Research Paper:
Buccal Fat Pad for Management of Cerebrospinal Fluid Leakage Using Endoscopy: A Randomized Clinical Trial

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ABSTRACT

Background and Aim: Several surgical techniques have been so far used for treating Cerebrospinal Fluid (CSF) leakage (rhinorrhea) such as using abdominal fat or fascia lata, but these methods have complications such as the presence of several surgeons in variable fields in the operating room or cosmetic complications for donors such as the surgical scar. This study aimed to investigate using buccal fat pad for management of traumatic CSF leakage.

Methods and Materials/Patients: In this clinical trial, 46 patients with traumatic CSF leakage were enrolled according to inclusion criteria and randomly divided into intervention and control groups. Buccal fat pad for the intervention and abdominal fat for the control were inserted in the defect of the anterior cranial cavity by applying endoscopic sinus surgery. The patients were followed up for 1 year postoperatively.

Results: All patients were improved with no recorded report of CSF leakage relapse. In the intervention group, temporary complications such as edema (18.2%), numbness (9.1%) and facial asymmetry (9.1%) were observed in resected buccal fat pad areas. Also the control group all developed abdominal scar. The duration of surgery in the intervention group was significantly shorter than control (P=0.02).

Conclusion: Using buccal fat pad for management of CSF leakage is a highly effective and reliable method which requires simple procedure with low cosmetic complication and short duration of surgery compared with other methods such as an abdominal fat graft. In addition, using buccal fat pad has better cosmetic results, so we suggest this surgical method for patients with CSF leakage

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Highlights

- Buccal fat pad can block CSF leakage similar to abdominal fat pad.
- Using buccal fat pad did not have relapsing outcome.
- There were temporary complications such as edema, numbness, and facial asymmetry in place of the buccal fat pad.

Plain Language Summary

The use of abdominal fat for blocking Cerebrospinal Fluid (CSF) leak create some complications for the management of CSF leakage including, but not limited to, the requirement of several surgeons in different fields for each of resection and insertion levels and of course cosmetic complications such as the surgical scar on donor's body. It seems that usage of a facial fat such as buccal fat is more beneficial in the management of CSF leakage because all procedures are done at the same site and all can be done with only one surgeon. Taken together, we used buccal fat pad flap in treating cerebrospinal fluid leakage and compared it with using the abdominal fat pad. Using buccal fat pad for filling the defect was a simple and reliable procedure with fewer complications and short duration of surgery while using abdominal fat is associated with abdominal scar and long duration of surgery.

1. Introduction

Rhinorrhea or Cerebrospinal Fluid (CSF) leakage refers to leakage from the nose due to a defect between subarachnoid and upper respiratory spaces [1-3]. In order to prevent CSF leakage, surgeons use an autologous material such as fat, fascia, muscle graft, septal flap, or mucosal graft for reconstruction of the defective area. All these methods have beneficial effects on the management of CSF leakage [4, 5]. Using autologous fat grafts is a well-tolerable technique for filling of superficial intromission in traumatic and congenital defects and the subcutaneous fat such as abdominal fat is commonly used [6].

Buccal Fat Pad (BFP) usage has been mentioned for the first time by Heister [7] in 1732. BFP is a biconvex, encapsulated, rounded, and adipose structure. The anatomy area of buccal fat is in masticatory space between masseter muscle (in lateral area) and the buccinator muscle (in medical area). Moreover, BFP includes 3 lobes: anterior, posterior, and intermediate [8]. The blood supply of BFP is driven by superficial temporal and facial arteries which together, prevents necrosis of BPF (Figure 1) [9, 10]. Based on Khiabani et al. [6] report, the BFP flap is a small to medium flap for filling soft and bony defects, however, few studies exist about the usage of BFP as the fat flap.

The usage of other flap or graft such as abdominal fat create some complications for management of CSF leakage, including but not limited to, the requirement of several surgeons in different fields for each stage of resection and insertion and of course cosmetic complications such as the surgical scar on donor's body. It seems that usage of a facial fat such as buccal fat is preferable in the management of CSF leakage because all procedures are at the same site and can be done with only one surgeon. Taken together, we hypothesized that using BFP flap could be an effective and beneficial technique in treating CSF leakage and to the best of our knowledge, this technique has been administered for the first time.

