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ORIGINAL ARTICLE - BRAIN TUMORS

The use of dehydrated amniotic membrane allograft for augmentation of dural repair in transsphenoidal endoscopic endonasal resection of pituitary adenomas

Daniel G. Eichberg[1,2] · Angela M. Richardson[1] · G. Damian Brusko[3] · Sheikh C. Ali[4] · Simon S. Buttrick[1] · Ashish H. Shah[1] · Elie S. Alam[5] · Zoukaa B. Sargi[5] · Ricardo J. Komotar[1]

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Abstract

Background In transsphenoidal endoscopic endonasal surgery (TEES), watertight separation of the sinonasal cavity and intracranial compartment is the primary goal of closure. However, even when meticulous closure technique is implemented, cerebrospinal fluid (CSF) leaks, dural scarring, and meningitis may result. Particularly when intraoperative CSF leak occurs, materials that facilitate the creation of a watertight seal that inhibits disease transition and minimizes inflammatory response after durotomy are sought. Dehydrated amniotic membrane (DAM) allograft appears to confer these attributes as studies have shown it augments epithelialization, facilitates wound healing, and minimizes and impedes bacterial growth. We detail the use of DAM allograft to augment sellar closures after TEES.

Methods We conducted a feasibility study, retrospectively reviewing our institution's database of TEES for resection of pituitary adenomas in which DAM was utilized to supplement sellar closure.

Results One hundred twenty transsphenoidal surgery cases with DAM were used during sellar closure, with a 49.2% intraoperative CSF leak rate. Of this cohort, two patients experienced postoperative CSF leak (1.7%), and no patients developed meningitis. CSF leak rate for TEES-naïve patients was 0.9%.

Conclusions This feasibility study demonstrates that dehydrated amniotic membrane allograft can be safely utilized as an adjunct during sellar closures for TEES for pituitary adenoma resection with very low rates of CSF leak and meningitis.

Keywords Dehydrated amniotic membrane · Dural repair · Brain tumor · Skull base · Cerebrospinal fluid leak · Pituitary adenoma

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✉ Daniel G. Eichberg
Daniel.eichberg@jhsmiami.edu

[1] Department of Neurological Surgery, University of Miami Miller School of Medicine, Miami, FL 33125, USA

[2] Department of Neurological Surgery, University of Miami School of Medicine, 1095 NW 14th Terrace (D4-6), Miami, FL 33136, USA

[3] University of Miami Miller School of Medicine, Miami, FL 33125, USA

[4] College of Osteopathic Medicine, Nova Southeastern University, 3200 South University Drive, Ft. Lauderdale, FL 33328, USA

[5] Department of Otolaryngology, University of Miami Miller School of Medicine, Miami, FL 33125, USA

Abbreviations

TEES	Transsphenoidal endoscopic endonasal surgery
CSF	Cerebrospinal fluid
DAM	Dehydrated amniotic membrane
FDA	Food and Drug Administration
NSF	Nasoseptal flap

Introduction

In transsphenoidal endoscopic endonasal surgery (TEES), successful closure is defined as the establishment of a watertight separation of the intracranial and extradural compartments, in order to prevent complications such as cerebrospinal fluid (CSF) rhinorrhea, development of meningitis, or pneumocephalus [26]. Watertight sellar closure is particularly important in cases when intraoperative CSF leak is encountered. Closure may be augmented with locally harvested

nasoseptal flaps or more distally harvested free grafts (abdominal fat, fascia). Because each technique is associated with tradeoffs between efficacy, complication rates, and level of invasiveness and morbidity associated with tissue harvest, no consensus exists regarding the optimal TEES closure technique. Thus, there is a demand for a non-invasively obtained dural augmentation material that does not generate an inflammatory response and is watertight and prevents microbial migration into the intracranial compartment.

