

Original Research Article

Augmentation of dural closure following cerebro-spinal surgeries using Evicel- an experience of 105 patients in India

Batuk D. Diyora*, Nilesh More, Gagan Dhali

Department of Neurosurgery, Lokmanya Tilak Municipal General Hospital and Lokmanya Tilak Municipal Medical College, Sion, Mumbai, India

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***Correspondence:**

Dr. Batuk D. Diyora,

E-mail: bddiyora@gmail.com

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ABSTRACT

Background: For the neurosurgeon, CSF leaks are a frustrating post-operative complication, and for the patient, it can result in unanticipated morbidity and mortality. Immediate intra-operative recognition of incidental durotomy and dural closure may avoid it. Fibrin sealant is a two-component topical hemostat, dura sealant, and tissue adhesive consisting of fibrinogen and thrombin. We conducted this study to evaluate the efficacy of fibrin sealant Evicel in the management of postoperative CSF leaks as an adjunct to dural suture in patients undergoing a variety of neurosurgical procedures.

Methods: This was a retrospective, single-center clinical study conducted on 105 patients who underwent elective neurological surgery from August 2015 to May 2016 at Sion Hospital, India. The efficacy endpoint was the prevention of clinically evident and verified postoperative CSF leak.

Results: In all patients, the dural defect was effectively repaired intraoperatively, indicated by the absence of CSF leakage. The success rate of using Evicel was 100% in our cohort for the durasealant efficacy. No adverse effects were reported.

Conclusions: We conclude that the use of fibrin sealant Evicel was successful to manage CSF leaks and achieve predictable watertight dural closure resulting in a reduction of intraoperative and postoperative fluid collections. It possesses an acceptable safety profile, consistent with previous findings from other similar studies and studies evaluating the role of Evicel in other surgical indications.

Keywords: Cerebrospinal fluid leak, Cerebro-spinal surgery, Dural repair, Dural sealant system, Fibrin glue, Fibrin sealant, Incidental durotomy

INTRODUCTION

Watertight dural closure is of utmost importance in neurosurgical practice. Incidental durotomy (ID), or unplanned perforation of the thecal sac, is a common occurrence following neurosurgery with an incidence ranging from 0.3 to 13%.¹⁻³ This allows cerebrospinal fluid (CSF) to leak into the extradural space. Given the advancements in surgical technique and even in very experienced hands a 100% success rate in hermetic dural repair is yet to be realized.

Though dural suturing is the widely used method of closure, suturing is challenging to perform, especially in times when dural defects are in comparatively unreachable areas or encircled by friable dura.^{4,5} For instance, endonasal endoscopic skull base surgery or root axillary durotomies where primary suturing of the dura mater may be very difficult. Other predisposing factors for ID may be prior surgery with the subsequent development of scar tissue, altered anatomy, poor dissection planes, and adherence of tissue to the dura, etc.⁶ The lengthier operative times, instrumentations, and

a less skilled and expert surgeon represent other significant risk factors for DT.⁷

For the neurosurgeon, CSF leaks are a frustrating post-operative complication, while for the patient, these can result in unanticipated morbidity and mortality.^{8,9} The cerebrospinal fluid (CSF) fistula is a common neurosurgical complication, occurring in 1% to 27% of cases. High-flow CSF leaks are the most challenging variety. Furthermore, the sequelae of ID include the formation of a pseudomeningocele, arachnoiditis, meningitis, epidural abscess, deterioration in neurological status or need for re-operation.^{10,11} Allen and co-workers demonstrated that the relative risk of developing meningitis in patients with postoperative CSF leak is more than 10%.¹² This has been further associated with increased length of hospitalization and worse neurological outcome.

The main clinical manifestations of ID and resultant CSF leak are postural headache, nausea, dizziness, photophobia, and tinnitus. A persistent CSF leak may cause a chronic pain disorder accompanying with other conditions such as cranial nerve palsies, radiculopathy, and/or postural headaches.^{7,13} CSF leak is also reason causing poor wound healing and possible wound dehiscence. The health-economic perspective points out that economically the treatment of this complication affects the patients 141% more than that of patients without a CSF leak.¹³

The management of cerebrospinal fluid leaks is by preventing their manifestation. The instantaneous, intraoperative recognition of ID and dural closure may prevent these situations from happening.¹⁴ Currently, modalities to reinforce the site of the dura mater closure include additional suture, autologous, allogeneic, or artificial grafts, and various sealant products and collagen sponges. The products may be classified as topical hemostats (lead to blood clotting), sealants (create sealing barriers), and adhesives (to bond tissue components together).¹⁵