2. Methods & Materials/Patients

Study patients

We conducted a research on 46 of 55 patients who had traumatic CSF leakage. The inclusion and exclusion criteria of the study were summarized in Table 1. The enrollment was done in Amin Hospitals-Isfahan-Iran between 2013 and 2016. The patients were diagnosed according to clinical, preclinical (β2-transferrin test) and imaging (CT scan with contrast in axial and coronal views and Magnetic Resonance Imaging [MRI]) findings. Additionally, before treatments, endoscopic sinus (zero degree) was recommended for all patients in order to evaluate the extent of the defect. All information of the patients such as age, gender, trauma mechanism, underlying diseases, and localization were recorded in a checklist. Before the intervention, patients were divided into intervention and control groups. The randomization was done using Random Allocation Software that

was a blinded method. The intervention group were treated with using buccal fat pad and the control group with using abdominal fat.

Surgical technique

All patients underwent general anesthesia with standard protocol and also 0.25 mg of 10% fluorescein solution (25 mg) was injected intrathecally. The patients were in supine position with their head bend toward the surgeon and all operations were performed by a single ear, nose and throat surgeon. Nasal area was impregnated with adrenaline mesh. Adrenaline (1:100000) and lidocaine 1% were injected into the nasal cavity, also endoscopic performance was done with rigid 0° to 30° in order to identify the defects. There are 3 approaches for extracting of the buccal fat pad.

In this study, we used the most common approach for the intervention group, i.e. an incision is made on superior gingivobuccal sulcus in the superomedial wall of the buccal space [9]. Then, a 2-3 cm vestibular incision is done from the second molar to the first premolar and this incision is disseminated to the mucosa, buccinators muscle and periosteum up to the zygomatic bone. Next, the fascia of the buccal fat pad is dissected off with caution to avoid making injuries to nerves in the lateral wall of buccal space. Afterward, the buccal fat pad as a pedicle flap is freed [6] (Figure 2). If filling the defect needed more fat, buccal fat would extracted from the other side, too. It is worth mentioning that the incision place was sutured with 5.0 Vicryl. The extracted buccal fat pad was inserted into defect with the endoscopic method and afterward, a layer of hemostasis such as Gelfoam was placed between the fat flap and nasal pack.

In the control group, we used graft harvesting technique for using abdominal free fat. In this technique, the abdominal fat is prepared according to the standard method and a curvilinear incision is done on periumbilical area (4 to 8 cm) [11]. In our study, we prepared abdominal fat 30% to 40% more than the defect size. After removing the fat from the abdomen and suturing of the abdominal incision, we inserted fat with endoscope similar to the intervention group.

After operations, all patients received co-amoxiclav 150 mg/kg/d for 14 days and patients with meningitis were treated according to standard protocol. Additionally, patients remained in half-sitting and resting position for 1 week. Nasal packs were removed after 2 days and the patients were visited in the first and second weeks, first, second, and fourth months and 1 year after operation. In the follow-up, neurological exam, CT scan with contrast and MRI (for evaluation of defect), paraclinical exam (for meningitis) such as CRP, ESR, CBC were performed for all patients including those who had symptoms such as rhinorrhea and were tested with β2-transferrin test and endoscopic evaluation. In addition, the complications of patients were recorded in each visit. One patient in intervention and 1 patient in control group did not continue their follow up for 1 year (Figure 3).

Statistical analysis

The sample size was calculated according to formula and a previous study. Assuming a power detection of 80%, and confidence level of 95%, the standard deviation of 1.32 and difference between means as 0.5, the sample size was obtained as 46 (23 for each group). The data were analyzed by using of SPSS 24 (Chicago, IL). In addition, the Independent t test and Chi-square test were used to compare results of the intervention and control groups. The quantitative data are presented as Mean±SD and also qualitative data are presented as number or percentage. In addition, $P<0.05$ was considered a significant difference.

3. Results

In this study, 46 patients (31 males and 15 females, Mean±SD age: 33.34±10.08 y) with CSF leakage were participated. They were divided into two groups as intervention (18 males and 13 females, Mean±SD age: 31.91±11.03 y) and control (13 males and 10 females, Mean±SD age: 34.78±9.05 y). The mechanisms of trauma were blunt in 33 (71.7%) patients and penetrating in 13(28.3%). Three (6.5%) patients had diabetes, 3 (6.5%) had hypertension, 5 (10.9%) had hypothyroid and the 8(17.4%) had ischemic heart disease, also 18(39.1%) patients had a history of meningitis during the time of trauma and the Mean±SD duration of trauma was 9.08±10.79 months.