Dehydrated amniotic membrane (DAM) prevents fibrosis, decreases the inflammatory response, inhibits bacterial growth, and promotes epithelization; [11]; therefore, it may be an ideal dural supplement. Successful DAM use has been described in numerous non-neurosurgical clinical applications such as oral cavity reconstruction, corneal repair, and burn treatment [6, 7, 10, 12, 18, 19, 28]. In neurosurgery, autologously harvested amniotic membrane has been used to repair dural defects in myelomeningocele, [14] as well as to augment dural repair in craniotomies [8]. Despite is application in cranial and spinal neurosurgery, there has been no report specifically describing the use and outcome of DAM as a dural adjunct in TEES. In this feasibility study, we present our institution's experience using DAM allograft during sellar closure for TEES for pituitary adenoma resection in 120 patients.

Materials and methods

Patient selection

All consecutive patients undergoing endoscopic endonasal transsphenoidal surgery for resection of pituitary adenomas performed by one neurosurgeon (R.J.K.) from August 2016 to April 2018 underwent sellar closure supplemented by Cygnus Solo® (Vivex Biomedical, Miami, FL) dehydrated amniotic membrane (DAM) and were included in the current retrospective study (Table 1). Cygnus Solo® is approved by the US Food and Drug Administration (FDA) under the criteria of minimal manipulation and homologous use as a wound covering or barrier for dura mater defects.

Institutional review board approval was obtained. The clinical database was searched to obtain all patients undergoing endoscopic endonasal transsphenoidal resection of pituitary adenomas, and the electronic medical record was analyzed to determine patient demographic data, operative information, and postoperative course. Patients undergoing combined approaches (craniotomy and transsphenoidal), surgery for other pituitary pathologies (i.e., Rathke's cleft cyst), and patients undergoing biopsy only were excluded.

DAM layering technique

In endoscopic endonasal transsphenoidal surgeries, the sella is packed with Surgicel original absorbable hemostat (Ethicon, Bridgewater, NJ), and a layer of DAM sized for the dural opening is placed into the dural defect (Fig. 1, Video (Online Resource 1)). A piece of intermediate thickness AlloDerm (AlloDerm, LifeCell Corp., Branchburg, NJ) is rehydrated per manufacturer instruction and is trimmed to a piece measuring approximately 1.5 times the defect size. It is positioned with the rough side facing the intracranial contents. Its center is gently tucked into the sellar defect and filled with pieces of Gelfoam absorbable sponge (Pfizer, New York City, NY) wrapped in Surgicel. The edges of the AlloDerm graft are flattened around the edges of the skull base defect. The reconstruction is challenged with a Valsalva maneuver sustained at 40 cm of water for 10 s in order to observe for bleeding or CSF leak. Several pieces of Gelfoam are then used to cover the skull base defect. An 8-cm Merocel sponge (Medtronic, Dublin, Ireland) is then advanced through the nasal cavity into the common sphenoidotomy cavity and allowed to expand between the skull base defect and the posterior aspect of the nasal septum. For large defects with high-flow CSF leak, a pedicled nasoseptal flap is utilized.

Results

One hundred twenty endoscopic endonasal transsphenoidal cases (Table 1) for resection of pituitary adenoma using DAM were performed at our institution from August 2016 to April 2018 by the senior neurosurgeon/otolaryngologist team (R.J.K./Z.B.S.). Table 1 shows a summary of patient demographics. The average patient age was 53.5 years (range, 20–83). Fifty-four (45%) patients were male, and 66 (55%) were female. A total of 72.5% were non-functioning pituitary adenomas. Seven cases were revision TEES for recurrent tumors (5.8%).

