Evaluation of complication rates of pediatric spinal procedures in which a polyethylene glycol sealant was used

Clinical article

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Object. Cerebrospinal fluid leakage following durotomy in spinal surgery can lead to significant patient morbidity and mortality, including meningitis and even death. Usage of a polyethylene glycol (PEG) sealant in combination with standard closure techniques has been shown to be effective in preventing CSF leaks in animal models and adult patients, but the results of its use have not been reported in the pediatric population.

Methods. A retrospective analysis was performed of pediatric neurosurgery patients (0–18 years of age) treated at The Johns Hopkins Hospital from 2003 to 2010. There were 93 spinal surgery patients identified in whom PEG was applied. The incidence of CSF leakage, meningitis, and neurological injury was recorded. There were 54 males and 39 females in this study with an average age of 8.7 years. Of the identified patients, 16.1%, 28%, and 55.9% underwent surgery in the cervical region, thoracic region, and lumbar region, respectively.

Results. At 90-day follow-up, 5 patients (5.4%) had a CSF leak, 4 patients (4.3%) required a reoperation, and 1 patient (1.1%) had meningitis within this time period. No deaths or associated neurological deficits were observed.

Conclusions. The use of a PEG sealant to augment dural closure in pediatric spine surgery appears to be a safe adjunct to standard dural closure in pediatric spine patients. (http://thejns.org/doi/abs/10.3171/2013.12.PEDS13456)

Key Words • polyethylene glycol sealant • dural sealants • technique • pediatric spinal procedures • CSF leak • infection • durotomy

Closure of durotomies, whether deliberate or incidental, is important in reducing complication rates associated with spinal surgeries. Incidental durotomy is the most common complication following spinal surgery. With more than 1 million spinal surgeries performed each year, the estimated incidence of incidental durotomies is 0.3%–13% with reported rates of 1.8%, 5.3%, and 17.4%, for microdiscectomy, laminectomy, and repeat microdiscectomy, respectively. The incidence of incidental durotomies during spinal surgeries is higher in patients who have undergone prior surgeries due to the development of scar tissue, distortion of anatomy, adherence of tissue to dura, and resultant poor dissection planes. Cerebrospinal fluid leakage after incidental durotomy can lead to significant patient morbidity, including pseudomeningoele, meningitis, epidural abscesses, sensory and/or motor deficits, and even death. Notably, CSF leaks can also cause a chronic pain disorder that manifests with radiculopathy, cranial nerve palsy, and postural headache. In addition, a persistent CSF leak can lead to poor wound healing and wound dehiscence.

A number of techniques can be used to close durotomies. The most common technique uses a simple running suture to create a “watertight” seal. Alternatively, autologous fascia or muscle may be sutured in place to plug the dural defect. More recently, fibrin glue has been used to augment dural repairs. Fibrin glue is a solution that contains fibrinogen, other clotting factors, calcium, and thrombin. This biological adhesive then forms fibrin monomers, which help to plug microscopic holes by hardening around tissues. Prior studies have suggested that polyethylene glycol (PEG) dural sealants may reduce incisional CSF leakage rates and lower postoperative complications. The combined use of standard surgery and the application of a chemical adhesive are hypothesized to decrease the frequency of postoperative complications following durotomy.

Synthetic dural sealants, such as PEG, have been de-
veloped as an alternative to human-derived fibrin glue. Du
raSeal (Covidien) is a PEG-formulated dural sealant that
has been approved by the FDA in adults to augment prima-
dary dural closures using traditional suture methods for spi-
nal and cranial surgeries. The application of PEG sealant
in combination with standard closure techniques has been
shown to be effective in preventing CSF leaks in animal
models and adult patients, but the results of its use in the
pediatric population have not been reported. In this study,
we evaluated the complication rates in pediatric spinal sur-
gery after the use of a PEG sealant. The incidence of CSF
leakage, meningitis, and neurological injury was evaluated
in pediatric spinal surgery patients in whom a PEG sealant
was used to augment dural closure.