Before treatments, all patients had symptoms such as a headache (41.3%), hyposmia (15.2%) or anosmia (17.4%) and rhinorrhea (93.5%). The most common symptom was rhinorrhea. Locations of defect were ethmoidal (56.5%), frontal (13%) and sphenoidal (30.4%) regions. In addition, there were no significant differences between intervention and control regarding age (P=0.32), gender (P=0.11), mechanism of trauma (P=0.32), underlining disease (P=0.84), localization of defect (P=0.37), meningitis (P=0.54), duration of trauma (P=0.52) and symptoms such as headache

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Table 1. Criteria for patients' enrollment into the study

Criteria	
Inclusion criteria	Active and traumatic CSF leakage
	Rhinorrhea
	Patients who required surgical management
	Aged between 18 to 80 years
Not meeting inclusion criteria	Non-traumatic CSF leakage
	Increased Intracranial Pressure (ICP)
	Brain tumors
	Pseudotumor cerebri
	Orbital problems such as diplopia, enophthalmos
	Limitation in the opening of the mouth
Exclusion criteria	Unwilling to continue in the study
	Patients who required other procedures such as osteotomy or bone graft
	Not follow up within 1 year

(P=0.36), rhinorrhea (P=0.55) and olfactory dysfunction (P=0.40) (demographic and clinical data of patients were presented in Table 2). The Mean±SD duration of operation in the intervention and control groups were 53.69±12.81 and 75.08±20.59 minutes, respectively, so the duration of surgery in the intervention group was significantly shorter than control (P=0.02). All patients were followed up for 1 year and CSF leakage was improved in all patients with no report of recurrence of symptoms. The complications of the intervention group were 18.2% edema, 9.1% numbness, and 9.1% facial asymmetry, these symptoms, however, were temporary. In addition, all patients of the intervention group had an abdominal scar, therefore this difference was significant (P=0.00) (Table 3).

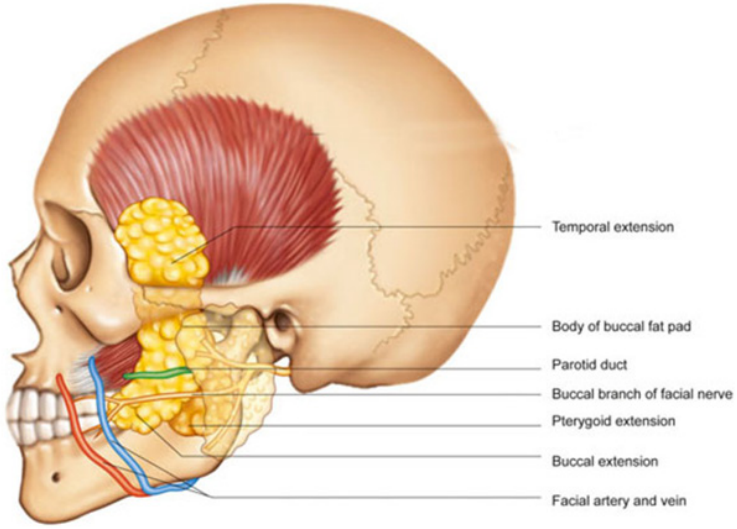

Figure 1. The anatomical regain of BFP [10]