Fifty-nine patients (49.2%) had an intraoperative CSF leak. In our cohort, postoperative complications were rare (Table 2), and most were not related to closure. The overall rate of postoperative CSF leak was 1.7%, occurring in 2 patients. For patients with recurrent tumors, 1 of 7 developed a postoperative CSF leak; for TEES-naïve patients, 1 of 113 developed CSF leak, for a TEES-naïve rate of 0.9%. One patient had a resolution of the leak with lumbar drain placement, and one required a return to the operating room for reconstruction. Both required readmission to the hospital for treatment. Hospital readmissions for other causes were rare. Seven total patients (6.9%) were readmitted within 30 days—most commonly for hyponatremia ($n = 4$) (Table 3). Only one patient had a neurologic complication—development of acute aphasia following surgery due to a small ischemic stroke. The

Table 1 Summary of patient demographic characteristics

Mean age (years)		53.5 (range, 20–89)
Gender (% of cohort)		54 (45%) male, 66 (55%) female
Pathology (% of cohort)	Non-functioning pituitary adenoma	$n = 86$ (71.7%)
	Functional pituitary adenoma, Cushing's*	$n = 13$ (10.8%)
	Functional pituitary adenoma, acromegaly	$n = 11$ (9.2%)
	Functional pituitary adenoma, prolactinoma**	$n = 10$ (8.3%)

*1 patient with functional tumor with components of corticotroph adenoma and prolactinoma

**Medically refractive or patient unable to tolerate medications

aphasia improved prior to discharge. Five patients developed epistaxis. Three were evaluated in the emergency department and did not require admission. Two were hospitalized with one requiring a return to the operating room for coagulation of a small septal arterial bleed.

Discussion

Despite advances in endoscopic endonasal pituitary surgery, there is no universally accepted closure method. A recent systemic review stratified the success of various skull base defect repairs by location, as well as the presence of low-flow or high-flow intraoperative CSF leak [26]. Soudry and colleagues (2014) found that for 104 cases of reported sellar repairs utilizing biomaterials, non-vascularized free tissue grafts, or vascularized pedicled flaps, the overall successful closure rate was 93% [26]. When the repairs were stratified by flow rate and non-vascularized versus vascularized closure techniques, non-vascularized free tissue graft and biomaterial-based closures for low-flow intraoperative CSF leak repairs resulted in 0–13% CSF leak rate [20, 26, 29]. Similarly, vascularized pedicled flaps used during low-flow intraoperative CSF leak repairs had a 0% CSF leak rate [21, 24]. Vascularized pedicled flaps are the preferred closure for high-flow CSF leak repairs with postoperative CSF leak rates of 0–6% [24, 33]. These results led Soudry and colleagues (2014) to conclude that for low-flow intraoperative CSF leak repairs, multilayered free tissue grafts and biomaterials produce similar CSF leak rates as compared to pedicled vascularized flaps; however, for high-flow intraoperative CSF leak repairs, pedicled vascularized flaps conferred superior results [26].

Autologous free tissue grafts, biosynthetic materials, and vascularized pedicled flaps have varying effectiveness and invasiveness profiles and are preferred in different clinical settings. As such, no one TEES closure technique has emerged as the gold standard. Autologous free tissue grafts, such as the fascia lata, abdominal fat graft, or temporalis fascia, while generally easily accessible, low cost, and without risk of disease transmission or triggering of an immune response, do require additional surgical incisions for harvesting and may have associated morbidity. Graft harvest may be associated with local tissue injury, impaired cosmesis, infection, or postoperative pain. Efficacy may also be mixed, as some reports document as high as a 3% bacterial meningitis rate and up to 20% CSF leak rate [9, 15, 25].

Biosynthetic materials such as bovine pericardium and acellular bovine collagen matrix are obtained atraumatically. However, because they are foreign bodies, several reported complications have been attributed to their use [1] including eosinophilic-aseptic meningitis [3], Creutzfeldt-Jakob disease transmission (likely from cadaveric dura mater graft) [30], hemorrhage [22], prolonged wound healing time [27], increased scarring from foreign body reaction [27], and premature graft dissolution [27].

