

Prospective Randomized Comparative Assessment of Efficacy of Amniotic Membrane in Preventing Failures in External Dacryocystorhinostomy

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Conflict of interest: Nil

Abstract

Aim: To evaluate the efficacy of amniotic membrane in preventing failures in external dacryocystorhinostomy.

Methodology: The study was a prospective randomized comparative study of external DCR and external DCR with AM conducted 1 year. The study included 50 cases that were diagnosed with primary nasolacrimal sac or duct obstruction or chronic dacryocystitis out of which 35 patients underwent external DCR and 35 patients underwent external DCR with AM. The surgeries were performed by the same surgeons. Patients above 20 years were included in the study. A detailed ocular and systemic history were taken. Patients were examined with particular reference to lacrimal apparatus. A detailed ocular examination and a thorough anterior rhinological examination were done to rule out any nasal pathology by otorhinolaryngologist. The patency of nasolacrimal duct was found by lacrimal sac syringing and by both primary and secondary Jones dye test. Routine blood investigations like complete hemogram, blood glucose level, serological tests to rule out HIV, Hepatitis B and C were done.

Results: 50 patients were randomized into 2 groups of 25 each, group 1 patients underwent External DCR, group 2 patients underwent external DCR with AM. In group 1, 28%, 52%, and 20% patients belonged to 21-40, 41-60, and 61-80 years of age group respectively. Similarly in group 2, 24%, 52%, and 24% patients belonged to 21-40, 41-60, and 61-80 years of age group respectively. Group 1 includes 40% males and 60% females, while in group 2, 44% were males and 56% were females. Youngest patient studied was 21 years old and oldest was 78 years old.

Out of 50 patients included in the study, 8 (16%) patients had mucocele (3 in Group 1 and 5 in Group 2), 42 patients (84%) had chronic dacryocystitis (22 in Group 1 and 20 in Group 2). 15 patients (30%) had DNS (8 patients in Group 1 and 7 in Group 2). There were 7 cases of bleeding in Group 1 and 5 in Group 2 (total 12 cases out of 50) intraoperatively. On 6 months follow-up, it was found that out of 50 cases, total of 6 patients had failure. Out of this 4 were in group 1 and 2 were in group 2.

Conclusion: From this study, it can be concluded that there was more success rate in DCR with AM as compared to DCR only. There were less intraoperative as well as postoperative complications in DCR with AM as compared to DCR only but the difference was not

statistically significant. More studies on large scale should be done to evaluate the results properly.

Keywords: dacryocystitis, lacrimal sac, amniotic membrane

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Introduction

Dacryocystorhinostomy (DCR) surgery is a procedure that aims to eliminate fluid and mucus retention within the lacrimal sac, and to increase tear drainage for relief of epiphora (water running down the face). A DCR procedure involves removal of bone adjacent to the nasolacrimal sac and incorporating the lacrimal sac with the lateral nasal mucosa in order to bypass the nasolacrimal duct obstruction. This allows to restore the flow of tears into the nose from the lacrimal sac when the nasolacrimal duct does not function [1]. Nasolacrimal duct obstruction occurs as a congenital or acquired disease. The obstruction of the nasolacrimal excretory system may occur in the proximal puncta, canaliculi, common canaliculus, or more distally within the lacrimal sac or nasolacrimal duct. Acquired nasolacrimal duct obstruction may develop for a variety of reasons, including secondary to facial trauma, chronic environmental allergies, toxicity from chemotherapeutic drugs or topical medications, neoplasms, long-standing sinus disease, or following sinonasal surgery [2].

Dacryocystorhinostomy is the procedure of choice to treat nasolacrimal duct obstruction by creating an ostium for bypassing tears into the nasal cavity. There are two main approaches for this surgery: the conventional (external) and intranasal (endonasal) [3, 4]. External DCR is the most common surgery and the preferred method among ophthalmologists. It is performed by standard skin incision and removal of maxillary and lacrimal bones to create a connection path between the lacrimal sac and nasal cavity mucosa [5]. It

is the gold standard treatment of Primary acquired nasolacrimal duct obstruction (PANDO) and other methods are measured and compared with it. This method was first introduced in 1904 by Adeo Totti [6, 7].