Table 2. Demographic and clinical data of patients in both groups

Characteristics		Intervention	Control	P
Number		23	23	-
Age (Mean±SD), y		31.91±11.03	34.78±9.05	0.32*
Gender	Male	18(78.3%)	13(56.5%)	0.11**
	Female	5(21.7%)	10(43.5%)	
Mechanism of trauma	Blunt	18(78.3%)	15(62.2%)	0.32**
	Penetrating	5(21.7%)	8(34.8)	
Underlying diseases	Diabetic mellitus	2(8.7%)	1(4.3%)	0.84**
	Hypertension	1(4.3%)	2(8.7%)	
	Hypothyroid	2(8.7%)	3(13%)	
	Ischemic heart disease	5(21.7%)	3(13%)	
Localization of defect	Ethmoidal	14(60.9%)	12(52.2%)	0.37**
	Frontal	4(17.4%)	2(8.7%)	
	Sphenoidal	5(21.7%)	9(39.1%)	
Meningitis		8(34.8%)	10(43.5%)	0.54**
Duration of trauma (Mean±SD), mon		8.32±10.37	11.29±11.23	0.52*
Symptoms	Headache	8(34.8%)	11(47.8%)	0.36**
	Rhinorrhea	22(95.7%)	21(91.3%)	0.55**
	Hyposmia	2(8.7%)	5(21.7%)	0.40**
	Anosmia	5(21.7%)	3(13%)	
Duration of surgery (Mean±SD), min		53.69±12.81	75.08±20.59	0.02*

* Independent T test; ** Chi square test

4. Discussion

The current study was the first report of buccal fat pad usage for patients with CSF leakage. We demonstrated that all patients were improved 100% with no recurrence of the problem. Moreover, there were temporary complications in the intervention group such as edema, numbness, and facial asymmetry in place of the

Table 3. Complications of patients after operation (until 12 months)

Complications	Intervention	Control	P
Without complications	14(63.6%)	0	0.00
Edema	4(18.2%)	0	
Numbness	2(9.1%)	0	
Facial asymmetry	2(9.1%)	0	
Abdominal scar	0	22(100%)	

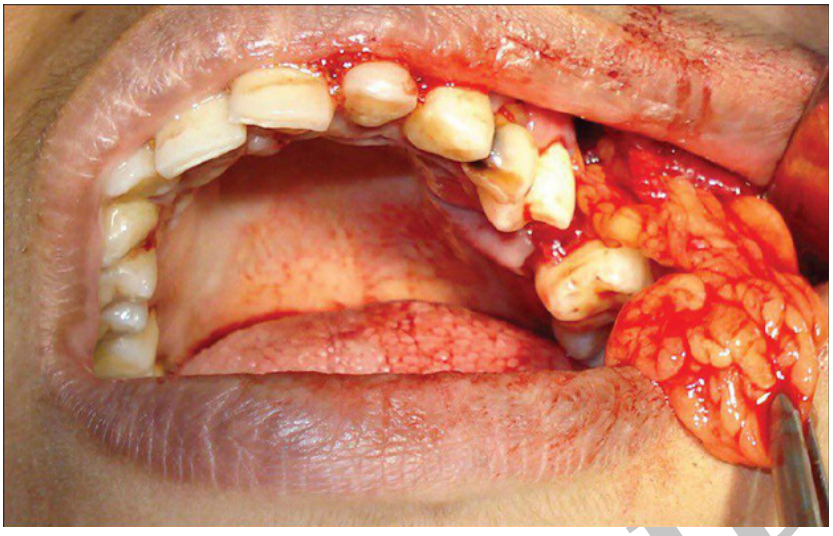

Figure 2. The dissection of buccal fat pad in a 32-year-old female patient

buccal fat pad due to endoscopic procedures for management of CSF leakage. However, these complications were totally improved after 6 months. On the contrary, there was an abdominal scar in all patients of the control group. In addition, the duration of operation in the intervention group was shorter than the control group.

The anterior cranial cavity is highly susceptible to trauma and iatrogenic injuries. The diagnosis of CSF leakage is usually simple. A nasal discharge following a head injury or intranasal surgery is suggestive of cerebrospinal fluid rhinorrhea. Furthermore, the patient might have recurrent meningitis after a traumatic event [12]. The initial treatment of traumatic cerebro-

