Efficacy and safety of polyethylene glycol dural sealant system in cranial and spinal neurosurgical procedures: Meta-analysis

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INTRODUCTION

Cerebrospinal fluid (CSF) leakage after neurosurgical operations is a common phenomenon at either infratentorial or supratentorial surgeries. It ranges from 10 to 25%.[1228] Indeed, it is regarded as one of the most important causes of morbidity after neurosurgical operations;
complications of CSF leak include wound dehiscence, wound infections, meningitis, and encephalitis.\textsuperscript{[3,25]} CSF leakage is frequently and significantly cost-effective across all types of neurosurgical operations.\textsuperscript{[1]}

The main method of dural closure is the primary surgical closure; however, this is not enough to achieve a watertight approximation.\textsuperscript{[20,24,31]} The pinholes created by the suture itself may increase the incidence of leakage when intracranial pressure increases as well and moving back in a ball and valve mechanism.\textsuperscript{[25,29]}

At present, the techniques used to achieve a watertight dural closure include the application of interrupted sutures, dural replacement materials (duraplasty), and hemostatic agents.\textsuperscript{[9,15]} Tissue adhesives are mostly used as an adjunct to primary dural closure to achieve a watertight dural closure. Tissue adhesives are of two types; fibrin sealants and hydrogel-based sealant systems.\textsuperscript{[23,26,28,36]}

The most widely used method is fibrin sealants, a two-component system with one containing fibrin, factor XIII, and calcium; it forms a coagulum which prevents CSF leak on the suture sites.\textsuperscript{[21]} However, many side effects have been reported about fibrin sealant systems. Bovine fibrin may induce allergic reactions and even cause anaphylaxis or aseptic meningitis.\textsuperscript{[2,16,34]}

Polyethylene glycol (PEG)-based hydrogel is a new sealant used as an adjuvant to augment primary dural closure after craniotomy.\textsuperscript{[4]} A synthetic hydrogel is effective in sealing the suture pinholes and tiny gaps between the suture stitches. Data from preclinical animal studies provided objective evidence that the PEG sealant was safe and effective.\textsuperscript{[25]} PEG is also superior to fibrin sealants in being nonimmunogenic and with no risk of transmitting infection.\textsuperscript{[3,5,17]} One study showed that the reduction of CSF leakage high costs was achieved using the PEG sealant system.\textsuperscript{[11]}

In this meta-analysis of clinical trials, we aimed to assess the efficacy of PEG to achieve watertight closure of the dura and prevention of CSF leak and to investigate its possible side effects.

**MATERIAL’S AND METHODS**

We performed all steps of this systematic review in strict accordance with the Cochrane handbook of systematic reviews and meta-analysis. We also followed the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement guidelines while drafting our manuscript.\textsuperscript{[14,27,33]}

**Literature search strategy**

We searched Medline (through PubMed), Scopus, and the Cochrane Library through December 2019, using the following keywords: “PEG,” “Hydrogel,” “Dural Sealant,” “Dural Closure,” “Neurosurgery,” “Cranial,” and “Spinal.”

No restrictions by language, country, or publication date were employed. We also searched the bibliography of eligible studies for relevant articles.

**Eligibility criteria**

We included both randomized controlled trials and noncontrolled studies assessing the use of PEG hydrogel for dura matter closure in cranial or spinal neurosurgical procedures.

We excluded nonhuman studies, studies from which data cannot be reliably extracted, duplicate references, case reports, and conference abstracts.

**Selection of studies**

We independently applied the selection criteria; eligibility screening was conducted in two steps, (a) titles and abstracts screening for matching the inclusion criteria and (b) full-text screening for eligibility to meta-analysis. Disagreements were resolved on discussion.

**Outcomes of interest**

We included studies reported at least one of the following outcomes: (1) intraoperative watertight closure, (2) CSF leak, and (3) surgical complications such as meningocele, surgical site infection, sepsis, subarachnoid hemorrhage, and pneumocephalus.