The use of clotting substances sourced from the blood for hemostasis during surgical procedures dates back to 1909. The modern fibrin sealing was developed in Vienna in 1972. Fibrin sealant consists of a two-component topical hemostat, sealant, and tissue adhesive i.e. fibrinogen and thrombin. Fibrin sealants successfully supplement watertight dural closure during neurosurgery and also provide intraoperative hemostasis with reduced postoperative drainage, reduced transfusion requirements, reduced length of hospital stay, cost, and scarring. They contain two main active ingredients, fibrinogen, and thrombin (human/animal/recombinant origin), that when mixed form a fibrin clot.¹⁶

These products play an important role in sealing biological tissues owing to their two-component liquid glue or as a two-component dry patch properties. Liquid

glue formulations include Tisseel[®] or Tissucol[™] (Baxter), Evicel[®] (Ethicon, Johnson & Johnson), and dry patch products such as Tachosil[®] (Baxter). Few commercially available sealants are restricted by less bonding strength, viral transmission (bovine/porcine source), and bothersome preparation.¹⁷

An ideal durasealant should be developed from biocompatible and nontoxic material. It should be water-soluble, absorbable, flexible, and durable (so that it does not degrade overtime). It should adhere to tissue and must protect cortex from inflammation. The material shouldn't adhere to brain and should be transparent if brain imaging needs to be performed. The prevention of CSF leakage and humidity from escaping the craniotomy are crucial parameters while selecting durasealant. It should be easy to apply and handle requiring shorter operative time. The hemostatic effectiveness of fibrin sealant in surgery has already been well established in a Cochrane review which showed a reduction of both postoperative blood loss and perioperative exposure to allogeneic red blood cell transfusion.¹⁶ Further, this study was conducted to assess the efficacy of Evicel durasealant in the management of postoperative/post-instrumentation CSF leaks in patients undergoing several neurologic or spinal procedures in India.

METHODS

This was a retrospective, single-center clinical study conducted on 105 patients who underwent elective neurological surgery from August 2015 to May 2016, with a 12 month follow-up period for each patient at Sion Hospital, India. Informed consent was obtained from all patients before the initiation of surgery. All eligible patients who provided informed consent were included. The study was approved by the Institutional Ethics Committee (IEC). All operative notes, inpatient records, clinic notes, and imaging studies were analyzed for the first 3 months of the postoperative period to identify patients experiencing an ID, possible or persistent CSF leak, followed by application of Evicel.

Evicel application technique

Evicel was used after sutured closure of the dura mater, after confirmation of dural leak by subdural irrigation and Valsalva maneuver. Small dural gaps (<5 mm in diameter), when present, were plugged with muscle (when available) before the application of Evicel, in order to create a barrier to CSF leak and to avoid the adhesion of the sealant to the cerebral tissue. The manufacturer's instructions were followed while applying Evicel.

A durotomy was defined as any unintended perforation of the dura that occurred during surgery. A persistent CSF leak was if continued drainage of CSF from the operative incision within 90 days of surgery and required an intervention greater than simple bed rest or over-sewing of the wound with non-absorbable suture. CSF was

differentiated from serous drainage by the use of a B-2 transferrin assay in all cases if the diagnosis was in question.

After thawing, the two components of Evicel (BAC2 and Thrombin) were used. Evicel was sprayed or dripped onto the tissue in short bursts (0.1-0.2 ml) to produce a thin, even layer using pressurized CO₂ gas. A second layer was applied if the hemostatic effect was not complete. Following Evicel application, intra-operative CSF leakage was again assessed through the sealed durotomy with a second Valsalva maneuver for 10 seconds. In all cases, a “water-tight” dural closure was achieved intra-operatively. The closure was performed with 4-0 dural silk sutures. A simple running or figure-of-eight stitch was the method of suture repair. Every attempt was made to oppose muscle so as to eliminate dead space overlying the durotomy. CSF diversion using a lumbar drainage device was not employed in this patient cohort. Prophylactic antibiotic therapy was administered during and after surgery in accordance with the standard of care at the institute.