The success rate of this approach varies in different studies from 63% to 97%. Overall, there is still a failure rate of 4% to 13% in which the patients' epiphora recurs [3, 8]. Anatomical variations and intranasal pathologies are the most common reasons that can cause narrowing of the nasal airway and the subsequent failure of the surgery [9]. Some causes of the failure include granulation of tissue and scar formation, insufficient rhinostomy, presence of nasal polyps and rhinosinusitis, inappropriate location or closure of the ostium, concha bullosa, intranasal adhesion, abnormal size of fistula, sump syndrome, previous maxillofacial trauma, enlargement of agger nasi cells, and paradoxical or hypertrophic middle turbinate [8, 10-18]. Cause of failure in most cases is the obstruction of the new drainage channel by an occluding membrane, which on histological examination shows organised granulation tissue.

Amniotic membrane is the innermost layer of the fetal membranes. It has a stromal matrix, a thick collagen layer, and an overlying basement membrane with a single layer of epithelium [19]. Amniotic membrane has unique properties including anti adhesive effects, epithelialisation effects, and lack of immunogenicity [20]. Amniotic membrane has been successfully used in patients with persistent epithelial defects, [21] pterygium,

[22] symblepharon,[23] and for ocular surface reconstruction [24]. These natural biological properties make it a logical tool in excessive healing at the site of stoma without any scar.

Materials and Methods:

The study was a prospective randomized comparative study of external DCR and external DCR with AM conducted in Department of Ophthalmology, Nalanda Medical College and Hospital, Patna, Bihar, India from Jan 2018 to December 2018. The study included 50 cases that were diagnosed with primary nasolacrimal sac or duct obstruction or chronic dacryocystitis out of which 35 patients underwent external DCR and 35 patients underwent external DCR with AM. The surgeries were performed by the same surgeons. Patients above 20 years were included in the study. Patients with canalicular and punctual obstruction, congenital nasolacrimal duct obstruction, associated nasal pathology like nasal polyp, grossly deviated nasal septum(DNS), hypertrophied inferior turbinate, repeat DCR, post-traumatic bone deformity, lower lid laxity, suspicion of malignancy, radiation therapy were excluded from the study.

Methodology:

A detailed ocular and systemic history were taken. Patients were examined with particular reference to lacrimal apparatus. A detailed ocular examination and a thorough anterior rhinological examination was done to rule out any nasal pathology by otorhinolaryngologist. The patency of nasolacrimal duct was found by lacrimal sac syringing and by both primary and secondary Jones dye test. Routine blood investigations like complete hemogram, blood glucose level, serological tests to rule out HIV, Hepatitis B and C were done.

In DCR with AM group a multi-layered AM was placed as spacer in the osteotomy opening and held in place by suturing to the periosteum lining the margins of osteotomy

as well as to the posterior surface of the anterior flaps. All patients were followed at 1st week, 1st month, 3rd month and 6th month. In every follow up patients were asked about the presence or absence of discharge and watering of the eye outdoor or indoor. Patency of the lacrimal passage was investigated by sac syringing. Incision area was inspected for healthy healing. In some patients who complained of watering and with blocked sac syringing, osteotomy site was visualized with endoscope and pathology was accordingly dealt. In all patients at 1st week and at the end of 6th month endoscopic examination was done to check for any crusting, granulation tissue formation and size of the ostium.

Results:

50 patients were randomized into 2 groups of 25 each, group 1 patients underwent External DCR, and group 2 patients underwent external DCR with AM. In group 1, 28%, 52%, and 20% patients belonged to 21-40, 41-60, and 61-80 years of age group respectively. Similarly in group 2, 24%, 52%, and 24% patients belonged to 21-40, 41-60, and 61-80 years of age group respectively. Group 1 includes 40% males and 60% females, while in group 2, 44% were males and 56% were females. Youngest patient studied was 21 years old and oldest was 78 years old.

Out of 50 patients included in the study, 8 (16%) patients had mucocele (3 in Group 1 and 5 in Group 2), 42 patients (84%) had chronic dacryocystitis (22 in Group 1 and 20 in Group 2). 15 patients (30%) had DNS (8 patients in Group 1 and 7 in Group 2). There were 7 cases of bleeding in Group 1 and 5 in Group 2 (total 12 cases out of 50) intraoperatively. There was injury to nasal mucosa only in 1 case in Group 1, while no injury to nasal mucosa in group 2. Postoperatively, total 8 patients had epistaxis out of which only 3 cases were from group 2 and no cases of postoperative bleeding as complication in group 2.

