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Clinical Study

Polyethylene glycol (PEG) hydrogel dural sealant and collagen dural graft matrix in transsphenoidal pituitary surgery for prevention of postoperative cerebrospinal fluid leaks

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ABSTRACT

Cerebrospinal fluid (CSF) rhinorrhea is the most common complication after transsphenoidal pituitary surgery. The authors compare their previous experience using an autologous fat graft and lumbar drain placement in 107 patients with their current technique of using a dural sealant and collagen matrix in 97 patients to prevent postoperative CSF leak after pituitary tumor resection. The failure rate for CSF leak repairs between the two groups was similar. The use of a dural sealant and collagen matrix, however, has the advantages of decreased length of hospital stay, decreased length of Intensive Care Unit stay, avoidance of the morbidity of an extra abdominal incision, and avoidance of the risks of lumbar CSF drainage.

1. Introduction

The transsphenoidal surgical approach is the preferred method for pituitary tumor resection. This procedure is considered safe and effective for the treatment of sellar and parasellar pathology. The mortality rate is low and the perioperative complications are mainly limited to CSF leakage.[1] Unfortunately, obtaining a watertight skull base dural closure can be challenging as a result of the limited working space within the sphenoid sinus and complex anatomy of the sella. To avoid complications as a result of a CSF leak (for example, meningitis, tension pneumocephalus), numerous techniques of sellar reconstruction have been described.[2–23]

Since April 2005 our group has been using a combination of polyethylene glycol (PEG) hydrogel dural sealant (DS) (DuraSeal, Confluent Surgical, Waltham, MA, USA) and collagen dural graft matrix (CM) (DuraGen, Integra Life Sciences, Plainsboro, NJ, USA) in all transsphenoidal pituitary operations to reinforce and reconstruct the operative site. We present our most recent experience with transsphenoidal pituitary surgery and compare these results with a more traditional technique of fat graft harvest and lumbar drain (LD) placement.

2. Methods and materials

2.1. Patient population

The pituitary tumor database of University of South Florida/Tampa General Hospital was retrospectively reviewed. Patients who underwent transsphenoidal pituitary tumor resection, were older than 18 years of age, and who were followed-up for at least 18 months were included in the study. Two groups were identified. Group 1 consisted of all patients from July 2000 to March 2005 who had undergone transsphenoidal pituitary surgery with placement of a fat graft to reinforce the operative site and an LD if necessary. Group 2 consisted of all patients from April 2005 to December 2009 who had undergone transsphenoidal pituitary surgery with the placement of a DS/CM to reinforce the operative site. Both groups were analyzed and compared in our series. Operative notes were reviewed to determine the magnitude of intraoperative CSF leak. Medical records were reviewed to identify any complications or adverse effects associated with the use of the DS/CM. All procedures were performed by the senior authors (FLV, TP). The collection of data for this study was approved by the university hospital's Internal Review Board and was performed in accordance with Health Insurance Portability and Accountability Act requirements.

Clinical data were stored in Microsoft Excel (Microsoft, Redmond, WA, USA) files. Descriptive statistics were reported as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables. Continuous

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variables were assessed for normality using the Kolmogorov–Smirnov test and were analyzed using the non-parametric Mann–Whitney *U*-test. Categorical variables were analyzed using the chi-squared and Fisher Exact tests.

2.2. Intraoperative CSF leak grading and repair methods

Intraoperative CSF leaks were classified according to the following grading system: grade 0, no noticeable leak; grade 1, small weeping CSF leak confirmed by a Valsalva maneuver without a visible diaphragmatic defect; and grade 2, obvious diaphragmatic defect with associated leak. The degree of CSF leak was reported in all operative dictations.

2.3. Surgical technique

All patients underwent an endoscopically assisted microscopic endonasal transsphenoidal approach to the sella as previously described.[24] After tumor resection, a Valsalva maneuver was performed to determine whether there was evidence of a CSF leak.

Repair of each grade of CSF leak in patients in group 1 was as follows: grades 0 and 1, fibrin sealant and gelfoam; and grade 2, fibrin sealant, gelfoam, abdominal fat graft, nasal packing, and lumbar CSF diversion for 5 days. Repair of each grade of CSF leak in group 2 was as follows: grades 0 and 1, a layer of the DS/CM; and grade 2, a layer of DS/CM, and nasal packing (Table 1).

