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Clinical Study

Orthosis versus no orthosis for the treatment of thoracolumbar burst fractures without neurologic injury: a multicenter prospective randomized equivalence trial

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Abstract

BACKGROUND CONTEXT: Thoracolumbar burst fractures have good outcomes when treated with early ambulation and orthosis (TLSO). If equally good outcomes could be achieved with early ambulation and no brace, resource utilization would be decreased, especially in developing countries where prolonged bed rest is the default option because bracing is not available or affordable.
PURPOSE: To determine whether TLSO is equivalent to no orthosis (NO) in the treatment of acute AO Type A3 thoracolumbar burst fractures with respect to their functional outcome at 3 months.
STUDY DESIGN: A multicentre, randomized, nonblinded equivalence trial involving three Canadian tertiary spine centers. Enrollment began in 2002 and 2-year follow-up was completed in 2011.
PATIENT SAMPLE: Inclusion criteria included AO-A3 burst fractures between T11 and L3, skeletally mature and older than 60 years, 72 hours from their injury, kyphotic deformity lower than 35°, no neurologic deficit. One hundred ten patients were assessed for eligibility for the study; 14 patients were not recruited because they resided outside the country (3), refused participation (8), or were not consented before independent ambulation (3).
OUTCOME MEASURES: Roland Morris Disability Questionnaire score (RMDQ) assessed at 3 months postinjury. The equivalence margin was set at $\delta=5$ points.
METHODS: The NO group was encouraged to ambulate immediately with bending restrictions for 8 weeks. The TLSO group ambulated when the brace was available and weaned from the brace after 8 to 10 weeks. The following competitive grants supported this work: VHHSC Interdisciplinary Research Grant, Zimmer/University of British Columbia Research Fund, and Hip Hip Hooray Research Grant. Aspen Medical provided the TLSOs used in this study. The authors have

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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no financial or personal relationships that could inappropriately influence this work.
RESULTS: Forty-seven patients were enrolled into the TLSO group and 49 patients into the NO group. Forty-six participants per group were available for the primary outcome. The RMDQ score at 3 months postinjury was 6.8±5.4 (standard deviation [SD]) for the TLSO group and 7.7±6.0 (SD) in the NO group. The 95% confidence interval (−1.5 to 3.2) was within the predetermined margin of equivalence. Six patients required surgical stabilization, five of them before initial discharge.
CONCLUSIONS: Treating these fractures using early ambulation without a brace avoids the cost and patient deconditioning associated with a brace and complications and costs associated with long-term bed rest if a TLSO or body cast is not available.

Keywords: Thoracolumbar burst fracture; Orthosis; Brace; Functional outcome; Equivalence trial

Introduction

Burst fractures of the thoracolumbar spine without neurologic deficit are a relatively common injury [1]. A burst fracture results from a compression load without associated shear, rotation, or translational injury [1,2]. Treatment is controversial because there is generally an equivalence between operative and nonoperative treatments with respect to pain, function, and return to work status [3,4]. Nonoperative treatment has evolved from 6 to 12 weeks bed rest in hospital, to mobilization in a body cast, and currently to early mobilization using ''off-the-shelf'' adjustable thoracolumbosacral orthosis (TLSO) [5–12]. The latter approach has the advantage of maintaining a successful treatment outcome, while decreasing hospital stay and associated costs and facilitating rehabilitation and earlier functional recovery. The evolution toward less restrictive treatment protocols suggests that the thoracolumbar burst fracture is inherently stable.

Unfortunately, early mobilization is hindered for some patients without an access to a TLSO (or body cast) as a result of socioeconomic or geographic restraint, along with treatment bias. Anecdotal and lower level evidences suggest this fracture is stable enough to allow early mobilization without any external prosthesis [10,13–15]. Verification that such an approach is both safe and effective would probably reduce resource utilization and enhance patient reactivation. Such a finding would have significant ramifications to patients and hospitals without access to braces, such as those in developing countries where 6 to 12 weeks in bed is the current practice.

The purpose of this trial was to compare the functional and quality of life outcomes in patients 3 months post thoracolumbar burst fracture treated either with or without a TLSO. We hypothesize that treatments will be equivalent in outcome and have thus, chosen an equivalence study design. Secondary outcomes included quality of life and functional outcomes up to 2 years, patient satisfaction with treatment, and evaluation of potential prognostic variables.

Methods

Patients were recruited into this randomized controlled trial from three Canadian spine centers: Vancouver General Hospital, Vancouver, BC (2002–2009); Victoria Hospital, London, Ontario (2004–2009); and Foothills Hospital, Calgary, Alberta (2004–2006). Inclusion criteria were: isolated AO-A3 burst fracture between T10 and L3 with kyphotic deformity lower than 35°, neurologically intact, 16 to 60 years of age, and were recruited within 3 days of injury. An AO-A3 burst fracture has vertebral body compression with retropulsion of the posterior vertebral body into the canal and excludes posterior element injury. Exclusion criteria included patients who could not wear a brace (ie, pregnancy/body mass index more than 40), mobilized with or without a brace before recruitment, suffered a pathologic or open fracture, were alcohol or drug abusers, had previous injury or surgery to the thoracolumbar region, or were unable to complete the outcome questionnaires. At all sites, local medical research ethics board approval was obtained. The protocol was registered in the ClinicalTrials.gov protocol registration system, Identifier: NCT01741168.

A fellowship trained orthopedic or neurosurgical spine surgeon assessed eligibility and recruited patients for the study. Afterward participants were enrolled by the study coordinator and randomly assigned through 1:1 allocation to the TLSO or no orthosis (NO) treatment group based on a concealed, computer-generated, site-specific randomization list. The allocation was concealed from the recruiting surgeon before the randomization assignment. Subjects were stratified based on the workman's compensation status and the severity of kyphotic deformity (<20° vs. ≥21°) based on a supine lateral X-ray standardized to normal segmental sagittal angulations [16].

Patients in the TLSO group were maintained on strict bed rest until fitted with a TLSO (Aspen Medical Products, Irvine, CA, USA). The TLSO was provided at no charge. Participants were mobilized in the brace by a physiotherapist. The TLSO was required to be worn at all times except when lying flat in bed. All patients were instructed to wear the brace for a total of 10 weeks and to begin weaning from the brace at 8 weeks. Brace compliance was self-reported by the patient at the 2-, 6-, and 12-week follow-up visits. Patients randomized to the NO group were mobilized immediately as tolerated by a physiotherapist with restrictions to limit bending and rotating through their trunk. They were encouraged to return to normal activities after 8 weeks. Both treatment groups were placed under 90° hip flexion