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Adel Almelesy

Neurosurgery Department, Faculty of Medicine, Al-Azhar University, Cairo, Egypt,
adelalmelesy@gmail.com

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Collagen Matrix Dural Substitute versus Auto-graft in Endoscopic Endonasal Sellar Reconstruction

Adel R. Al Melesy^{1,*} MD.

*** Corresponding Author:**

Adel R. Al Melesy

adelalmelesy@gmail.com

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¹Neurosurgery Department, Al-Azhar University, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

ABSTRACT

Background: Endoscopic endonasal sellar reconstructions (EER) were associated with leaks of cerebrospinal fluid (CSF) after pituitary surgery. Collagen matrix dural substitutes are used for watertight dura closure. **Aim of work:** To assess the effectiveness and safety of collagen matrix dural substitute in compare with autograft for EER.

Patient and Methods: A retrospective randomized comparative clinical review of 24 patients underwent (EER) after pituitary surgery with intraoperative CSF leaks. 24 EER patients between (17 – 55) years were included. And classified into 2 groups (A and B), each group 12 patients. Group A (Collagen matrix dural substitute) and group B (fascia lata). Followed up for at least 3 months, the primary outcome was success rate (representing efficacy), while the secondary outcomes were repair failure rate, and complications rate (representing safety).

Results: 19 patients (79.2%) had successful EER, 9 group A patients, and 10 group B patients. Only 5 patients (20.8%) had repair failure and need recurrent sellar reconstruction with vascularized septal flap, 3 (25%) from group A, and 2 (16.6%) from group B. No perioperative mortalities. 3 patients (12.5%) had pneumocephalus, 1 group A patient, and 2 group B patients. 4 patients (16.7%) had postoperative headache, 3 patients from group A, and 1 from group B. No substantial statistical difference between the 2 groups regarding efficacy and safety data, ($p > 0.05$ respectively).

Conclusion: Collagen matrix dural substitute is an efficient and safe material and the initial findings were similar to autograft.

Keywords: Cerebrospinal Fluid Leak, Endoscopic Endonasal, Collagen Matrix, Reconstructions.

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INTRODUCTION

Closure of the dura mater is essential for the prevention and complications of cerebrospinal fluid (CSF) fistula, such of morbidity and mortality.^{1,2}

Various materials and methods for the reconstruction of defects smaller than 1 cm are available. Avascular grafts comprise autologous grafts and engineered collagen grafts. Autologous grafts involve fat, fascia, bone, cartilage, and free mucosa grafts taken from patients.³

Autologous grafts advantages involve negligible costs, near-universal availability, and biocompatibility between the host and the graft. The drawbacks include the second surgical incision of the patient, extra healing period, operating room time increased for extra tissue collection, and additional patient discomfort.⁴

Ideally, a dural substitute does not cause an immunological or inflammatory response or current

neurotoxicity. In addition, since the graft offers a biomatrix for the development of a new structure of conjunctive tissues, it must be absorbed promptly for the growth of the endogenous neodura. The material is meant to have watertight closure, retain its shape, and not rupture. Another very important feature of an ideal dural substitute is the absence of viral and prion risk of infection, and an acceptable final cost. Recently, collagen-derived substitutes have been widely accepted because that ideal substitute is close to them.⁵

Engineered collagen grafts (i.e., DuraGen; Integra Neurosciences, Plainsboro, NJ, USA), thought to act as scaffolding for the growth of indigenous cells can be used suturelessly, but post-operative complications may predispose the patient and the surgical cost may be increased.⁶

Recently the collagen-derived substitutes have been highly accepted because that ideal substitute is close to them.

This research aimed to evaluate the efficacy and safety of a new collagen matrix dural substitute (Duragen Integra LifeSciences Corp., Plainsboro, New Jersey, United States) in compare with autograft (fascia lata) for endoscopic endonasal sellar repair.

PATIENT AND METHODS

A prospective randomized comparative clinical study was performed for patients with intraoperative CSF leak after pituitary tumors surgery that was treated with devascularized tissues (free tissue fascia lata graft or Duragen [Integra Life Sciences, Plainsboro, NJ]).

During a 30-month period from May 2016 to December 2018 upon the Local Ethics Committee's approval and informed written consent was adopted.

A total of 24 patients 15 female and 9 male patients with an age range of 17–55 years were included. All patients were managed with the same operative technique for reconstruction of the sellar after pituitary tumors surgery with intraoperative CSF leak, with median follow-up of 6 months.

Exclusion criteria: Patients undergoing surgery without intraoperative CSF leak were excluded and Patients with an expanded endonasal approach.

