Cauda Equina Syndrome After a TLIF Resulting From Postoperative Expansion of a Hydrogel Dural Sealant

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Published online: 28 September 2011
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Abstract

Background DuraSeal™ (Covidien, Waltham, MA, USA), a hydrogel sealant, is primarily used as an adjunct to a dural repair. Its use has also been described to seal off an annulotomy after a transforaminal lumbar interbody fusion when recombinant human bone morphogenetic protein-2 (rhBMP-2) is used. This aids in the reduction of postoperative radiculitis caused by rhBMP-2. However, as a result of its hydrophilic properties, DuraSeal™ has the potential to swell, which could lead to compression of the thecal sac.

Case Description We report a 57-year-old woman who developed cauda equina after a transforaminal lumbar 47 interbody fusion (TLIF) procedure in which the expansion of the DuraSeal™ was believed to be the causative factor. The patient developed urinary retention, bowel incontinence, and paresthesias in the saddle region on postoperative Day 3. She underwent emergent exploration and decompression of the thecal sac. The gel-like DuraSeal™ material was causing significant compression of the thecal sac.

Literature Review Multiple reports have documented that DuraSeal™, used as an adjunct to dural repair, can swell leading to compression of the spinal cord and/or neural elements. Our case demonstrates the use of DuraSeal™ both over a site of a dural repair and over an annulotomy site, through which a TLIF was performed, is associated

with the risk of developing postoperative cauda equina syndrome as a result of swelling of the DuraSeal™.

Clinical Relevance Those using DuraSeal™ to seal off the annulotomy after a TLIF procedure performed with rhBMP-2 should use the product with an understanding of the potential postoperative swelling of the product and resulting neurologic sequela, particularly if DuraSeal™ is used concomitantly at the site of dural repair.

Introduction

DuraSeal™ (Covidien, Waltham, MA, USA) is a synthetic, hydrogel sealant approved by the FDA for use in the spine as an adjunct to dural repair [2]. It has also been used “off-label” in transforaminal lumbar interbody fusion (TLIF) surgery to seal off the annulotomy site and cover the exposed nerve root(s) when recombinant human bone morphogenetic protein-2 (rhBMP-2) is used. Postoperative radiculitis is a well-described complication when rhBMP-2 is used in TLIF surgery [3, 4, 8, 9, 11]. The use of DuraSeal™ in this “off-label” fashion has reportedly resulted in a decreased rate of radiculitis in the postoperative period [13].

The downside to using DuraSeal™ within the spinal canal is that it swells substantially after it is injected because it absorbs water (DuraSeal™ Product information FDA approval documentation, Confluent Surgical, 2005). We report a patient who developed cauda equina on postoperative Day 3 after a TLIF procedure in which the expansion of the DuraSeal™ was believed to be the causative factor.

Case Description

A healthy 57-year-old woman presented with severe low back pain and radiating right leg pain with associated

One or more of the authors (JR) has received funding from Medtronic Sofamor Danek Riddle Hospital/Rothman Institute, Media, PA, USA.

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numbness and tingling in the L5 nerve root distribution. The patient had undergone discectomy at L4-L5 approximately 20 years previously. Six months before presentation she had undergone a right-sided L4-L5 revision discectomy for symptoms similar to those before the initial discectomy. After revision surgery her symptoms completely resolved. However, similar symptoms returned 6 weeks before her current presentation. She denied any constitutional symptoms and denied any bowel or bladder dysfunction. On physical examination, she had a well-healed, nontender, posterior lumbar spine incision. Neurologic examination revealed $\frac{4}{5}$ motor strength in her right extensor hallucis longus (EHL) and decreased sensation to light touch and pin prick in the dorsum and lateral aspect of her right foot. She had a markedly positive sitting straight-leg raise test on the

right side. Infection laboratory values (ie, C-reactive protein, erythrocyte sedimentation rate, and white blood cell count) were within normal limits. Plain lumbar radiographs (ie, AP, lateral, flexion, and extension views) revealed substantial degenerative disc disease and loss of disc height at L4-L5 and L5-S1, and evidence of a slight Grade 1 spondylolisthesis at L4-L5, only noted on the lateral flexion radiograph. A lumbar MRI with gadolinium revealed a right-sided L4-L5 disc protrusion causing moderate right lateral recess stenosis and severe neuroforaminal narrowing with impingement of the right L4 nerve root and the transversing L5 nerve root (Fig. 1). The options of nonoperative versus surgical management were discussed with the patient. After a thorough discussion of the risks, benefits, and alternative options to surgical management, the patient elected to undergo surgery.

Fig. 1A–E Preoperative lumbar MRI consisting of T2 sagittal views that demonstrate a right-sided L4-L5 disc herniation (A–B) narrowing the right side neuroforamen and (C–D) the central canal and (E) T2

axial view, which demonstrates L4 nerve root compression and compression of the transversing L5 nerve at the L4-L5 level.