**Data extraction**

We independently extracted and tabulated data on the first author, publication year, study design, baseline characteristics of the study population, type of intervention including the type of prosthesis, study period, follow-up period, and relevant outcomes data. Disagreements were resolved on discussion.

**Risk of bias (ROB) assessment**

Two independent reviewers used the Cochrane ROB assessment tool, clearly described in Chapter 8.5 of the Cochrane handbook of systematic reviews of interventions 5.1.0. The Cochrane ROB assessment tool is designed to detect five types of bias, including selection bias (sequence generation and allocation concealment), performance bias (blinding of participants and investigators), detection bias (blinding of outcome assessors), attrition bias (incomplete outcome data), and reporting bias (selective outcome reporting).\textsuperscript{[6-8,10]} Each study is classified in each domain as low, high, or unclear ROB.
Data analysis

We included both controlled and noncontrolled studies. We used OpenMeta (Analyst) software to calculate an overall estimate and 95% confidence interval (CI) for the outcome in the experimental groups in both sets of studies. We used Review Manager software (version 5.3) to calculate the risk ratio (RR) and 95% CI for outcomes of the controlled studies.

Assessment of heterogeneity

Heterogeneity was assessed by visual inspection of the forest plots and measured by Q statistic and $I^2$ statistic. Significant statistical heterogeneity was indicated by Q statistic $P < 0.1$ or by $I^2$ more than 50%.

Publication bias

According to Egger's et al., publication bias is not reliable for <10 pooled studies. Therefore, in the present study, we could not assess the existence of publication bias by Egger's test for funnel plot asymmetry.

RESULTS

Literature search results

The results of searching databases yielded 255 studies. After excluding duplicates, 169 studies entered the screening phase. Twelve studies entered full-text screening, and a total of six studies were finally included in our study. Half of the included trials were controlled trials, and the other three studies were noncontrolled. [Figure 1] shows a PRISMA flow diagram summarizing our literature search.

Characteristics of the included studies' population

The included studies were six studies. Controlled and uncontrolled studies were in a ratio of 3:3. The total number of recruited patients from randomized studies was 493 patients. The uncontrolled studies contain 181 patients. The controlled trials measured PEG efficacy against conventional method used for dural closure. The summary of the baseline characteristics of the included studies is shown in [Table 1].

Assessment of study validity

We detected an overall moderate ROB for the included clinical trials. Regarding randomization and blinding of outcome assessors, three studies did not report the methodology of randomization nor blinding of outcome assessors, therefore, were categorized as unclear ROB. As for allocation concealment, blinding of patients, attrition bias, and selective reporting, all studies were put to low risk, as they provided sufficient data for supporting these domains. Except for Osbun et al.,[22] we could not assure proper allocation concealment, therefore, the study was put to unclear risk for this domain. [Figure 2] shows a summary and a graph for the overall ROB.

Synthesis of results

We conducted two analyses for selected outcomes; one for controlled trials and another single-arm analysis for both controlled and noncontrolled studies.

Analysis of controlled trials [Figure 3]