The EER patients were randomized into two equal groups: Group-A “collagen matrix graft group”: (N=12): A total number of 12 patients were treated with a dural substitute Engineered collagen matrix grafts (i.e., DuraGen; Integra Neurosciences, Plainsboro, NJ, USA). Group-B “fascia lata graft group”: (N=12): A total number of 12 patients were treated with free tissue fascia lata graf. The vast majority (21 of 24) of the pituitary adenomas were classified as “macroadenoma”

The patients had at least 3 months of follow-up, for:
Efficacy: The primary outcome was success rate (representing the efficacy of each technique) and Safety: The secondary outcomes were repair failure rate (intra-operative CSF leak), and complications rate, such as CSF leakage, infection, and allergy (representing the safety of each technique).

Statistical Analysis:

Data entry, processing and statistical analysis shall be performed with MedCalc ver. 18.2. (MedCalc, Ostend, Belgium). Significance tests (Mann-Whitney's U, and Chi square tests) were used. Data was presented and an appropriate analysis was performed for each variable depends on the data type obtained (parametric and non-parametric). P-values were considered statistically significant to be less than 0.05 (5 %)

RESULTS

In this study, a total of 24 EER patients between (17–55) years were included in the study. Regarding (tables 1,2) describing basic demographic, surgical and pathological characteristics, we found that; all EER patients were of median age (44.5) years ranging

from 17 to 55 years. Regarding gender, most patients were females (62.5%), and (37.5%) were males as shown in (table 1).

Regarding (table 2) describing surgical and pathological characteristics, we found that; (16.6%) of patients had history of prior surgery. Regarding pathology, most patients had pituitary macro-adenomas (87.5%), and only (12.5%) had pituitary micro-adenomas as shown in (table 2).

Variables		Frequency (%)
Total number of patients		24 (100%)
Age (years)		44.5 (17 – 55)
Sex	Female	15 (62.5%)
	Male	9 (37.5%)

* Median (IQR). IQR: interquartile range.

Table 1: Demographic data

Variables		Frequency (%)
History of prior surgery		4 (16.6%)
Pathology	Pituitary micro-adenoma	3 (12.5%)
	Pituitary macro-adenoma	21 (87.5%)

Table 2: Surgical and pathological data

Regarding overall efficacy results, 19 patients (79.2%) had successful EER reconstruction, 9 group A patients, and 10 group B patients.

Regarding overall safety results, Only 5 patients (20.8%) had repair failure and required re-operation for repair of persistent CSF leak and need recurrent sellar reconstruction with vascularized septal flap, 3 (25%) from group A, and 2 (16.6%) from group B. None of the patients suffering from wound infections, hydrocephalus, pseudomenigocele, meningitis, brain abscesses or signs of dural substitute related toxicity. There were no perioperative mortalities. 3 patients (12.5%) presented with pneumocephalus, 1 group A patient, and 2 group B patients. 4 patients (16.7%) presented with postoperative low pressure headache, 3 patients from group A, and 1 from group B.

Comparative studies between A and B groups revealed the following: As regards primary outcome (success rate), follow up period revealed the following: Non-significant difference as regards success rate ($p > 0.05$). The success rate in A group was (75%); while in B group was (83.3%); as shown in (table 3, figure 1).

Variable		A group (12)	B group (12)	Chi square test P value
Success rate	+ve	9 (75%)	10 (83.3%)	= 0.6227

Table 3: Comparison between A and B groups as regards success rate.

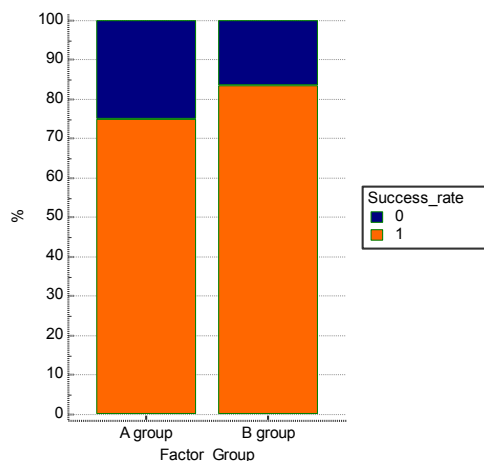


Fig. 1: Comparison between the 2 groups of patients regarding success rate.

As regards secondary outcomes (repair failure or intra-operative CSF leak rate, and complications rate), follow up period revealed the following: No substantial difference with respect to repair failure rate ($p > 0.05$). The repair failure rate in A group was (25%); while in B group was (16.7%); as shown in (table 4, figure 3). No substantial difference with respect to the grade of CSF leak ($p > 0.05$). The grades of CSF leak in A group were (8.3%) grade-2, and (16.7%) grade-3 leak. The grades of CSF leak in B group were (16.7%) grade-3 leak; as shown in (table 4). No substantial difference with respect to pneumocephalus complication ($p > 0.05$). The pneumocephalus rate in A group was (8.3%), while in B group was (16.7%); as shown in (table 5). Non-significant difference as regards low-pressure headache complication ($p > 0.05$). The low-pressure headache rate in A group was (25%), while in B group was (8.3%); as shown in (table 5).