Study outcome

The primary objective was to demonstrate the efficacy of Evicel as an adjunct in sealing the dura mater. The primary efficacy endpoint was the prevention of clinically evident and verified postoperative CSF leak or clinically evident pseudomeningocele within 7 weeks after surgery upon dura closure. The secondary efficacy endpoint was the presence of clinically evident blood loss and need for blood transfusion. Safety was assessed by a recording of adverse events (AEs) reported by the patient, on clinical examination, and by CT or MRI imaging.

Statistical analysis

For continuous variables, the clinical and demographic data were summarized as means and standard deviations and categorical variables are denoted as frequencies. For comparison of categorical variables χ^2 test was used, and $p < 0.05$ was accepted as statistically significant. All statistical comparisons were performed using the SPSS software version 20.

Preoperative assessment

Pre-operative admission criteria included adult patients undergoing elective non-trauma-related neurological surgery involving opening and closure of the dura mater and who had a clean surgical wound. Previous radiotherapy, previous surgery, and chronic corticosteroid therapy were also included in the study.

Intraoperative

Presence of a dural opening and failure to obtain a watertight primary closure with a standard dural microsuture (leakage evidenced by subdural irrigation of

the surgical cavity prior to completion of suturing, followed by Valsalva maneuver and/or positive pressure ventilation to test the completed primary suture closure) was the intra-operative inclusion criteria. In the surgeon's opinion, patients received Evicel to augment the dural closure. Valsalva maneuver was performed for all cases to test the integrity of the DT repairs and the absence of any intraoperative CSF leakage. The fascial and subcutaneous muscles and skin layers were individually and separately sutured after DT repair. There was no insertion of drains in any of the cases.

Postoperative care

All patients went through daily postoperative wound examination in order to evaluate the incidence of CSF collection, incisional CSF leak, any inflammatory reaction, or wound infection. A brain CT or MR scan was performed within 48 hours in all patients to observe and manage post-operative complications. A clinically evident verified CSF leak was defined as clear fluid leaking through the surgical incision or orifice (e.g., rhinorrhea or otorrhea) verified by a glucose concentration test or β -2 transferrin test. Clinically evident pseudomeningocele was defined as a subcutaneous visible or palpable fluid accumulation adjacent to or at the site of surgical incision suspected to be CSF. A non-clinically evident pseudomeningocele was defined as CSF accumulation detected only by CT or MRI scan at discharge or any time after surgery.

If an ID had occurred during surgery, patients were instructed to remain flat in bed for 24-72 hours after surgery.

The wound was then evaluated at 2 weeks and 6 months after surgery. In addition, patients were instructed to contact the treating team in case of a wound leak.

All procedures in this study were performed by one senior neurosurgeon.

RESULTS

Of 105 patients who underwent elective neurological surgery, 64 (61.5%) were males and 40 (38.5%) were females. The mean age of patients was 36.66 ± 19.99 and a range of 0.83-105 years. Evicel was used as a fibrin sealant in all patients. 20 cases (19%) had diabetes as a comorbidity. The mean duration of surgery was 233.27 ± 045.46 minutes. The baseline characteristics are described in Table 1.

There were 105 index neurological surgeries reviewed that had an ID. Evicel was used in all of these ID cases to augment the dural closure.

Table 2 depicts that there were no cases with the occurrence of postoperative fluid collections or drainage.

There were no anastomotic or staple line bleeding after Evicel was used.

Table 1: Baseline demographic characteristics.

Parameters	
No. of cases	105
Age (years)	
Mean	36.66
SD	19.59
Median	38.00
Range	0.83-105.00 years
Sex (%) (N = 105)	
Male	64 (61.5 %)
Female	40 (38.5 %)
H/O other indication	0
Co-morbidities	
Diabetes	20 cases (19%)
Hypertension	-
Chronic kidney disease	-
Arthritis	-
Other	-
Mean duration of surgery (minutes)	233.27±045.46
Indication for surgery	
Spinal sol	21 (20%)
Spinal deformity	15 (14.3%)
Dramatic spine	14 (13.3%)
Intracranial sol	43 (41%)
Vascular malformation	12 (11.4%)

Table 2: Proportion of cases with occurrence of postoperative fluid collections/drainage.

Duration	N	Yes		No	
		No.	%	No.	%
Baseline-at surgery	105	01	01.0	104	99.0
48 hours	96	-	-	96	100.0
15 days	98	-	-	98	100.0
30 days	95	-	-	95	100.0

There was no requirement for repeat surgery to control bleeding of CSF leak.

