

Safety of epidural triamcinolone acetonide use during lumbar decompression surgery in pediatric patients: an association with delayed pseudomeningocele formation

Jonathan N. Sellin, MD, Aditya Vedantam, MD, Thomas G. Luerssen, MD, and Andrew Jea, MD

Division of Pediatric Neurosurgery, Texas Children's Hospital, Department of Neurosurgery, Baylor College of Medicine, Houston, Texas

OBJECTIVE The complication profile of epidural triamcinolone acetonide use during lumbar decompression surgery is not known. However, isolated reports of increased risk of delayed CSF leakage with the use of triamcinolone acetonide in adult spinal surgery patients have been published. The purpose of this study was to determine the safety of epidural triamcinolone acetonide use in conjunction with lumbar decompression surgery in pediatric patients.

METHODS The medical records of all patients who underwent lumbar decompression surgery with or without discectomy between July 1, 2007, and July 31, 2015, were retrospectively reviewed.

RESULTS During the study period, 58 patients underwent 59 spine procedures at Texas Children's Hospital. There were 33 female and 25 male patients. The mean age at surgery was 16.5 years (range 12–24 years). Patients were followed for an average of 38.2 months (range 4–97 months). Triamcinolone acetonide was used in 28 (of 35 total) cases of discectomy; there were no cases of delayed symptomatic CSF leaks (0%) in the minimally invasive and open discectomies. On the other hand, triamcinolone acetonide was used in 14 (of 24 total) cases of multilevel laminectomy, among which there were 10 delayed CSF leaks (71.4%) requiring treatment. The use of triamcinolone acetonide in patients who underwent multilevel laminectomy was significantly associated with an increased risk of delayed CSF leaks or pseudomeningoceles (Fisher's exact test, $p < 0.001$).

CONCLUSIONS There was an unacceptable incidence of delayed postoperative CSF leaks when epidural triamcinolone acetonide was used in patients who underwent multilevel laminectomy.

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KEY WORDS epidural steroid; triamcinolone acetonide; lumbar decompression; pediatric population; cerebrospinal fluid leak; pseudomeningocele; spine

LUMBAR decompression surgery is a staple of the spine surgeon's armamentarium. The primary goal of any lumbar decompression is to decompress neural elements to address or to correct neurological deficits. Pain, however, and the relief of pain are often of primary concern to patients and are an important secondary aim of lumbar decompression surgery, particularly when it adversely affects quality of life (QOL).

In advance of open surgery, epidural steroid injections have become commonplace, despite FDA warnings against their use in the epidural space.³⁶ They are often efficacious in improving symptoms of back pain and radiculopathy secondary to lumbar spondylosis.^{1,22,25,37}

Triamcinolone acetonide is a steroid frequently used in epidural injections in an "off-label" manner.^{6,7,32,34} Despite their widespread use and reported efficacy, epidural ste-

roid injections have also been associated with significant complications, including but not exclusive to reports detailing the use of triamcinolone acetonide.^{4,13,20} Application of epidural steroids has also become widely used in open lumbar decompression surgery, with reported improvement in short-term pain control.^{2,17,18,27,28,31}

The complication profile of epidural triamcinolone acetonide, in particular during lumbar decompression surgery, is not known. Yet there has been an isolated report of increased risk of delayed CSF leakage with its use in adult spine patients.¹¹ In the study of 231 adult patients, the authors noted 11 delayed CSF leaks in the epidural triamcinolone acetonide group, compared with no delayed CSF leaks in the patient cohorts using other types of epidural steroids, a difference they reported as statistically significant.

ABBREVIATIONS HR = health-related; QOL = quality of life.

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Although the occurrence of lumbar CSF leakage or pseudomeningocele following incidental durotomy is well described,^{3,5,8,33,35,38} the senior author of the present study (A.J.) noted an alarming rate of symptomatic delayed lumbar spine pseudomeningoceles at our institution following lumbar decompression in the absence of intraoperative durotomy. This observation led to a review of our institutional lumbar decompression series to evaluate for factors associated with delayed pseudomeningocele and to further examine the safety of epidural triamcinolone acetonide use in conjunction with lumbar decompression surgery in pediatric patients.

Methods

The medical records of all patients who underwent lumbar decompression surgery with or without discectomy between July 1, 2007, and July 31, 2015, at Texas Children’s Hospital were retrospectively reviewed. Data obtained from the electronic medical records included patient demographics (e.g., age, sex, and date of surgery); diagnosis; operative procedure (including dosage of epidural triamcinolone acetonide, use of other topical agents [e.g., morphine and vancomycin powder] in the epidural space, concurrent fusion, and intraoperative complications [e.g., unintended durotomy]); outcomes (e.g., infection, pain, CSF leak/pseudomeningocele, and reoperation for CSF leak/pseudomeningocele); timing of presentation with delayed CSF leak/pseudomeningocele; and length of follow-up.