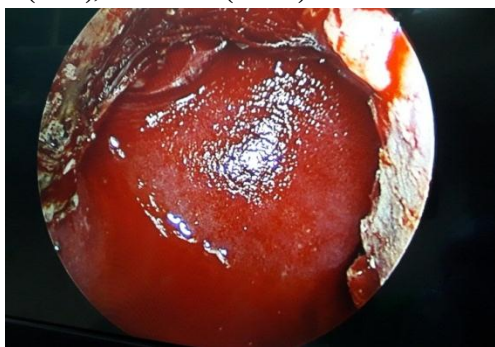


Fig. 2: Endoscopic sellar view of collagen dura repair

Variable		A group (12)	B group (12)	Chi square test P value
Pneumocephalus	+ve	1 (8.3%)	2 (16.7%)	= 0.5457
Low-pressure headache	+ve	3 (25%)	1 (8.3%)	= 0.2835

% per column total.

Table 4: Comparison between A and B groups as regards repair failure rate.

Variable		A group (12)	B group (12)	Chi square test P value
Repair failure rate	+ve CSF leak	3 (25%)	2 (16.7%)	= 0.6227
Grade of CSF leak	Grade 1	0 (0%)	0 (0%)	= 0.4142
	Grade 2	1 (8.3%)	0 (0%)	
	Grade 3	2 (16.7%)	2 (16.7%)	
	Grade 4	0 (0%)	0 (0%)	

% per column total.

Table 5: Comparison between A and B groups as regards complications rate.

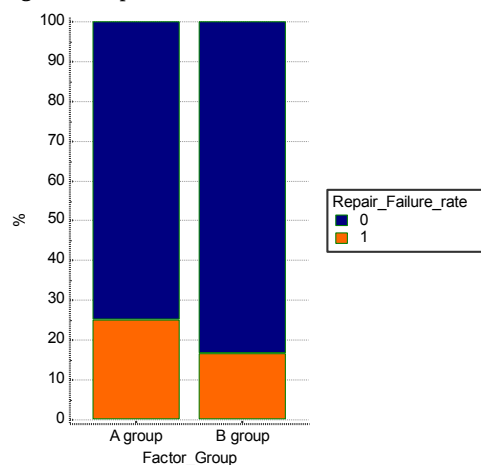


Fig. 3: Comparison between the 2 groups of patients regarding repair failure rate.

DISCUSSION

The goal of this research was to assess the effectiveness and safety of a new collagen matrix dural substitute (Duragen Integra LifeSciences Corp., Plainsboro, New Jersey, United States) in compare with autograft (fascia lata) for endoscopic endonasal sellar repair. There were non-significant statistical difference between group A and B, as regards efficacy data (success rate), and safety data (repair failure and complications rates), ($p > 0.05$ respectively). This result agree with Yuanliang Ye, et al.⁷ to evaluate the impact of endoscopic endonasal transsphenoidal sellar reconstruction using artificial cerebral dura mater patch during pituitary adenoma resection surgery. Compared to other methods of

% per column total.

reconstruction, the sellar reconstruction surgery that uses only artificial dura mater as repair material was found to have a low complications rate.

Thorp et al.⁸ used a vascular mucosal flap to correct the skull's base defects in 152 patients and their rate of CSF leakage was 3.3%. They regarded a vascular mucosal flap suited for leakage of high-flow CSF. This result not agree with our result which we find the rate of CSF leakage was (16.7%) with avascular fascia lata graft group.

Nevertheless, autologous fascia lata graft repair has the following drawbacks: longer surgery; additional corporeal incisions are necessary. But, there are some benefits to using an artificial dura patch because it offers collagen type I scaffolding allowing fibroblast growth and the formation of novel dura mater on the defect site. This artificial dura is absorbable and has an antibacterial influence, and also causes epithelial cell formation, fibroblasts, and the layer of collagen⁹. It also has outstanding biodegradability and historocompatibility, and does not increase the risk of infection.¹⁰

In this series, reconstructions of less weeping CSF leakage, are in harmony with the result reported by Dehdashti et al.,¹¹ they found that it is unnecessary to utilize autologous grafts for patients with low, weeping intraoperative CSF leaks (grade I leak). It was sufficient to add a manufactured dural onlay graft.

Our study find 5 patients (20.8%) had repair failure and required re-operation for repair of persistent CSF leak and need recurrent sellar reconstruction with vascularized septal flap, due to higher flow CSF leaks these findings are similar to Harvey et al.,¹² in the meta-analysis of 38 studies endoscopic studies on the reconstruction of significant dural defects.

CONCLUSION

To conclude, collagen matrix dural substitute is an efficient and safe material, and the initial findings were similar to autograft. It avoids donor site morbidity, but carries additional cost.

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