ELSEVIER

CrossMark

The Spine Journal 15 (2015) 2157–2165

THE SPINE JOURNAL

Clinical Study

# Adverse events associated with fluoroscopically guided lumbosacral transforaminal epidural steroid injections

Christopher Plastaras, MD[a], Zachary L. McCormick, MD[b,*], Cynthia Garvan, PhD[c], Donald Macron, MD[d], Anand Joshi, MD[e], Gary Chimes, MD[f], Wesley Smeal, MD[g], Joshua Rittenberg, MD[h], David J. Kennedy, MD[i]

[a]*Department of PM&R, University of Pennsylvania, 1800 Lombard Street, Philadelphia, PA, 19146, USA*
[b]*Department of Physical Medicine and Rehabilitation, Rehabilitation Institute of Chicago, McGaw Medical Center, Northwestern University Feinberg School of Medicine, 240 E. Huron St., Chicago, IL, 60611, USA*
[c]*College of Nursing, University of Florida, 1225 Center Drive Gainesville, FL 32610, USA*
[d]*Department of Neurological Surgery, Stony Brook Neurosciences Institute, 24 Research Way, Suite 200, East Setauket, NY 11733, USA*
[e]*Department of Orthopaedics, Duke University Medical Center, 200 Trent Dr, Durham, NC 27710, USA*
[f]*Lake Washington Sports and Spine, 1600 116th Avenue Northeast #206, Bellevue, WA 98004, USA*
[g]*Alegent Health Physical Medicine and Rehabilitation Clinic, 17021 Lakeside Hills Plaza Omaha, NE 68130, USA*
[h]*Department of Physical Medicine and Rehabilitation, Kaiser Permanente, 3701 Broadway, 5th floor, Oakland, CA 94611, USA*
[i]*Department of Orthopaedics, Stanford University, 450 Broadway Street Pavilion C, 4th Floor Redwood City, CA 94063, USA*

Received 15 April 2014; revised 3 April 2015; accepted 29 May 2015

**Abstract**

**BACKGROUND CONTEXT:** Although the types and incidence of adverse events (AEs) associated with transforaminal epidural steroid injection (TFESI) have been described, no study has used a systematic standardized questionnaire to solicit AEs from patients to capture an accurate range and incidence of complications.

**PURPOSE:** The aim was to systematically identify the types and incidence of AEs associated with TFESI. Additionally, this study evaluated demographic and clinical factors that may predict a higher risk of an AE.

**STUDY DESIGN/SETTING:** This was a retrospective cohort study from a multiphysician academic PM&R clinic.

**PATIENT SAMPLE:** Patients, aged 19 to 89, who underwent a fluoroscopically guided TFESI for lumbosacral radicular pain between 2004 and 2007 were included.

**OUTCOME MEASURES:** The relationship of AEs with gender, age, trainee presence, steroid type, preprocedure visual analog scale (VAS) pain score, systolic blood pressure, fluoroscopy time, and corticosteroid injectate volume was analyzed.

**METHODS:** Adverse event data were collected using a survey both immediately and at 24 to 72 hours after TFESI. Statistical analysis was performed using the chi-square, Fisher exact, or Wilcoxon rank sum two-sided tests. Logistic regression analysis was also performed. C.P. is the owner of Rehabilitation Institute of Chicago Physiatric Log & Analysis System computer software.

**RESULTS:** In 1,295 consecutive patients undergoing 2,025 TFESI procedures, immediate AEs and delayed AEs occurred after 182 (9.2%) and 305 (20.0%) injections, respectively. The most common immediate AEs were: vasovagal reaction (4.2%) and interrupted procedure from intravascular flow (1.7%). Common delayed AEs included: pain exacerbation (5.0%), injection site

FDA device/drug status: Not applicable.

Author disclosures: ***CP:*** Consulting: Senior Medical Consultant (Expense Reimbursement); TLG Associates (B); State of Pennsylvania (E). Speaking & Teaching Arrangements: Elite Rehabilitation Solutions, LLC (A), Oakstone Publishing (A); NASS (A); Europ Phys & Rehab Med Congress (Expense Reimbursement); Arcadia University (A). Other: Copyright ownership of RICPLAS software (nonfinancial). ***ZLM:*** Nothing to disclose. ***CG:*** Nothing to disclose. ***DM:*** Nothing to disclose. ***AJ:*** Nothing to disclose. ***GC:*** Nothing to disclose. ***WS:*** Nothing to disclose. ***JR:*** Nothing to disclose. ***DJK:*** Speaking and/or Teaching Arrangements: ISIS (A), NASS (A); Trips/Travel: ISIS (A), NASS (A); Board of Directors: ISIS (nonfinancial), AAP (nonfinancial).

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

* Corresponding author. Department of Physical Medicine and Rehabilitation, Rehabilitation Institute of Chicago, McGaw Medical Center, Northwestern University Feinberg School of Medicine, Chicago, IL, USA. Tel.: (510) 388-7084.