Pain was classified in a binary manner as either “resolved” or “persistent” based on the clinician’s impression at the time of follow-up. Unfortunately, health-related QOL (HRQOL) outcome instruments, such as the 36-Item Short-Form Health Survey, Oswestry Disability Index, visual analog scale–pain, and Pediatric Quality of Life Inventory, were not used. Thus, further analysis to determine the efficacy of epidural triamcinolone acetonide use for the resolution of preoperative pain symptoms was not performed.

Application of Triamcinolone Acetonide

Forty milligrams of triamcinolone acetonide injectable suspension (1 ml) was obtained from the pharmacy. The triamcinolone acetonide was allowed to soak into a piece of dry Gelfoam, which was cut to the size of the bony defect. After irrigating the wound with bacitracin, the triamcinolone acetonide–soaked Gelfoam was laid directly onto the surface of the dura.

The routine use of surgical Gelfoam in the epidural space at the completion of surgery prompted the use of Gelfoam as an extended-release drug delivery system for medications such as morphine²³ and steroids. The rationale for choosing Gelfoam as an extended delivery device is that Gelfoam has the capability to absorb fluid several times its weight.

Statistical Methods

Univariate analysis for the incidence of CSF leaks and the resolution of preoperative pain symptoms was performed using Fisher’s exact test. Statistical analysis was performed using SPSS 20.0 (IBM Corp.). Statistical

significance was set at $p < 0.05$. The institutional review board of Baylor College of Medicine approved this study.

Results

During the study period, 58 patients underwent 59 spine procedures at Texas Children’s Hospital. There were 33 female and 25 male patients. The mean age at surgery was 16.5 years (range 12–24 years). Patients were followed for an average of 38.2 months (range 4–97 months). Diagnoses included 41 cases of herniated disc and 18 cases of spinal canal stenosis. Overall, there were 31 minimally invasive discectomies, 4 open discectomies, and 24 multilevel decompressive laminectomies with or without discectomy. There were 3 reported intraoperative incidental durotomies. No infections were seen in our study population. No patients in our study had placement of spinal instrumentation.

Delayed CSF Leaks and Pseudomeningocele

Epidural triamcinolone acetonide was used in 42 of 59 (71%) cases. Delayed CSF leaks/pseudomeningoceles were observed in 0 of 17 cases where no steroids were used (0%) versus 10 of 42 cases where steroids were used (24%) (Table 1). This difference was significant (Fisher’s exact test, $p = 0.049$).

No CSF leaks were observed in 35 discectomies (both open and minimally invasive) (0%) versus in 10 of 24 laminectomies (42%) (Table 2). This difference was also significant ($p < 0.001$, Fisher’s exact test).

Triamcinolone acetonide was used in 28 of 35 (80%) cases of discectomy; there were no cases of delayed, symptomatic CSF leaks in the minimally invasive and open discectomy groups, with or without triamcinolone acetonide use. On the other hand, triamcinolone acetonide was used in 14 of 24 cases of multilevel laminectomy, with 10 delayed CSF leaks (71.4%) requiring treatment, compared with 0 of 10 (0%) cases of CSF leakage observed in the multilevel laminectomy cohort without triamcinolone acetonide (Table 3). The use of steroids in patients undergoing multilevel laminectomy was significantly associated with an increased risk of delayed CSF leaks or pseudomeningoceles (Fisher’s exact test, $p < 0.001$).

Delayed CSF leak presentation ranged from 5 to 58 days after surgery (mean 24.9 days). Incidental durotomy at the time of surgery occurred in 3 patients, all in cases of multilevel lumbar laminectomies. Of these 3, 2 patients went on to develop CSF leaks in a delayed fashion, with a presentation at 28 and 58 days, respectively. Although these delayed CSF leaks/pseudomeningoceles could be directly attributable to intraoperative durotomy, the delayed

TABLE 1. Association between the use of triamcinolone acetonide and postoperative CSF leak/pseudomeningocele in 59 patients who underwent lumbar decompression surgery*

Triamcinolone Acetonide Use	CSF Leak/Pseudomeningocele		Total
	Yes	No	
Yes	10	32	42
No	0	17	17

* Fisher’s exact test, $p = 0.04$.

TABLE 2. Association between surgical procedure and postoperative CSF leak/pseudomeningocele in 59 patients who underwent lumbar decompression surgery*

Surgery	CSF Leak/Pseudomeningocele		Total
	Yes	No	
Discectomy	0	35	35
Multilevel laminectomy	10	14	24

* Fisher's exact test, $p < 0.001$.

presentation raises the question of whether alternative factors contributed to their symptomatic presentation. Even excluding these 2 instances, the incidence of delayed CSF leaks in patients who underwent multilevel laminectomies remains strikingly high (8 of 14 patients, 57.1%).