Methods

A retrospective analysis was performed of pediatric patients (0–18 years of age) who underwent spinal surgery
at The Johns Hopkins Hospital from 2003 to 2010. A total
of 93 patients with durotomies were identified, and in all
cases a PEG sealant was applied as an adjunct to standard
sutured dural closure techniques. The primary indication
for the use of PEG sealant was an exclusive adjunct tech-
nique in all cases of durotomy during this time period.

In our management paradigm, immediately after sur-
gery, patients undergoing lumbar procedures were kept
on bed rest for 48 hours. On postoperative Day 2, patients
were elevated 10° per hour until the head of bed was 60°.
Once the patient reached a head of bed of 60°, the patient
was allowed to be out of bed. For cervical procedures the
patients were kept with a minimum head of bed of 30°
with no restrictions.

All documentation in the electronic patient record
was analyzed for the first 3 postoperative months to iden-
tify patients who experienced complications. Basic demo-
graphic information was collected for each patient includ-
ing age, sex, date of surgery, indication for surgery, and
location of surgery (cervical, thoracic, or lumbar). Any
postoperative complications within 90 days were noted.
Specifically, CSF leaks were confirmed clinically, and
those requiring operative repair and/or repair of pseudo-
meningocele were recorded. In addition, surgical site in-
fected and any motor deficits were also recorded.

Results

There were 54 males and 39 females in this study with
an average age of 8.7 ± 0.7 years. We used PEG seal-
ant in 20 patients (21.5%) who were 0–2 years old, in 15
patients (16.1%) who were 2–4.9 years old, in 16 patients
(17.2%) who were 5–9.9 years old, in 23 patients (24.7%)
who were 10–14.9 years old, and in 19 patients (20.4%) who
were 15–18 years old (Table 1). Of the identified pa-
tients, 15 patients (16.1%) underwent surgery in the cervi-
cal region, 26 patients (28%) in the thoracic region, and
52 patients (55.9%) in the lumbar region. The surgical di-
agnoses for the patients included in our series were 31 in-
tradural spinal cord tumors (33.3%), 29 lipomyelomenin-
gocele repairs (31.2%), 20 tethered cord revisions (21.5%),
9 incidental durotomies (9.7%), 2 cases of diastematomy-
elia (2.2%), 1 case of meningocele repair (1.1%), and 1
case of syrinx (1.1%) (Table 2). We used an autologous
dural graft in 3 cases (3.2%), a nonautologous graft in 15
patients (16.1%), and no dural graft in 75 patients (80%).

Evaluating the 90-day clinical course of this cohort,
we found that 5 patients (5.4%) had a CSF leak, 4 patients
(4.3%) required reoperation, and 1 patient (1.1%) had
meningitis within this time period (Table 3). Of the 5 CSF
leaks, 4 were in the lumbar region and 1 was in the cervi-
cal region. All 4 cases of CSF leak in the lumbar region
were associated with tethered cord release and required
revision surgery for repair of the leak. The one case of
CSF leak in the cervical area occurred in a patient who
underwent resection of an intramedullary ependymoma.
In that case, the postoperative leak occurred at the surgi-
cal drain site. On presentation, the site was oversewn and
the patient was observed for a brief hospitalization with
no signs of persistent leak or meningitis postintervention.
There were no deaths in our series.