The endpoint of clinically evident and verified postoperative CSF leak, clinically evident pseudomeningocele or treatment failure was observed in none of the patients. Thus, the success rate of using Evicel was 100% in our cohort for the durasealant efficacy. In all patients with DT, the dural defect was effectively repaired intraoperatively, indicated by the absence of CSF leakage. No signs of post-operative CSF leakage or neurological and infection-related complications were observed in any of the patients treated with Evicel. This was further verified by MRIs performed during follow-up which confirmed that there

were no cases of CSF leaks, hemorrhages, pseudocysts, or spinal arachnoiditis.

The healing of the dural plasty was monitored during the following weeks and no untoward events were noted. There was no specific inflammatory reaction or healing difficulties occurred in the patients treated with this sealant. No local or systemic AEs were considered related to trial treatment in the current practice group. No AE leading to death occurred. Evicel was not felt to be detrimental to wound healing in any case.

In safety viewpoint, there were no reports of allergic reactions.

From the neurosurgeon’s viewpoint, the application of Evicel was found to be easy and convenient.

DISCUSSION

The introduction of fibrin sealants has resulted in the rate of postoperative CSF leakage being dramatically reduced thus also reducing the costs related to the management of CSF leak, its complications, and the length of postoperative hospitalization. Fibrin sealants are widely used for a variety of neurosurgical indications for dural closure and/or reinforcement.

Surgeons have their predilections for the effective treatment of DTs, and the literature reports several strategies like and absorbable hydrogels; autologous fibrin tissue adhesive; blood patches; closed subarachnoid drainage; fibrin adhesive or cyanoacrylate polymer sealants; gel foam; laser tissue welding; muscle, fat or fascial grafts; prolonged subfascial drain placement; sutures; polyglycolic acid mesh with fibrin glue. At our institution, we utilize Evicel as a dural sealant. The strong bonding property is the most desirable attribute of fibrin sealant; it makes the area robust to internal CSF pressure and pulses which could subsequently force the suture to open and dislocate the applied sealant.

Efficacy

In this study, Evicel was used to plug CSF leaks in all 105 patients. Application of the sealant achieved full duroplasty in 100% of study participants. There were no CSF leaks found following Valsalva maneuvers.

A number of systematic reviews have examined the efficacy and safety of fibrin sealants in cardiac surgery, thoracic surgery, plastic and reconstructive surgery, and orthopedic surgery settings.¹⁸⁻²¹ The main components of the sealant are fibrinogen, thrombin, factor XIII, and antifibrinolytic agents, such as tranexamic acid or aprotinin. The local hemostatic effects of Fibrin sealants are attained by reproducing the latter stage of the coagulation cascade, and thus facilitating the development of a stable fibrin clot and the following hemostasis.²² The neurosurgical literature supports the

use of fibrin sealant for dural closure including specific surgeries like duraplasty after suboccipital decompression for Chiari 1 malformation in conjunction with autologous pericranium, for the healing of dural tears related to ossification of the ligamentum flavum, and also, as a radiographically guided instillation for a nerve root tear (trigger for intracranial hypotension).²³⁻²⁵

In this retrospective study, the primary endpoint of the estimated leak event rate favored Evicel with events in none of the patients in a real-world scenario. Our retrospective cohort demonstrated a 100% success rate in managing dural tears. Similarly, there was not a single case of a postoperative fluid collection or anastomotic or staple line bleeding after Evicel was used. As such, these findings indicate that, even without the closely monitored setting of a clinical trial, it is possible to achieve very low incidences of CSF leak and pseudomeningocele in patients undergoing neurological surgery by using Evicel. Cammisa et al reported that 3.1% durotomies occurring during 2144 spinal operations which were immediately treated with dural suturing and fibrin glue.²⁶ Green et al demonstrated the superiority of fibrin sealant over sutures alone in establishing intra-operative tight closure of a dural incision.²⁷ They showed that intra-operative watertight closure was achieved in 92.1% Evicel-treated subjects. Furthermore, Hobbs et al reported that fibrin sealant was found effective in 120 patients who underwent pituitary surgery procedures with intraoperative CSF leaks.²⁸ All intraoperative leaks were managed well resulting in a low incidence of postoperative CSF leakage of 1.7%. Other authors also analyzed fibrin sealant in preventing postoperative cerebrospinal fluid leaks. Its use was mainly in cranial procedures with fewer occurrences of postoperative CSF leaks.²⁹ Many cases involving patients undergoing transsphenoidal surgery in which postoperative CSF leaks were significantly decreased have been reported. For example, Yoshimoto et al evaluated a fibrin sealant for the prevention of postoperative extradural fluid collection through the dural sutures in patients undergoing craniotomy for an unruptured aneurysm.³⁰ Once again, the study demonstrated the superiority of the fibrin sealant over sutures alone (fluid collection 26% versus 42%; $p < 0.05$). Furthermore, a retrospective study by Kassam et al evaluated the efficacy (4-16% versus 0%) and cost-effectiveness of fibrin in patients with intracranial lesions.³¹