Intraoperative watertight closure

The overall RR showed that PEG resulted in significantly more intraoperative watertight closures than standard care (RR = 1.44, 95% CI [1.24, 1.66], $P < 0.001$). Pooled results were homogeneous ($I^2 = 59\%, P = 0.12$), Figure 3.1.
| Study                  | Study design                        | Patients number | Age   | Gender | Intervention | Population | Main finding                                                                                                                                 |
|-----------------------|------------------------------------|-----------------|-------|--------|--------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Wright et al, 2015    | Randomized single-blind, multicenter trial. | 74              | 44.3  | 30     | PEG hydrogel sealant versus any standard method | Patients were having elective spinal surgeries | Patients treated with the PEG hydrogel spinal sealant had a significantly higher rate of watertight closure than the control (98.6% vs. 79.2%, P=0.003). No statistical differences were seen in postoperative cerebrospinal fluid, infection, and wound healing. No neurological deficits were seen attributable to the sealant. |
| Kim et al, 2011       | Randomized single-blind, multicenter trial. | 102             | 47.7  | 48     | PEG hydrogel sealant versus any standard method | Patients were having elective spinal surgeries | Patients treated with the PEG hydrogel spinal sealant had a significantly higher rate of watertight closure than the control (100% vs. 64.3%, P<0.001). No statistical differences were seen in the postoperative cerebrospinal fluid leak, infection, and wound healing. No neurologic deficits were seen attributable to the sealant. |
| Osbun, Ellenbogen, Chesnut et al, 2012 | Randomized single-blind, multicenter trial. | 120             | 49.6  | 42     | PEG hydrogel sealant versus any standard method | Patients were having elective cranial surgeries | The incidences of neurosurgical complications, surgical site infections, and CSF leaks were similar between treatment and control groups, with no statistically significant difference between the measures. The PEG hydrogel sealant was 100% effective in stopping CSF leakage in all patients. There were no sealant-related adverse events, and all clinical outcomes were consistent with expectations for seriously ill patients undergoing prolonged neurosurgical procedures. |
| Cosgrove et al, 2007  | Single-arm, multicenter trial        | 111             | 49    | 43     | PEG hydrogel sealant | Patients were having elective cranial surgeries |                                                                                                                                               |
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Study design | Patients number | Age | Gender | Intervention | Main finding
--- | --- | --- | --- | --- | ---
Boogaarts, et al. 2005 | Single-arm multicenter trial | 46 | 52 | Exp. group | Of the 46 patients included, there was one case of overt CSF leak. One patient had a pseudomeningocele. There were no adverse events other than those related to the disease or to the surgical procedure itself.

Nishimura, et al. 2012 | Single-arm trial | 24 | Not available | Exp. group | Of the 24 patients included, only two patients developed subcutaneous CSF collection. In all patients, intraoperative watertight closure of the dura could not be obtained after primary closure. CSF: Cerebrospinal fluid, PEG: Polyethylene glycol

**CSF leak**
The combined effect estimate did not reveal any significant difference between both groups in terms of CSF leaks (RR = 0.87, 95% CI [0.37, 2.04], P = 0.7). Pooled results were homogenous (I² = 0%, P = 0.5), Figure 3.2.

**Surgical site infections**
The net result of analysis did not favor any of the two groups regarding the incidence of surgical site infections (RR = 0.74, 95% CI [0.33, 1.63], P = 0.45). Pooled results were homogenous (I² = 0%, P = 0.8), Figure 3.3.

**Neurological deficits**
The combined RR did not show a significant difference between PEG and standard care (RR = 0.96, 95% CI [0.46, 2.03], P = 0.92). Pooled results were homogenous (I² = 0%, P = 0.5), Figure 3.4.

**Analysis for both controlled and noncontrolled trials**

**Intraoperative watertight closure**
The overall effect estimate did not reveal significant results (RR = 0.994, 95% CI [0.986, 1.002]). Pooled results were homogenous (I² = 0%, P = 0.9), Figure 4.1.

**CSF leak**
Combined effect estimates and 95% CI showed marked significance (RR = 0.0238, 95% CI [0.0102, 0.0373]). Pooled results were heterogeneous (I² = 61%, P = 0.026), Figure 4.2.

**Neurological complications**
The net results of neurological complications (pseudomeningocele, surgical site infection, and neurological deficit) from surgery revealed significant results (RR = 0.035, 95% CI [0.018, 0.052]). Pooled results were heterogeneous (I² = 50%, P = 0.089), Figure 4.3.

**DISCUSSION**

**Summary of main results**

Analysis of controlled trials only revealed that PEG increases intraoperative watertight closures. However, it did not show any difference between PEG and standard care in terms of neurological deficits, postoperative CSF leaks, and surgical site infections.

Single-arm analysis of all trials showed no difference in terms of intraoperative watertight closures; this may be
stronger evidence than controlled trials, as the strength of meta-analysis is increased by increasing the number of included studies, provided that results remain homogeneous. However, postoperative CSF leaks and surgical site infections were significant.