Discussion

Cammisa et al. evaluated a large cohort of cervical
and lumbar spine surgeries and found a 3.1% overall inci-

| TABLE 1: Demographics in 93 children who underwent surgery in which a PEG sealant was used |
| Parameter | No. of Patients (%) |
| sex |  |
| male | 54 (58.1) |
| female | 39 (41.9) |
| age (yrs)* |  |
| 0–2 | 20 (21.5) |
| 2–4.9 | 15 (16.1) |
| 5–9.9 | 16 (17.2) |
| 10–14.9 | 23 (24.7) |
| 15–18 | 19 (20.4) |

* The mean age was 8.7 years.

| TABLE 2: Surgical site and diagnosis |
| Parameter | No. of Patients (%) |
| surgical site |  |
| cervical | 15 (16.1) |
| thoracic | 26 (28.0) |
| lumbar | 52 (55.9) |
| surgical diagnosis |  |
| intradural spinal tumor | 31 (33.3) |
| lipomyelomeningocele | 29 (31.2) |
| tethered cord revision | 20 (21.5) |
| incidental durotomy | 9 (9.7) |
| diastematomyelia | 2 (2.2) |
| meningocele | 1 (1.1) |
| syrinx | 1 (1.1) |
Use of a PEG sealant in pediatric spinal procedures

TABLE 3: Postoperative complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>No. of Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSF leak</td>
<td>5 (5.4)</td>
</tr>
<tr>
<td>reoperation</td>
<td>4 (4.3)</td>
</tr>
<tr>
<td>meningitis</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>neurological deficit</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>death</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

dence of incidental durotomy in 2144 pediatric and adult patients. The authors found that intraoperative recognition of durotomy and subsequent repair resulted in 0 persistent CSF leaks at a mean follow-up of 22.4 months. Of 68 repairs made with direct suturing, 44 had adjunctive therapy with grafts of adjacent muscle, fat, fascia, or fibrin glue. Wang et al. also conducted a review of 641 patients who underwent lumbar spine surgery and found a 14% overall incidence of durotomy. The vast majority of the 88 durotomies were repaired with interlocking suture and Gelfoam with 1 tear requiring a fascial graft. Only 2 of the 88 patients with repaired durotomies developed a persistent CSF leak.

A number of methods exist for repairing durotomies intraoperatively. The most popular method remains performing a primary suture closure that forms a “watertight” seal, which is then followed by prolonged bed rest. Other modalities include filling the dural tears with biological grafts of fascia or muscle from adjacent structures and suturing them into place. A fairly recent adjunctive therapy has been the use of fibrin glues. Fibrin glues are prepared by mixing primarily fibrinogen and thrombin to produce fibrin and a clot. The activation of the cascade results in a viscous and adherent gel that can be used as an adjunct to suture closing of dural tears. A biodegradable hydrogel formed by the combination of PEG and tri lysine (DuraSeal, Covidien) results in an extensive and rapid cross-linking that creates an adherent gel. Polyethylene glycol sealant is highly adherent to tissues and has been used to join nerves together. Following its efficacious period of augmenting sutures and forming a tighter seal around tears, PEG sealant is eventually broken down by water molecules 4–8 weeks later and is absorbed by the body.

Six studies, 5 prospective and 1 retrospective, have evaluated the use of PEG hydrogel sealant as an adjunct method to ensure watertight dural closure. Boogaarts et al. performed a nonrandomized, prospective single-institution trial in which 46 patients received either PEG hydrogel in conjunction with autologous duraplasty materials or standard closure techniques when undergoing elective cranial or spine surgery. There was only 1 reported CSF leak in that study. The safety and efficacy of the PEG hydrogel was evaluated in a prospective, multicenter, single-arm trial (DuraSeal Pivotal Trial) by Cosgrove et al., leading to approval of PEG hydrogel by the FDA. A total of 111 patients from 11 institutions were assessed for a postoperative CSF leak. The incidence of CSF leaks and surgical site infections in their study was determined to be 1.8% (2 patients) and 3.9% (2 patients), respectively. All CSF leakage or surgical site infection complications in this study required further surgical intervention.

