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Clinical Studies

Complications associated with single-level transforaminal lumbar interbody fusion

Jeffrey A. Rihn, MD[a,*], Ravi Patel, BS[b], Junaid Makda, MD[a], Joseph Hong, MD[a], David G. Anderson, MD[a], Alexander R. Vaccaro, MD, PhD[a], Alan S. Hilibrand, MD[a], Todd J. Albert, MD[a]

[a]*Department of Orthopaedic Surgery, The Rothman Institute, Thomas Jefferson University Hospital, 925 Chestnut Street, Fifth Floor, Philadelphia, PA 19107, USA*

[b]*Thomas Jefferson Medical College, 1025 Walnut Street, Philadelphia, PA 19107, USA*

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Abstract

BACKGROUND CONTEXT: The transforaminal lumbar interbody fusion (TLIF) procedure has become an increasingly popular means of obtaining a circumferential fusion while avoiding the morbidity of the anterior approach. Concerns remain, however, regarding the clinical efficacy and safety of its use.

PURPOSE: The purpose of this study was to evaluate the complications of the single-level TLIF procedure. The difference in complications observed with the use of iliac crest autograft compared with rhBMP-2 will be assessed.

STUDY DESIGN: Retrospective cohort study; a review of complications.

METHODS: Patients who underwent a single-level TLIF between January 2004 to May 2007 with either autograft iliac crest or rhBMP-2 were identified. A retrospective review of these patients included operative reports, pre- and postoperative medical records, most recent postoperative dynamic and static lumbar radiographs, and computed tomography scans (when available).

RESULTS: A total of 130 patients met the study criteria; 119 patients were available for follow-up, with an average radiographic follow-up of 19.1 months and an average clinical follow-up of 27.6 months. Thirty-three patients received iliac crest autograft and 86 patients received rhBMP-2. Complications occurred in 40 of the 119 study patients (33.6%). The autograft group had a higher complication rate (45.5% vs. 29.1%), but the difference was not statistically significant ($p=.09$). Complications in the autograft group included persistent donor-site pain (30.3%), donor-site infection (3.1%), lumbar wound infection (6.1%), and postoperative radiculitis (3.0%). Complications in the rhBMP-2 group included postoperative radiculitis (14.0%), vertebral osteolysis (5.8%), ectopic bone formation (2.3%), and lumbar wound infection (3.5%). A hydrogel sealant (Duraseal; Confluent Surgical Inc., Waltham, MA, USA) was used in 37 out of 86 patients in the rhBMP-2 group. The use of this sealant decreased the rate of postoperative radiculitis in the rhBMP-2 group from 20.4% to 5.4% ($p=.047$). The radiographic nonunion rate at most recent follow-up was 3.0% in the autograft group and 3.5% ($p=.90$) in the rhBMP-2 group.

CONCLUSIONS: The most common complications in the autograft group were related to the donor site. The most common complication in the rhBMP-2 group was postoperative radiculitis, the incidence of which is reduced by the use of a hydrogel sealant.

Keywords: Complications; Transforaminal lumbar interbody fusion; TLIF; BMP; Bone morphogenetic protein

FDA drugs: not approved for this indication (rhBMP-2 and Duraseal [off-label use]).

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* Corresponding author. Tel.: (267) 339-3500; fax: (215) 503-0054.
E-mail address: jrihno16@yahoo.com (J.A. Rihn)

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EVIDENCE & METHODS

Context
Surgical manipulation, scarring, and bone formation near the dorsal root ganglion have been concerns when considering the TLIF procedure. The off-label use of rhBMP-2 in TLIF has become increasingly popular, though the effects of this technique, compared with autograft use, are not well studied.

Contribution
In this retrospective case series from one institution, the authors have found a relatively high complication rate using the TLIF technique, with specific complications associated with both rhBMP and autograft methods. Osteolysis and radiculitis rates in the rhBMP group (6% and 14%, respectively) are reported.