Management of CSF Leak/Pseudomeningocele and Operative Findings

The 10 patients with delayed CSF leak complications were initially managed conservatively with a period of bed rest, administration of caffeine, and abdominal binders. Seven of these 10 patients (70%) had persistent debilitating low-pressure headaches. Of the 7 patients with persistent symptoms, 2 received blood patches with resolution of symptoms; 2 underwent primary open repair of their pseudomeningoceles; and 3 initially received epidural blood patches without resolution of symptoms and eventually required open repair. Prolonged lumbar drainage was used in all 5 cases of open repair to allow for wound healing.

One patient was noted to have a small durotomy in the left lateral recess, which was repaired with a Prolene suture. Four patients were found to have a sharp ridge of bone in the lateral gutter juxtaposed with the dural dehiscence; in these cases, the ledge of bone was removed and the dural defects were repaired with Prolene sutures. None of these patients who underwent open repair of their pseudomeningoceles had unintended durotomies at the time of lumbar decompression.

Discussion

The use of epidural steroids, both via injection and during open decompression surgery, is widely reported as efficacious in improving pain symptoms in the short term.^{1,2,17,18,22,25,27,28,31,37} Similarly, our findings suggest that epidural steroid use is beneficial in relieving postoperative pain.

Nevertheless, our senior author (A.J.) observed a notable rate of symptomatic delayed lumbar spine pseudomeningoceles at our institution following lumbar decompression in the absence of intraoperative durotomy. This observation led to a review of our institutional lumbar decompression series to evaluate for factors associated with delayed pseudomeningocele, in particular the use of epidural steroids. Our data suggest a significant association between the use of epidural triamcinolone acetonide in multilevel lumbar decompressions and delayed CSF leak/pseudomeningocele in the absence of intraoperative durotomy.

Literature review revealed no peer-reviewed publication reporting on this association or, more generally, on the side-effect profile of triamcinolone acetonide when used in open decompression lumbar spine surgery in an

TABLE 3. Association of triamcinolone acetonide use in multilevel laminectomy with increased risk of postoperative CSF leak/pseudomeningocele*

Procedure	CSF Leak/Pseudomeningocele		Total
	Yes	No	
Discectomy w/o triamcinolone acetonide	0	7	7
Discectomy w/ triamcinolone acetonide	0	28	28
Multilevel laminectomy w/o triamcinolone acetonide	0	10	10
Multilevel laminectomy w/ triamcinolone acetonide	10	4	14

* Fisher's exact test, $p < 0.001$.

adult or pediatric population. However, an abstract submitted to the 18th Annual Meeting of the North American Spine Society by Dick and Holte reported similar findings.¹¹

In their retrospective review, Dick and Holte compared the complication profile of triamcinolone acetonide (used in 98 patients) with Celestone (betamethasone), Aristospan (triamcinolone hexacetonide), betamethasone, dexamethasone, and Depo-Medrol (methylprednisolone) used in 72, 7, 7, 4, and 2 patients, respectively. The authors noted 11 delayed CSF leaks in the triamcinolone acetonide group, compared with no delayed CSF leaks in the remaining steroid groups, a difference they reported as statistically significant. In their discussion, they reported initially switching to triamcinolone acetonide from Celestone after a national shortage in the latter and, more importantly, they noted a resolution of the CSF leak complication rate after the use of triamcinolone acetonide had been discontinued. In their series, 51 of 231 patients who were reviewed underwent multilevel lumbar decompression. However, the authors did not report on whether the delayed CSF leaks were seen exclusively in this cohort or also in patients who underwent other forms of lumbar decompression (primarily discectomy).

Although complications associated with epidural steroid use (including but not exclusive to triamcinolone acetonide) have been reported,^{4,13,20} scarce literature exists on the association of epidural steroids in general, and triamcinolone acetonide in particular, with delayed symptomatic CSF leaks/pseudomeningoceles in a pediatric cohort. The similarity between the report by Dick and Holte and our own findings, however, is remarkable. In their report, Dick and Holte suggest that the increased incidence of delayed CSF leaks with triamcinolone acetonide use may be attributable to its increased potency compared with other epidural steroids used, although these investigators concede that additional study is required to elucidate a potential mechanism.

