermoplastic removable brace ☐ Jewett hyperextension braces ☐ Anterior hyperextension brace (ASH) ☐ Taylor-Knight brace ☐ Plaster of Paris (POP) ☐ Other (any other non-surgical supportive measures, such as pain medication, physiotherapy, observation only with or without prescribed bed rest period etc.)
If you have selected surgical, please specify the recommended **surgical** intervention for this patient	☐ Open short segment surgical fixation (1 level above and below the fracture level) with or without posterior decompression ☐ Open long segment posterior fixation (2 or more levels above, 2 or more levels below) with or without posterior decompression ☐ Posterior short or long fixation with posterolateral corpectomy and reconstruction ☐ Anterior alone instrumentation ☐ Combined AP instrumentation ☐ Percutaneous posterior fixation combined with anterior instrumentation ☐ Percutaneous posterior fixation with or without vertebroplasty Intact ☐ Other ☐ Please specify what treatment would you recommend for this patient
Based on these CT images, normal neurology, and no other injuries or comorbidities, how strongly do you feel that this patient should be treated surgically? (0%-100%, with 0% = surgically is absolutely not necessary and 100% = patient must be treated surgically)	

Figure 1. Continued.

operating characteristic curve, or ROC curve, was utilized to assess the thresholds at which various factors lead to the recommendation for surgical treatment. A type of machine learning method known as regression trees was developed for paper 9.

Survey Results

Joint distributions of the recommended treatment proposed by the expert panel and the actual real-world surgeons' treatment were analyzed. Associations of various imaging characteristics (comminution, PLC status, and treatment recommendations were analyzed through a process of linear regression analysis and development of predictive modeling equations.

We also employed multivariable logistic regression model for making predictive models whenever it was necessary.

Results

The next seven papers in this focus issue will highlight the results of these analyses. The final paper will summarize next

steps and how these findings can be applied to the primary study results from the Spine TL A3/4 study.

The conceptual framework we are proposing begins with the surgeons' analysis of elements of injury visible morphologically on the CT scan taken acutely at the time of injury. The surgeon will identify features of vertebral body disruption or comminution and then will also infer the degree of integrity of posterior ligamentous and bony structures that comprise the PLC. Once the surgeon assesses the degree of morphological injury on the CT scan, the surgeon can then categorize the injury pattern based upon the features of a AO Spine B-type injury or an A4 or A3 injury. This classification system is meant to create comparable categories of injury severity and to guide treatment. Influencing the surgeons' treatment decision is his/her background, education, experience, resources and the geographic area in which the surgeon trained and is practicing. Finally, for both surgical and non-surgical care there is a determination of the optimal specific technique and elements of care that often are quite standardized at each centre, but vary widely across geographies.

Discussion

Prospective randomized clinical trials (PRCTs) have been widely recommended for assessing the efficacy and safety of therapeutic interventions in medical practice and form the basis of modern Evidence Based Medicine.[15] When considering surgical and non-surgical care in acute spine trauma patients, PRCTs suffer from difficulty standardizing both surgical and, more so, non-surgical interventions, patient recruitment and preference, as well as identifying surgeons who have true equipoise regarding the 2 treatments.[16] Observational cohort studies with strict inclusion and exclusion criteria and incorporation of many design principles of RCTs have been shown to demonstrate magnitudes of treatment effects similar to RCTs.[17,18] With respect to acute TL fractures, no definitive answer exists as to whether surgery or non-surgical treatment is best at returning patients to full function.

The concept of using clinical equipoise as an inclusion criterion in comparative studies has been introduced by Stadhouer et al.[19–21] We offer here an outline of the methodology that we have used in the papers in this focus issue that endeavors to determine to what extent surgical decision making is guided by objective morphological fracture characteristics and to what degree it reflects true equipoise. By better understanding the process of decision making, this Equipoise analysis will improve the prognostic effectiveness of the radiographic variables of these often-heterogeneous injuries.[22,23]

Given the fact that there is no definitive answer to the clinical question of how best to treat TL fractures, it is likely that individual investigators hold strong treatment preferences that are often based on their training or local practice patterns. We chose to use an expert panel to establish the validity and reliability of various radiographic parameters and how they lead to specific classification elements and finally how they influence therapeutic decision making. In many cases, both the interpretation of radiographic variables as well as the resultant clinical decision making is controversial and various treatments (surgical and nonsurgical) can be defended. In these situations, the preference of patients and surgeons can guide treatment decisions.

Based on the insights in the subsequent papers, it might be possible to identify improvements that could be made to the process of radiographic analysis as well as the process of classification such as new machine learning protocols. The degree to which various morphological characteristics influence decision making could be used to improve guidance in management of these patients. The work done in this preliminary Equipoise study can also be applied to the treatment outcomes in the broader Spine TL A3/4 study. Our ultimate goal is to provide the clinician with a predictable way of using radiographic observations to guide patient treatment to the optimal outcome at the lowest level of risk of adverse events and the lowest costs.

While the present study provides useful insight into a new methodology, its findings should be interpreted within the context of the study design. Expert panelists as a group may have clinical equipoise whereas an individual clinician is likely to have a preference for a particular therapeutic approach. We specifically benefit from the wide geographic heterogeneity in the membership of the AOSKFT which ensures that preferences are likely balanced among the overall panel with experts having varied international training background and having comparable expertise in both treatment options being evaluated representing real world clinicians. However, some regions may be more represented than others or some subregions may not be represented. The AOSKFT's goal is create opportunity for world collaboration and future efforts will continue to better global representation.

Conclusion

This report provides an outline of the methodology used in the subsequent papers in this focus issue. This is based upon the known clinical equipoise among surgeons and relies on an expert panel's assessment of a large cohort of prospectively recruited study participants in the prospective evaluation of the treatment of thoracolumbar burst fractures. This methodology will enhance our ability to conduct high quality comparative studies. Understanding the conceptual framework within which surgeons and other clinicians base therapeutic decisions is critical in reducing variability in care and achieving optimal outcomes for patients. Future studies will present comparative results using this methodology.

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