On 6 months follow-up, it was found that out of 50 cases, total of 6 patients had failure. Out of this 4 were in group 1 and 2 were in group 2. All failed cases in both groups were subjected to ENT evaluation. Most patients showed narrowed ostium and

soft tissue scar and membrane across the ostium. We had a success rate of 84% in external dacryocystorhinostomy group and 92% in external dacryocystorhinostomy with AM.

Table 1: Demographic details, etiology, symptoms, Intraoperative and postoperative complications of patients in both the groups

		Group 1		Group 2	
		Number	%	Number	%
Age (in years)	21-40	7	28	6	24
	41-60	13	52	13	52
	61-80	5	20	6	24
Sex	Male	10	40	11	44
	Female	15	60	14	56
Symptoms	Simple epiphora	8	32	7	28
	Simple epiphora with discharge	15	60	13	52
	Swelling	2	8	5	30
Nasal pathology	D.N.S. present	8	32	7	28
Etiology	Mucocele	3	12	5	20
	Chronic dacryocystitis	22	88	20	80
Intraoperative Complication	Bleeding	7	28	5	20
	Injury to nasal mucosa	1	4	0	0
Postoperative complications	Epistaxis	5	20	3	12
	Late postoperative bleeding	2	8	0	0

Discussion:

External DCR is an effective treatment to relieve the symptoms in primary acquired NLD obstruction. Although numerous percentages of failure rates and relapse of symptoms were reported in different studies, the success rate of this method is reported from 75% to 97% [25]. In the external method, the surgeon opens the lacrimal bone from the lateral aspect of the nasal bone and creates an ostium between the medial wall of sac and nasal mucosa. Occasionally, due to poor accessibility, the medial wall and bottom of the lacrimal sac may not sufficiently open into the nasal cavity and therefore, a pouch remnant of the lacrimal sac may remain that is called sump syndrome. This may cause fluid accumulation in the lower part of the lacrimal sac. Subsequently, accumulation

of tears and frequent infections may gradually close the ostium by mucins clots and inflammations [26].

In DCR with AM group a multi-layered AM was placed as spacer in the osteotomy opening and held in place by suturing to the periosteum lining the margins of osteotomy as well as to the posterior surface of the anterior flaps. Most common intraoperative complication was haemorrhage. Accidental entry into anterior ethmoidal air cells mostly happened while punching of lacrimal bone. Variation in anatomical position of sutural lines and lacrimal bones can be one of the reasons. However, these patients showed no postoperative failure. These findings correlated with the study by Hartikainen et al [27].

All the steps in both the groups are very much identical except for placing the AM over the osteotomy and suturing it to the surrounding periosteum and to the posterior surface of anterior flaps. That is why, there was very small difference in duration of surgery in both the groups. Thick bone, severe intraoperative bleeding, uncooperative patient due to reduced effect of anaesthesia are some of the causes of prolonged surgical duration.

We had a success rate of 84% in external dacryocystorhinostomy group and 92% in external dacryocystorhinostomy with AM. There was no statistically significant difference in success rate between the two groups. In the study by Robert M Sweet, Robert F Hoffman Mitomycin C group showed 95.5% patency whereas 70.5% patency in control DCR group [28]. In the study by Yua Ya, Fand CT [29] Mitomycin group had 100% success rate and control group had 83% success rate. Average osteotomy size at the end of 6 months was 22.2 mm in Mitomycin group and 13.2 mm in control group. Yalaz and others studied 60 cases of DCR. 20 were control cases. Mitomycin was used in 20, 5 fluorouracil in 20 cases [30, 31]. Control group showed 10% failure, other two showing 5% failure rate. In our study out of 50 cases total of 6 patients had failure. Out of this 4 were in group 1 and 2 were in group 2. All failed cases in both groups were subjected to ENT evaluation. Most patients showed narrowed ostium and soft tissue scar and membrane across the ostium.

Conclusion:

From this study, it can be concluded that there was more success rate in DCR with AM as compared to DCR only. There were less intraoperative as well as postoperative complications in DCR with AM as compared to DCR only, but the difference was not statistically significant. More studies on large scale should be done to evaluate the results properly.

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