Given the presence of a two-time recurrent disc herniation, substantial low back pain as well as the mild spondylolisthesis present on the lateral flexion radiograph, a revision right-sided discectomy and TLIF procedure with the use of an interbody cage and posterior instrumentation was performed. Graft material included rhBMP-2 (ie, Medium kit, Infuse; Medtronic Inc, Memphis, TN, USA) and morselized local autograft bone. One of the four sponges within the medium rhBMP-2 kit was placed in the anterior L4-5 disc space, one of the four sponges was placed within the interbody cage, and two of the four sponges were placed in the left posterolateral gutter (ie, contralateral to the side which the TLIF was performed). The morselized local autograft bone was placed in the posterolateral gutters bilaterally after decortication. During dissection through the prior surgery site, a small dural tear was encountered and repaired in a figure-of-eight fashion with 6-0 Gore-Tex® suture (W.L. Gore & Assoc. Inc., Flagstaff, AZ, USA). Before closure, a thin layer of DuraSeal™ was applied over the right-sided annulotomy site (ie, through which the TLIF was performed), the exposed right exiting L4 and transverse L5 nerve roots as well as over the site of the dural repair. The standard tip was used to apply the DuraSeal™. The total volume of DuraSeal™ used was 2.5 cc. A subfascial drain was inserted before closure. Intraoperative and postoperative radiographs demonstrated adequate position of the pedicle screws as well as the interbody cage.

The patient's postoperative Day 1 was uncomplicated and her motor and sensory examination was normal with the exception of 4/5 motor strength in her right EHL and decreased sensation in the dorsum of her right foot. The right leg pain that she had preoperatively was substantially decreased. On postoperative Day 2, the patient reported increased pain in her lower back and she started to experience burning in her vagina and rectum. The subfascial drain was still in place. During the 24 hours preceding the morning of postoperative Day 3, the subfascial drain had put out 110 cc of serosanguinous fluid. The morning of postoperative Day 3, the patient reported increased, severe burning and paresthesias in the saddle region. That morning she developed urinary retention and had an episode of bowel incontinence. A physical examination revealed she had no rectal tone or volition and decreased sensation to light touch and pin prick in her perineum and perirectal area. Her lower extremity motor and sensory examination remained normal with the exception of 4/5 strength in her right EHL and decreased sensation in the dorsum of her right foot.

An MRI of her lumbar spine was immediately obtained. MRI of the lumbar spine revealed severe central canal narrowing caused by a thick rind of T1 isointense, T2 hyperintense material. This material was within the epidural space, predominantly posterior to, to the right of, and

anterior to the thecal sac. The resultant mass effect from the material resulted in obliteration of the cerebrospinal fluid within the central canal at the L4-L5 level (Fig 2).

The patient was taken to the operating room immediately for exploration and decompression of the thecal sac. There was no major fluid collection superficial or deep to the fascia or evidence of a hematoma. Clear yellow gel-like material encased the thecal sac. The gel-like material was posterior, to the right of, and anterior to the thecal sac. A large amount of this gel-like material was removed from the spinal canal using a periosteal elevator, straight pituitary rongeur, and a Frasier-tip suction. We did not measure the volume of gel-like material removed although we presumed this gel-like material represented expanded DuraSeal™. The L4-L5 nerve roots and the thecal sac were thoroughly examined and showed no other signs of compression. Under a Valsalva maneuver, no cerebrospinal fluid was leaking from the site of previous dural repair. A subfascial drain was placed before closure.

The severe burning and paresthesias had resolved when the patient was awakened. On the morning of postoperative Day 1, the patient had normal perineal and perirectal sensation, normal rectal tone, and volition. The patient had return of normal bladder and bowel function on postoperative Day 2. The patient was discharged to home on postoperative Day 3. Her only complaint on discharge was slight incisional low back pain. The right leg pain reported preoperatively had completely resolved.

The patient had clinical and radiographic followup at 2 weeks, 8 weeks, and 3 months postoperatively. Her physical examination was normal and she had no complaints (Fig. 3).

Discussion

The primary use of DuraSeal™ as an adjunct to suture closure to obtain a "watertight" dural closure was first described in elective cranial and intradural spine procedures. Boogarts et al. [2] reported no evidence of postapplication cerebrospinal fluid leaks or adverse events in 46 patients who had a spontaneous dural tear treated with DuraSeal™. Cosgrove et al. [5] reported similar findings with no evidence of postapplication cerebrospinal fluid leaks in 95.5% of patients and no adverse events with the use of DuraSeal™. After these reports, the use of DuraSeal™ was extended as an adjunct to suture closure of an iatrogenic dural tear.

Rihn et al. described a novel technique extending the application of DuraSeal™ when rhBMP-2 as a graft alternative was used in a TLIF to minimize the risk of developing postoperative radiculitis [11]. Postoperative radiculitis has been frequently reported when rhBMP-2 is used as a graft alternative during a TLIF [9, 11, 12].