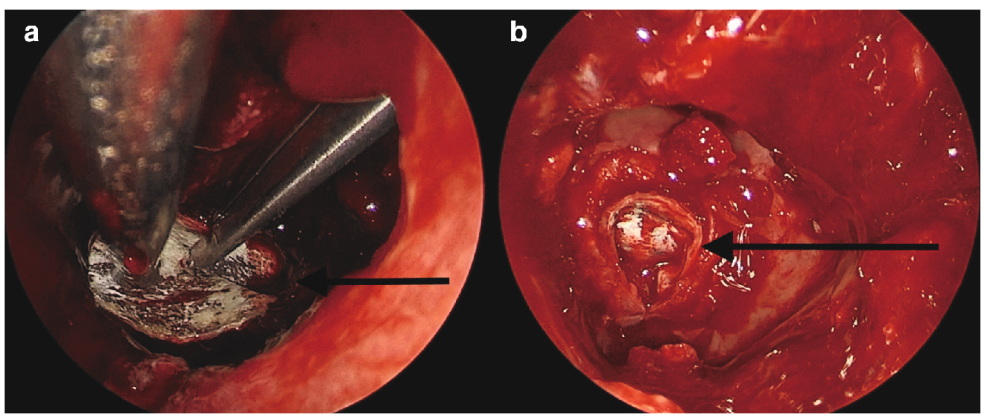

Fig. 1 Intraoperative photograph taken from endoscope depicting dehydrated amniotic membrane only (black arrow), sized for the dural opening, as it is first introduced into the skull base defect (panel A), and as it is tucked into the dural defect in its final conformation (panel B)

Table 2 Postoperative complication rates

	# Patients	CSF leak	Meningitis	Major inflammatory response	New neurologic deficit	All postoperative complications
TEES-naïve patients (*n*)	113	1 (0.9%)	0	0	1	2
Revision TEES for recurrent adenomas (*n*)	7	1 (14.3%)	0	0	0	1
Overall (*n*)	120	2 (1.7%)	0	0	1	3

Vascularized pedicled flaps such as nasoseptal flaps (NSFs) may have the lowest CSF leak rates of the previously discussed TEES closure techniques [26]. However, they are obtained invasively, and harvesting these flaps may be prohibited in cases of prior surgery, prior radiation, or extensive tumor invasion. Additionally, NSFs have been shown to necrose postoperatively (particularly in patients that have received prior radiation) [9]. Finally, a NSF may not have enough area to cover the entire dural defect, and they have been known to shrink between 20 and 40% over time [9].

TEES closure strategies have tradeoffs regarding CSF leak prevention efficacy, secondary complication potential, and invasiveness; additional closure strategies with more favorable risk/benefit profiles are sought. Dural augmentation is one potential strategy. The ideal dural augmentation material should promote epithelization or mucosalization as well as integration with native dura. Additionally, this material would be non-immunogenic to minimize the risk of fibrosis and local inflammatory reaction and prevent adhesion formation with underlying pituitary gland or brain. Finally, the optimal dural adjunct is resistant to bacterial growth to diminish the risk of postoperative infection [32].

Dehydrated amniotic membrane (DAM) may be endowed with all of these attributes. DAM is a non-immunogenic material due to a low expression of cell surface antigens; therefore, it does not generate an immunogenic response or trigger a graft rejection reaction [2, 4]. Additionally, amniotic epithelial cells minimize inflammatory responses in plastic surgery and ophthalmologic applications [11, 13]. Further, amniotic tissue has been shown to have antimicrobial properties [5, 16, 31]. DAM also contains growth factors that aid in the induction of proliferation, migration, and differentiation of epithelial cells and epithelialization, which in turn has been shown to reduce fibrosis. As such, fetuses have been shown to heal wounds without scar formation [17]. This anti-fibrosis attribute has created demand for DAM use in burn repair and plastic surgery applications [6, 7]. If a revision TEES is needed, postoperative adhesions and scar formation may complicate dural reopening if the dura is adherent to the pituitary gland. Thus, postoperative scar formation is ideally minimized.