*E-mail address*: zmccormi@gmail.com (Z.L. McCormick)

http://dx.doi.org/10.1016/j.spinee.2015.05.034

soreness (3.9%), headache (3.9%), facial flushing/sweating (1.8%), and insomnia (1.6%). Significant associations were identified between AEs and gender, age, preprocedure VAS, steroid type, and fluoroscopy time. Trainee involvement in the procedure did not impact the complication rate. **CONCLUSIONS:** Fluoroscopically guided lumbosacral TFESI is associated with a similar rate of minor AEs both immediately and 24 to 72 hours after procedure that are typical of other axial corticosteroid injections. Permanent AEs were not found in this sample. The most common AEs associated with TFESI include vasovagal episodes, procedure interruption from intravascular flow, pain exacerbation, injection site soreness, headache, and insomnia. 

*Keywords:* Fluoroscopic injection; Transforaminal; Epidural; Complications; Adverse effects; Steroid injection

## Introduction

Lumbosacral radicular pain is commonly treated with epidural steroid injection [1]. Evidence is more robust for the efficacy of the transforaminal epidural injection approach compared with other routes of epidural steroid deposition in the treatment of lumbosacral radicular pain [2–10]. Complications reported in association with transforaminal epidural steroid injection (TFESI) include major events such as epidural or subdural hematoma, epidural abscess, discitis, and paraplegia (Kennedy et al., MacVicar et al.) [8,11], as well as minor temporary adverse events (AEs) such as vasovagal reaction, pain exacerbation, headache, and facial flushing [12–15]. Only Karaman et al. have studied the rate of AEs prospectively. In a cohort of 562 patients, these investigators found no major complications and an 11.5% rate of minor AEs [13]. This study design suffered from the lack of a standardized questionnaire or protocol to solicit AEs from patients. Consequently, this study did not capture the true range and incidence of minor AEs accurately, as only a limited range of minor AEs that are known to occur with corticosteroid injections were reported. Thus, the goal of the present study was to systematically identify the types and incidence of AEs associated with TFESI. Additionally, this study evaluated demographic and clinical factors associated with these AEs with the goal of providing clinicians with valuable information that will help predict which patients are at higher risk of experiencing an AE.

## Methods

The Northwestern University Institution Review Board approved this retrospective cohort study. Consecutive subjects were identified through electronic medical record review of all individuals seen at an urban, academic, physical medicine, and rehabilitation outpatient musculoskeletal and spine center. The study included all individuals, aged 18 to 89 who underwent at least one lumbosacral TFESI at this facility between March 8, 2004 and April 19, 2007. There were no exclusion criteria. Physicians board certified in physical medicine and rehabilitation with additional subspecialty board certification in either pain medicine or sports medicine ordered and performed all injections. A trainee in Physical Medicine and Rehabilitation residency or Sports Medicine fellowship performed injections in 47% of cases, as the study was performed at an academic teaching facility. The aforementioned attending physicians supervised and/or intervened on these injections to ensure adequate technique. The indication for a lumbosacral TFESI in this practice was a clinical history consistent with radicular pain, corroborated with magnetic resonance imaging (MRI) findings of radiographic pathology at the level identified clinically. Although there is an inherent false positive rate of symptomatic pathology associated with MRI imaging of the lumbar spine [16,17], corroboration of clinical symptoms and MRI findings represents the current standard for diagnosing radicular pain [18]. An injection was performed only if an individual met these criteria, failed to respond to conservative treatment, and still had significant functional limitations. The specific level chosen for injection was based primarily on clinical history with imaging as supportive, not independently definitive, additional data.

All injections were performed using the subpedicular transforaminal technique [19]. The patient was placed in a prone position, and the skin was prepped with sterile technique. The fluoroscope was positioned appropriately to provide an oblique view of the subpedicular space. The skin and soft tissue were anesthetized using 1% lidocaine (preservative free). A sterile 22-gauge 3.5-, 5-, or 7-inch spinal needle was then advanced to the superior aspect of the neural foramen above the exiting spinal nerve. Anterior-posterior, oblique, and lateral fluoroscopic views were obtained to confirm accurate needle placement. Subsequently, 1 to 2 mL of Isovue 300 contrast (Bracco Diagnostics Inc., Monroe Township, NJ, USA) was injected through microbore tubing under live fluoroscopy. If intravenous uptake occurred, the needle was repositioned until intravenous uptake was absent and an epidural flow pattern was achieved. If intra-arterial, intrathecal, or intradiscal flow was identified, the procedure was aborted. Then, 1.5 to 2 mL of 1% lidocaine was injected as an anesthetic test dose; and if no AEs were noted after waiting 1 to 2 minutes, 1 to 2 mL of corticosteroid (betamethasone 6 mg/mL or