Fig. 2A–D Sagittal T1 and T2, axial T1, and T2-weighted images through the lumbar spine and L4-L5 level, respectively. Sagittal (A) and axial (B) T1-weighted sequences show amorphous T1 isointense material at the L4-L5 level without clear delineation between the thecal sac and material in the epidural space. Sagittal (C) and axial

(D) T2-weighted sequences show T2 hyperintense material throughout the epidural space, wrapping around the thecal sac. The thecal sac is compressed with obliteration of cerebrospinal fluid surrounding the nerve roots.

Potter et al. [9] described a 7% incidence of postoperative transient radiculitis when a TLIF is performed with BMP. Rihn et al. reported a 16.7% incidence of postoperative radiculitis [11]. The use of DuraSealTM to seal off the annulotomy site and as a protective covering to the nerve root decreased the incidence of postoperative radiculitis from 20.4% to 5.4% [12].

DuraSealTM is believed to be an ideal sealant for spine procedures because it is a nontoxic bioabsorbable synthetic hydrogel composed of 90% water with similar properties to tissue [2]. However, one of the drawbacks of using

DuraSealTM is its potential to swell up to 50% and its slow resorption rate. The peak expansion of DuraSealTM was between 3 and 14 days postapplication in a dog model with complete resorption at 8 weeks [6, 10]. Owing to these findings, we believe the application of DuraSealTM in a confined bony area is contraindicated as a result of the concern of swelling and nerve root compression (DuraSealTM product information. FDA approval document. Confluent Surgical, 2005).

To our knowledge, the first reported complication of DuraSeal was reported when used as a dural sealant after a

Fig. 3A–B Three-month postoperative (A) AP and (B) lateral radiographs are shown.

posterior fossa decompression for a Chiari malformation [1]. A 13-year-old patient underwent a reoperation for worsening quadriparesis from an expanding epidural collection of a thickened gelatinous hydrogel. A case of cervical cord compression has also been reported in a patient who underwent C5–C6 anterior cervical decompression and fusion who sustained a cerebrospinal fluid leak when excising the posterior longitudinal ligament with DuraSeal™ being used as the primary sealant [13]. Three hours postoperatively, the patient developed progressive upper and lower extremity motor weakness. During emergent exploration and decompression, the surgeons determined the expanded hydrogel was the cause of the compression. More recently, a case has been reported of DuraSeal™ causing cauda equina after a patient underwent a lumbar laminotomy and discectomy complicated by a dural tear [7]. This patient's dural tear was treated with DuraSeal™ and the patient developed symptoms of cauda equina 9 days postoperatively. The patient was taken emergently to the operating room and during exploration and decompression, a large amount of blue DuraSeal™ was visualized. The volume of DuraSeal™ removed was measured as 10 mL, which is more than three times the amount used primarily.

It is well documented that DuraSeal™ has the potential to swell when used as a sealant for a cerebrospinal fluid leak. Our case demonstrates a cauda equine syndrome resulting from expansion of DuraSeal™ used both to cover a site of dural repair and to cover the posterior annulotomy and the exiting and traversing nerve roots after a TLIF

procedure to minimize the risk of developing postoperative radiculitis. This complication is likely the result of (1) excess use of DuraSeal™, particularly in the annulotomy site; and (2) the area over which the DuraSeal™ was applied, essentially covering a 180° area of the thecal sac. The annulotomy site used to perform a TLIF can extend toward the midline of the posterior annulus, particularly when it is being performed for recurrent, paracentral disc herniation. After placing the interbody cage, there is usually a large void between the posterior aspect of the cage and the remaining posterior annulus. This void can accommodate a substantial volume of DuraSeal™ that can expand through the annulotomy site. We believe this likely occurred in our patient and is best demonstrated in the postoperative T2-weighted axial MRI image (Fig. 2D). This expansion, coupled with the expansion of the DuraSeal™ placed posteriorly over the site of dural repair, likely led to the severe compression of the thecal sac and cauda equine syndrome in our patient.

Great care should be taken when using DuraSeal™ in the spine. Situations such as the one here, in which DuraSeal™ is being applied to multiple areas of the thecal sac (eg, posteriorly and anterolaterally), should be avoided. Furthermore, DuraSeal™ should be applied using the Micromist applicator, which allows for delivery of a very thin layer of the product in a precise fashion. If DuraSeal™ is used in conjunction with the TLIF procedure to seal the annulotomy site, care should be taken to avoid filling the entire void posterior to the interbody cage with the product. This creates a thick layer of DuraSeal™, which can expand out of the

annulotomy site and compress the anterolateral aspect of the thecal sac. Rather, a very thin layer of DuraSeal™ should be delivered over the annulotomy site and the traversing and exiting nerve root on the involved side. We currently do not use more than 2 mL of DuraSeal™ at a single spinal level. The possibility of postoperative expansion of DuraSeal™ and subsequent neurologic sequelae should be recognized by the surgeon and considered if there are any neurologic signs or symptoms after surgery. Postoperative MRI should be obtained if there is a concern that the DuraSeal™ may be causing neural compression.

Acknowledgments We acknowledge and thank Dr Neerav Mehta from the Department of Radiology at Riddle Memorial Hospital for his assistance in interpreting the radiographs and MRI.

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