Implications
While TLIF technique is in some ways attractive, this study indicates adverse events are common. Operating through the foramen adjacent to sensory ganglion is associated with the risk of both direct intra-operative injury and the delayed radiculitis. The use of rhBMP in this area has additional unique problems, as noted in this study. The sobering complications reported in this study suggest the popularity of the TLIF, with or without rhBMP, may need reassessment and comparative studies evaluating competing strategies.

—The Editors

Introduction

The transforaminal lumbar interbody fusion (TLIF) procedure is traditionally performed with the use of iliac crest autograft. Although clinical success has been documented with iliac crest autograft, its use is not without consequence [1–3]. Approximately 2% to 3% of patients require reoperation at the donor site because of wound complications and/or infection and up to 58% of patients report persistent donor-site pain [3–6]. Because of the morbidity associated with iliac crest harvest, the ''off-label'' use of recombinant human bone morphogenetic protein type 2 (rhBMP-2) (InFuse; Medtronic Sofamor Danek, Memphis, TN, USA) in the TLIF procedure has become increasingly popular. Although several studies have demonstrated the successful use of rhBMP-2 for this indication [3,7–9] concerns remain regarding the safety of its use.

Prior studies have reported overall complication rates of up to 35% after the use of rhBMP-2 in the TLIF procedure [2,3,7,10,11]. These complications include pedicle screw malposition, interbody cage migration, hematoma, infection, CSF leak, transient and persistent nerve-related symptoms, heterotopic bone formation, and vertebral osteolysis.

Villavicencio et al. [7] reported a 12.7% (9/71 patients) incidence of postoperative neural injury after TLIF performed with rhBMP-2. Although most had resolution of their symptoms within 3 months, two of these patients had radiculopathy that persisted at most recent follow-up [7]. Potter et al. [2] in a retrospective study of 100 TLIF procedures performed with bone morphogenetic protein (BMP), reported a 7% incidence of postoperative transient radiculopathy. The most common nerve root affected was L5. Most cases resolved completely between 1 and 6 weeks postoperatively [2].

The use of rhBMP-2 for interbody fusion has raised concern for heterotopic bone formation in the epidural space. In a study by Paramore et al. [12], a canine model was used to investigate the effect of BMP that was intentionally placed into the subarachnoid space and fusion bed. At 16 weeks, new bone had developed in the subarachnoid space of all animals. Spinal cord compression and mild spinal stenosis were detected in all treated animals, but no clinical or pathological features of neurotoxicity were noted [12]. A recent study by Joseph and Rampersaud [13] assessed the incidence and clinical sequelae of heterotopic bone formation with the use of rhBMP-2 for posterior lumbar interbody fusion (PLIF) and TLIF. Heterotopic bone formation occurred in 20.8% with the use of BMP compared with 8.3% without the use of BMP. Despite the higher incidence, there does not seem to be any associated clinical sequelae [13]. Several past studies have demonstrated similar findings [3,12–15].

The reported rate of vertebral end plate resorption and osteolysis after TLIF using rhBMP-2 varies widely. This variability is likely because of differences in surgical technique, diagnostic imaging, and the definition of vertebral osteolysis used to make the diagnosis. A 2006 study by McClellan et al. [16] demonstrated vertebral bone resorption at 22 lumbar levels of the 32 reviewed by computed tomography (CT) scan (68.8%). The defects were characterized as severe in 31% (7 of 22), which were often associated with graft subsidence and loss of end plate integrity (5/7, 74%) [16]. Lewandrowski et al. [10] reported a 7.4% incidence (5 of 68) after single-level TLIF using cages and rhBMP-2. Each patient reported worsening back pain with variable radicular pain as early as 4 weeks and as late as 3 months from his or her date of surgery. The defects filled in spontaneously, and symptoms typically resolved within an additional 3 months of nonoperative care [10]. A study by Vaidya et al. [17] evaluating the complications with the use of rhBMP-2 in polyetheretherketone (PEEK) cages for interbody fusions noted an 82% (41/50) rate of lumbar end plate resorption. In this study, the diagnosis and extent of resorption was based on plain radiographic findings and even minor indistinctness of end