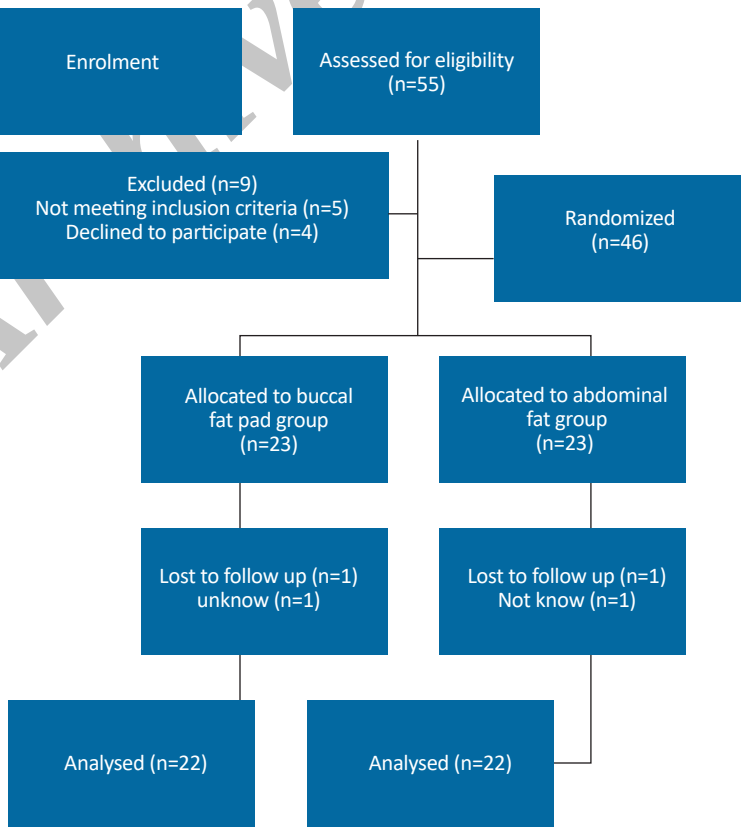

Figure 3. Consort diagram of patients in each group

spinal fluid leakage is conservative. One important factor is restriction of the activities that increase intracranial pressure (avoiding trendelenburg position). The use of prophylactic antibiotics is still under debate. If CSF leakage was not treated with conservative therapy within 6 weeks, surgical management would be required. Additional indications for a surgical approach is relapsing, intermittent, and spontaneous CSF leakage, as well as diagnosis of leakage within an operation, pneumocephalus, and repeated meningitis [13]. A great deal of material and a number of techniques have been used to close the CSF leakage, including using autologous materials such as abdominal fat, nasal septum, bone, fascia lata, and muscle grafts.

These autologous materials can be coated with a fibrin gel, Vaseline gas, surgical, and bone wax. Flaps of mucoperiosteal and middle concha have also been used. The size of the defect should be less than 15 mm in order to use the mucoperiosteal nail flap [14]. However, closure of the large defects with these flaps has also been done. The size of the flap should be a bit larger than the size of the defect, and if a combined flap is used, the size of the mucus must be larger than the interior cartilage [2]. Buccal fat pad is a graft with high blood supply which is used for filling of defects [6, 9].

It should be noted that to the best of our knowledge, there have been no studies about usage of buccal fat pad for filling of defect in CSF leakage and our study was first intervention about utilization of buccal fat pad in the management of traumatic CSF leakage. The volume of the buccal fat pad is approximately 10 mL [15]. Most studies have suggested that the usage of the buccal fat pad is effective and successful with low complication for the simple graft surgical procedure [16]. Likewise, in a review article reported by Kim [10], it is suggested that buccal fat pad is a reliable flap with simple surgical procedure and can be used in various clinical conditions.

5. Conclusion

In conclusion, our report along with other studies suggest that the use of the buccal fat pad for filling of the defect is a simple and reliable procedure with short complications and lower duration of surgery and usage of abdominal fat is associated with an abdominal scar and long duration of surgery. Additionally, there have been no studies about using the buccal fat pad for filling the defects in CSF leakage, so our study was the first study in this category. According to our results, usage of the buccal fat pad as a flap for management of CSF leakage was a highly effective and a very simple procedure with temporary complications and 100% improvement. In addition, using buccal fat pad has better cosmetic results with no or very little scar, so we suggest this surgical method for patients with CSF leakage. Finally, we recommend that more studies be conducted with larger sample size on using the buccal fat pad for management of CSF leakage.

Ethical Considerations

Compliance with ethical guidelines

This open, randomized trial was approved by Ethics Committee of Isfahan University of Medical Sciences and was registered in Iranian Registry of Clinical Trial (IRCT2017100312782N21). Also, All patients signed written informed consent for participating in the study.

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Authors contributions

All authors have read and approved the manuscript.

Conflicts of interest

The author declared no conflict of interest..

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