A retrospective review was performed by Weinstein et al. comparing PEG hydrogel in conjunction with nonautologous duraplasty materials with matched controls from the study by Cosgrove et al. Five CSF leaks (7.6%) were found in the PEG hydrogel plus nonautologous duraplasty group in comparison with 3 CSF leaks (6.0%) in the matched control group. In addition, there were no surgical site infections in the PEG hydrogel plus nonautologous duraplasty group compared with 4 infections (8%) in the control group. Than et al. performed a prospective review of 100 patients who underwent dural closure augmented with PEG hydrogel and 100 retrospectively reviewed patients who underwent dural closure augmented with fibrin glue after posterior fossa surgery. They reported 2 CSF leaks in the PEG hydrogel group compared with 10 CSF leaks (2% vs 10%) in the fibrin glue group. They also reported 4 surgical site infections in each group. Kim et al. also performed a prospective, multicenter, randomized study assessing the safety and efficacy of standard sutured dural repair and PEG sealant in patients undergoing intentional durotomy during spinal surgery. They analyzed 158 patients (102 patients in the PEG sealant group and 56 patients in the control group) and found that intraoperative watertight closure was significantly greater in the PEG sealant group (100% vs 64%), although no statistical difference was seen when the parameters of postoperative CSF leakage, infection, wound healing, or neurological deficit were analyzed. More recently, a prospective, randomized study on PEG hydrogel was performed. A total of 237 patients were enrolled in this study, and after intraoperative evaluation for CSF leakage following dural suture closure, patients were randomized to either PEG hydrogel or the surgeon’s choice of “commonly used” techniques to seal the dura. The control group underwent more infratentorial procedures (42.7% vs 30%, p = 0.04). There were 3 CSF leaks in all: 1 infratentorial leak in the PEG hydrogel group, 1 infratentorial leak in the control group, and 1 supratentorial leak in the control group. These studies were all performed in adult cohorts and did not examine pediatric patients.

Our study is the first to evaluate the use of PEG hydrogel dural sealant in the pediatric population. Studies on the use of PEG sealants have been performed previously in adult patients with the inclusion of patients who were 16 years of age and older; however, no study to date has solely evaluated the safety in pediatric patients. Pediatric patients are more commonly recalcitrant in complying with bed rest restrictions or other management paradigms for CSF leaks. This study demonstrated a 5.4% rate of CSF leak following standard dural closure and PEG sealant with no neurological deficits or deaths in our series. Moreover, our results are in line with earlier studies in adults in terms of the rates of CSF leakage and/or other complications following spinal surgery. Kaufman et al. reviewed their experience with nonpenetrating titanium clips that were augmented with a fibrin sealant depending on surgeon preference for dural closure in 27 pediatric spinal surgery patients and reported no significant complications. Our study demonstrates that PEG sealant is a safe adjunct to standard dural closure in
pediatric spine patients and provides evidence that PEG sealant can be safely added to the armamentarium of dural closure techniques.

Incidental durotomy and CSF leaks are more common in revision surgeries due to the development of scar tissue, distortion of anatomy, adherence of tissue to dura, and resultant poor dissection planes. Of the 5 CSF leaks, 4 cases were associated with tethered cord release. Analyzing the specific subset of tethered cord release, there was a 20% rate of CSF leak in this subgroup. Further studies will have to evaluate whether PEG sealant is effective in this higher-risk group.

Conclusions

When PEG sealant was used to augment dural closure in pediatric spine surgery patients, the incidence of a CSF leak, meningitis, or reoperation was 5.4% in this series. Thus, the use of a PEG sealant to augment dural closure in pediatric spine surgery appears to be a safe adjunct to standard dural closure in pediatric spine patients.

Disclosure

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 to the study and manuscript preparation include the following. Conception and design: Goodwin, Recinos, Jallo. Acquisition of data: all authors. Analysis and interpretation of data: all authors. Drafting the article: Goodwin, Recinos, Yang, Jallo. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Goodwin. Statistical analysis: Goodwin, Recinos, Yang, Jallo. Administrative/technical/material support: Goodwin, Recinos, Jallo. Study supervision: Jallo.

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