**Significance of main results**

Watertight closure is critical, and the dura seal is an excellent material to achieve zero leakage intraoperatively. However, stopping postoperative leakage cannot be guaranteed by the dura seal in controlled trials. Prevention of surgical site infection is the matter of achieving a good medium for healing and infection control rather than the application of foreign material.

**Agreement and disagreement with the previous studies**

Kim et al. studied the dural sealant in various procedures in neurosurgery; they found that using it was effective in the prevention of CSF fistula. Nakamura et al. conducted a randomized controlled trial for using dural sealants in spine surgery; they observed a different outcome between as regard drainage fluid between controlled and studied groups. Kim et al. studied the usage of sealants against the standard of care in case of spinal CSF leakage intraoperative; they found that superior results with dural sealants over traditional methods with no neurological injury can be attributed to it. Wright et al. conducted a randomized controlled trial to study the incidence of CSF leakage after unintended durotomy; they found that dural sealants were superior to standard of care techniques for closing dural defects after Valsalva trials. Watertight closure was a primary goal in Boogaarts et al. study; they found a marvellous reduction in CSF leakage (100%) with no undesired effects in cranial surgery. The same results were achieved by Cosgrove et al. when compared to dural sealants with traditional dural closure in cranial surgeries. Nishimura et al. studied the application of dura seal in a specific type of cranial surgeries (bypass surgery).
They found that easy and effective sealing of the field was achieved by the dura seal. Only 2/24 patients developed subcutaneous CSF fistula later on. The usage of the dura seal gave no negative effects on the patency of the anastomosis. Takumi et al. designated a prospective study but in functional neurosurgery (deep brain stimulation) to assess CSF leakage and brain shifting after DBS in a controlled trial. They found that the application of such material reduces CSF leakage and brain shifting to a minimum if compared to traditional methods. In the skull base surgery field, this material has been studied heavily by George et al. Up to date, it is the largest trial conducted in this field, with 726 patients who underwent skull base surgery were enrolled and randomized into classic control and study groups. They found CSF leakage events in 25 (6.9%) patients versus 30 (8.2%) current practice patients with no statistically significant difference (odds ratio: 0.82; 95% CI: 0.47, 1.43; \( P = 0.485 \)). Despite its safety, easy method of application, and low rate of CSF leakage, George et al. found that both treatments were well tolerated with similar frequency of adverse events.

Osbun et al. conducted a randomized controlled trial used the same material in cranial surgeries in a group (\( n = 120 \) against...
In the dural sealant group, the incidence of neurosurgical complications was 5.8% (n = 7), the incidence of surgical site infections was 1.7% (n = 2), and the incidence of CSF leak was 0.8% (n = 1). In the control group, the incidence of neurosurgical complications was 7.7% (n = 9), the incidence of surgical site infection was 2.6% (n = 3), and the incidence of CSF leak was 1.7% (n = 2). Hutter et al. studied the factors responsible for CSF leakage in elective cranial surgeries. They found several factors responsible for CSF leakage and observed that cases treated with dura sealant showed a minimum amount of leakage if compared to others.

In contrast, a different outcome was achieved by Green et al. Green et al. conducted a multicenter cohort study to assess the safety and effectiveness of dural sealant in cranial surgeries. Safety was assessed to 30 days postsurgery, including the incidence of CSF leakage. No deaths or unexpected serious adverse drug reactions were reported. CSF leakage within 30 days postoperatively was 2.2% and 2.0% in study and control groups, respectively.

Tew et al. conducted a large cohort study that included 17 centers to study the effectiveness of dural sealant versus traditional methods of dural closure in cranial surgeries.

CONCLUSION AND RECOMMENDATIONS

Dura seal material is an acceptable adjuvant for dural closure when the integrity of the dura is in question. However, marketing it as a factor for the prevention of surgical site infection is not scientifically proved. We suggest that, for neurosurgeons, using the dural sealants are highly recommended for duraplasty, skull base approaches, and in keyhole approaches.
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Declaration of patient consent

Patient’s consent not required as there are no patients in this study.

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Conflicts of interest

There are no conflicts of interest.

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