Published infection rates for endoscopic endonasal transsphenoidal surgeries vary widely; recently reported rates of postoperative CSF leak were between 1.9 and 4% of transsphenoidal surgeries [23]. Our series of 120 cases of TEES for pituitary adenoma resection using DAM had a low rate of CSF leak (0.9% for TEES-naïve patients, 1.7% overall). These results are promising, as we reported a 49.2% intraoperative CSF leak rate. Our intraoperative CSF leak rate is likely high due to case complexity as well as our aggressive tumor resection approach. We additionally report no postoperative infections or other closure related complications attributable to the use of the DAM. This provides evidence to the claim that DAM is a promising dural substitute as an adjunct to transsphenoidal procedures without an increased risk of CSF leak or postoperative infection.

The patient that experienced an ischemic stroke was a 75-year-old male with a history of atrial fibrillation and hypertension on oral anticoagulation. Anticoagulation was stopped 2 weeks before surgery. On postoperative day 2, the patient became aphasic. CT brain ruled out intracranial hemorrhage, and MRI brain demonstrated a small left MCA territory ischemic stroke. The patient was restarted on anticoagulation as recommended by the stroke neurology team. The patient's aphasia improved at the time of discharge. We believe the patient's medical comorbidities and discontinuation of therapeutic anticoagulation, not the use of DAM, was the cause of the ischemic stroke.

While this retrospective feasibility study does not prove the superiority of DAM over other dural augmentation materials, or efficacy of use, we demonstrate that it has an adequate safety profile with no complications directly related to its use in closures of TEES for pituitary adenomas. We also report promising CSF leak rates and infection rates. Our feasibility study is limited by the fact that it has no control group that used closure without DAM or with other dural adjuncts,

Table 3 Readmissions

Reason for readmission	# of patients
Total 30-day readmissions (*n*)	7
Hyponatremia (*n*)	4
CSF leak (*n*)	2*
Epistaxis (*n*)	2*

*One patient had two readmissions, 1 for CSF leak and 1 for epistaxis

and it was not randomized. Further, interpretation of the data is complicated by the fact that the patients in our study also received other closure materials such as nasal septal flap, Gelfoam, and AlloDerm; thus, outcomes may be due to these other materials. Future randomized controlled studies are warranted to further delineate the safety profile and efficacy in comparison with other closure techniques and dural adjuncts.

Conclusion

This is the first report of dehydrated amniotic membrane (DAM) allograft for closure of transsphenoidal endoscopic endonasal surgery for the resection of pituitary adenomas. With this feasibility study, in 120 patients with a 49.2% intraoperative CSF leak rate, we report a 1.7% postoperative CSF leak rate as well as a 0.9% CSF leak rate for TEES-naïve patients, as well as an adequate safety profile with no adverse reactions directly related to the DAM product. Future studies are warranted that compare DAM with other closure techniques and dural augmentation materials to prove efficacy.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

"For this type of study, formal consent is not required."

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Comments

The utilization of amniotic membranes in trans-sphenoidal surgery is a relatively new technique. It was first described by the authors for dural repair after craniotomies in a previous publication.

In this retrospective non randomized study, the same group of authors reports their outcomes using the same product in transnasal pituitary procedures.

The introduction makes an argument for the use of amniotic membranes in closure of pituitary adenoma resections as there currently is no consensus for CSF resistant closure in TEES. While this may be true, to demonstrate the appropriateness for DAM use, the authors simply describe the outcome data for a large series of TEES patients that underwent closure with DAMs (as well as other materials) and then compared those outcomes to non-risk-stratified data in existing literature.

The data shows an intraoperative CSF leak rate in half of their patients with postoperative rate of 1.7% in complex cases and 0.9% in naive patients but does not show statistically significant superiority. While intraoperative rate of CSF leak is a bit high, they consider the postoperative rate an improvement from published rates of CSF leak at 1.9–4%.

The authors believe very strongly in the superiority of DAMs, as laid out in the discussion. However, this conclusion could have been better supported if the study included a control group of different materials used for dural repair.

A. Samy Youssef
CO, USA