Repair of the CSF leak in patients in group 2 was conducted as follows: a layer of CM was tacked between the dural sleeve and the edge of the sellar defect (Fig. 1). Next, a layer of DS was applied with the air-assisted MicroMyst™ applicator (Covidien, Waltham, MA, USA) over the surface and edges of the skull defect (Fig. 2). Nasal packing was then used if the patient had an obvious CSF leak (grade 2 CSF leak).

2.4. Postoperative care

All patients were admitted to the Intensive Care Unit (ICU) after surgery. On postoperative day 1, patients with grade 0 and 1 repairs were transferred to the floor if clinically stable.

2.4.1. Group 1

Patients with grade 2 repairs remained in the ICU for LD management until postoperative day 5. Lumbar drains were clamped and nasal packing discontinued on postoperative day 4. Lumbar drains were discontinued on postoperative day 5 if there was no evidence of CSF leak. Patients were then transferred to a neurosurgery ward and discharged home on postoperative day 5.

Table 1
Intraoperative grading of cerebrospinal fluid (CSF) leak and skull base repair methods in two groups of patients who underwent transsphenoidal pituitary surgery

CSF leak grade	Group 1: 2000–2005	Group 2: 2005–2009
0: No noticeable leak	Fibrin sealant and gelfoam	PEG hydrogel dural sealant and collagen dural graft matrix
1: Small weeping leak without diaphragmatic defect	Fibrin sealant and gelfoam	PEG hydrogel dural sealant and collagen dural graft matrix
2: Obvious diaphragmatic defect with associated leak	Fibrin sealant, gelfoam, abdominal fat graft, nasal packing, and lumbar drain	PEG hydrogel dural sealant, collagen dural graft matrix, and nasal packing

PEG = polyethylene glycol.

Fig. 1. Illustration showing closure of dura with a layer of collagen graft matrix. (This figure is available in colour at www.sciencedirect.com.)

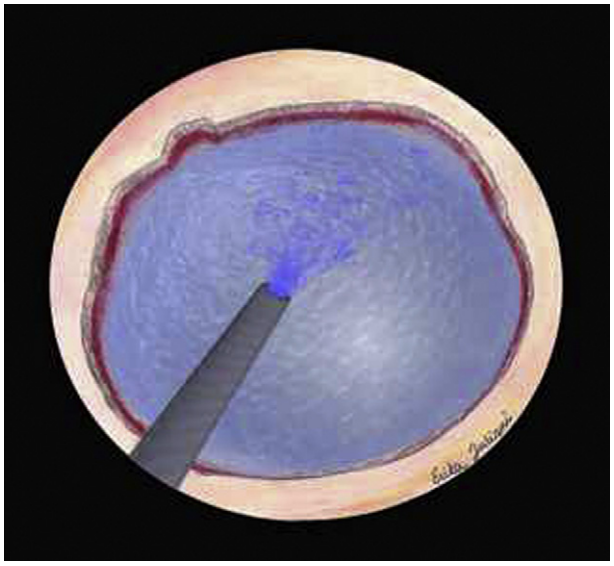

Fig. 2. Illustration showing the application of dural sealant over a layer of collagen matrix. (This figure is available in colour at www.sciencedirect.com.)

2.4.2. Group 2

Patients with grade 2 repairs were transferred to the neurosurgery ward on postoperative day 1 if clinically stable. On postoperative day 3, patients had nasal packing removed and were discharged to home if no CSF leak was identified.

All patients in both groups received postoperative antibiotics (vancomycin, cefepime and metronidazole) for at least 48 hours but no longer than 72 hours if the patient was an inpatient for more than 3 days.

3. Results

A total of 204 consecutive patients who met the inclusion criteria were enrolled in the study. Group 1 comprised 107 patients (50 male, 57 female) with a mean age of 51 years (range, 28–78 years) (Table 2). Pathologic indications for surgery were 105 macroadenomas (including four patients with pituitary apoplexies, five with