In another prospective analysis of 100 patients undergoing microneurosurgery with TachoSil, CSF leak was not observed in any patient.³² In a randomized trial in 229 patients undergoing elective craniotomy with dural opening, adjunctive use of TachoSil was associated with a non-significantly lower postoperative CSF leak rate compared with suturing alone (9.7% versus 17.2%; $p = 0.108$).³³

The effectiveness of Evicel as a dural sealant reflects its high tensile strength and dural water-tightness. In

addition, although it has not been assessed in this study, the use of sealants such as Evicel may also offer cost benefits, especially with regard to reduced postoperative complications and shorter length of hospital stay.

Evicel was well tolerated with no evidence of an increased frequency of AEs and no safety concerns. A similar favorable safety profile of Evicel was reported by Green et al also in which event rate was similar to the suture group. CSF leakage within 30 days post-operatively was observed in 2.2% cases and 2 cases of CSF rhinorrhoea were reported. Our results are also consistent with a previous report of reduced postoperative epidural hematoma, epidural empyema, and infection with another durasealant patch TachoSil.³⁴

There was not a single case of CSF fistula formation in our study. The study by Kim et al evaluated the use of DuraSeal in 158 spinal surgeries.³⁵ This study demonstrated that the use of DuraSeal in spinal surgeries is associated with absolute risk reduction in 35.6% (95% CI: 23.0-48.2%) for CSF fistula; there was no difference between the control and intervention groups regarding the development of further complications. The study by Osburn et al analyzed the use of DuraSeal in 237 randomized patients, having CSF fistula as the primary outcome and other complications as the secondary outcome.³⁶ There was no difference in the incidence of neurosurgical complications, including CSF leak, as well as incisional complications.

User experience

In our experience, Evicel was convenient to use. A single and very thin layer of Evicel is adequate to strengthen the dural repair site and to protect from any secondary ruptures. Moreover, the gradual resorption of Evicel permits enough time for local healing of the DT.

This observational study shows that Evicel use was effective in intraoperative DT repair and did not result in any complications including in surgeries where a scarred and fibrotic dura can lose its physiological elasticity and resilience, being exposed to mechanical stress and bulging of CSF pulses. It also demonstrated favorable adverse effect profile.

Safety

Since Evicel contains human components, there is possibly no potential for immunogenic reactions; however, although immunogenicity was not assessed in this study, there were no adverse events.

The study being a retrospective analysis has some inherent drawbacks. Also, the results of dura sealing are as much dependent on Evicel's efficacy as much on the technique and surgical skills of the operating surgeon. Thirdly, since there is a lack of a comparator arm, the results should be interpreted with caution.

CONCLUSION

The need to effectively manage tissue sealing has had a strong influence on the developments in modern surgery. One such development is the field of surgical tissue adhesives, with multiple products now available. Fibrin sealant was the first widely available tissue adhesive. The product is now fully mature as a hemostatic agent and durasealant in neurological surgery. We conclude from this study that use of fibrin sealant Evicel was successful to manage CSF leaks and achieve predictable watertight dural closure resulting in a reduction in intraoperative and postoperative fluid collections. It possesses an acceptable safety profile, consistent with previous findings from other similar studies and studies evaluating Evicel in other surgical indications. Furthermore, this may prove to be cost-effective by reducing the morbidity associated with CSF leakage. The ideal dura sealant must possess specific biological, mechanical, and structural properties, while presenting minimal risk of antigenicity, toxicity, and disease transmission. Additionally, it should be easy to handle, thus reducing operative time. Taking all these into account, the author is of the opinion that Evicel represents a consistent alternative. We emphasize that the strength of evidence identified in this retrospective single center study can be further enhanced by conducting additional well-designed and controlled clinical trials.

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