Proposed Mechanism of Epidural Triamcinolone Acetonide Use and Delayed CSF Leaks

An interesting parallel can be drawn to the historical experience with the antiadhesion gel ADCON-L (Gliatch), an inhibitor of fibroblast migration originally designed to prevent postoperative scarring in the epidural

space.^{10,12,14,15,21,29,30} During lumbar decompression surgery, very small dural tears may occur that are not noticed at the time of surgery.^{16,19} The true incidence of such tears is unknown, perhaps because epidural inflammation (dependent in part on fibroblast activity) allows for scar formation and the natural healing of small tears. As ADCON-L became more prevalent, however, several reports linked its use in lumbar decompression surgery (including multilevel laminectomy and microdiscectomy) to delayed CSF leaks and pseudomeningoceles.^{10,16,24} In almost all of the described cases, CSF leak symptoms presented in a delayed fashion, usually after 2–3 weeks. In all 3 reports, none of the patients were noted to have durotomies at the time of initial surgery.

It has been proposed that tiny durotomies caused at the time of surgery (or those that develop in the immediate postoperative period as dura mater rubs against serrated bone edges, which normally would heal) do not heal in the presence of ADCON-L and the absence of fibrin scar. Epidural corticosteroids, in a more expansive fashion, inhibit multiple steps in the inflammatory cascade, including fibroblast proliferation.²⁶ It is possible that the use of epidural steroids, particularly in instances of multilevel laminectomy where significant tissue dissection results in postoperative dead space, may, in a fashion similar to ADCON-L, inhibit postoperative epidural inflammation and scarring that, despite all the difficulties posed during reoperation, are important forms of native wound healing that often masks microdurotomies not noticed at the time of surgery.

Limitations to the Study

There are several limitations to this study. Most importantly, this is a retrospective chart review and is subject to all of the shortcomings associated with this type of analysis, including documentation omissions, missed relevant cases, and selection bias. For example, we were unable to determine severity and duration of preoperative symptoms, which are relevant factors in evaluating the efficacy of triamcinolone acetonide. Similarly, an exhaustive list of other factors such as obesity and nutritional status, which may affect the complication profile of a given patient, was not assessed nor analyzed. An accurate logistic regression analysis for our primary outcome of CSF leaks was not possible due to collinearity between variables, as well as the presence of cell values equal to 0.⁹

Although we noted an association among triamcinolone acetonide use, multilevel lumbar decompression, and delayed CSF leaks, causality has not been definitively established. We did not note any symptomatic CSF leaks in our discectomy cohort. However, it could be the case that CSF leaks occurred but the volume of dead space after discectomy, particularly minimally invasive discectomy, was not clinically significant enough for the accumulation of CSF and subsequent low-pressure symptomatology. Hence, these patients did not come to clinical attention. Our study was not able to detect asymptomatic radiographic pseudomeningoceles, because we did not use surveillance spine imaging to reveal this abnormality.

Furthermore, our study did not include validated HRQOL instruments to measure pre- and postoperative

pain levels. Instead, we recorded pain in a binary fashion as either “resolved” or “persistent” based on chart review. Admittedly, omission of HRQOL tools is a major limitation in assessing postoperative pain relief. Hence, resolution of pain with epidural triamcinolone acetonide use cannot be a primary outcome of our study.

Nevertheless, this review has resulted in a change in practice at our institution, namely the cessation of triamcinolone acetonide use in lumbar decompression surgery of any kind. One potential future direction of our studies will be to compare the delayed CSF leak/pseudomeningocele rate in this new operative cohort with our currently reported (now historic) operative cohort.

Conclusions

Triamcinolone acetonide use in lumbar decompression surgery in the pediatric age group is efficacious in helping to resolve preoperative pain symptoms. However, there may be an increased incidence of delayed postoperative CSF leaks when epidural triamcinolone acetonide is used in multilevel laminectomy cases. We recommend that the use of triamcinolone acetonide in the epidural space be avoided in these types of more extensive lumbar decompression surgeries. Furthermore, the complications of “off-label” epidural triamcinolone acetonide application, particularly delayed CSF leaks, should be discussed with patients and families as part of the informed consent process.

Future directions for our research may include a retrospective study comparing a historical cohort of patients in whom epidural triamcinolone acetonide was used routinely with a contemporary cohort of patients in whom epidural triamcinolone acetonide use is avoided. Moreover, coming research may include a prospective study to assess risk factors for delayed postoperative CSF leaks across institutions to generate higher-quality conclusions.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Jea. Acquisition of data: Jea. Analysis and interpretation of data: Drafting the article: Jea, Sellin, Vedantam. Critically revising the article: Jea, Sellin, Luerssen. Reviewed submitted version of manuscript: Jea, Sellin, Luerssen. Statistical analysis: Vedantam. Administrative/technical/material support: Luerssen. Study supervision: Jea.

Correspondence

Andrew Jea, Division of Pediatric Neurosurgery, Texas Children's Hospital, 6621 Fannin St., CCC 1230.01, 12th Fl., Houston, TX 77030. email: ahjea@texaschildrens.org.