

Evaluation of efficacy of amniotic membrane in preventing failures in external dacryocystorhinostomy

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Abstract

Aim: To Evaluate the efficacy of Amniotic Membrane in preventing failures in external Dacryocystorhinostomy.

Methods: It was a prospective randomized comparative study of external DCR and external DCR with AM. It was conducted at S. Nijalingappa Medical College, Bagalkot between October 2015 and April 2016.

The study included 100 cases with primary Nasolacrimal Duct obstruction or chronic dacryocystitis. Fifty patients underwent external DCR and 50 patients underwent external DCR with Amniotic Membrane. The results were compared at the end of 6 months follow up.

Results: 100 cases were randomized into 2 groups. Group I underwent External DCR and Group II underwent DCR with AM. Maximum incidence of disease was in 41-50 age group with 62% female patients and 38% males. Chronic Dacryocystitis was the commonest cause (88%) followed by mucocele (12%). The intra operative, post operative complications encountered in both the groups were identical. Time required for surgery was comparable between two groups, the extra time needed in group II was for the application of AM. A total success rate of 84% was observed in group I and 90% in group II.

Conclusion: In conclusion, though the success rate is higher in DCR with AM, it is not statistically significant ($p > 0.05$). Anti-fibroblastic activity of AM in preventing the scarring at osteotomy site in external DCR can go a long way in preventing the re-blockage and maintaining the post-operative patency of passages. Taking into consideration the long term side effects of Mitomycin C, AM can be considered as a simple and effective modification of conventional external DCR.

Keywords: Amniotic Membrane, External Dacryocystorhinostomy.

Introduction

Among the diseases of ocular adnexa, chronic dacryocystitis is a very common and troublesome condition. Resultant stagnation of tears, epiphora is a constant source of irritation to the patient's eye. Subsequent complications like acute dacryocystitis, corneal ulcer etc. can be prevented if the patency of nasolacrimal passage is established successfully. Dacryocystorhinostomy (DCR) is a time honoured surgical treatment with excellent results for obstruction at the level of lacrimal sac and nasolacrimal duct.

Toti, Dupuy Duteemps originally described external DCR.⁽¹⁾ Review of literature shows an average success rate ranging from 70-90%. The failure rate of around 10-30% after DCR shows that there is a need to improvise the technique by some means or the other.

Silastic intubations combined with DCR, Jones tube procedure of Conjunctivo dacryocystorhinostomy, endonasal laser DCR are some of the procedures with improved average success rates compared to conventional DCR. In spite of all these modifications, a small percentage of cases (about 10% overall) fail to maintain a normal patency of the passage.

Post-surgical scarring prevents the maintenance of desired patency of passages. Many studies involving cases of second operation on failed DCR have shown a dense scar tissue to be the cause of closure of osteotomy site.⁽²⁾ 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. The findings regarding the cause of re-blockage draw a conclusion that any process by which we can suppress this scarring in the new drainage passage should definitely help to achieve higher success rates after DCR procedure.

The human Amniotic Membrane is the innermost layer of the placenta. Histologically the amnion is 0.02mm-0.5mm thick 5 layered membrane composed of three basic layers,

- Epithelial monolayer
- Thick basement membrane
- Avascular hypocoelular stromal matrix.

AM is believed to be non-immunogenic and has anti-angiogenic, anti-scarring, anti-fibrotic and anti-inflammatory properties. These natural biological properties make it a logical tool in preventing scarring and excessive healing at the site of stoma.

Hence, we are evaluating the efficacy of AM in preventing failures in external DCR.

Materials and Methods

The study was a prospective randomized comparative study of external DCR and external DCR with AM. The study was conducted between October 2015 and April 2016.

The study included 100 cases who were diagnosed with primary nasolacrimal sac or duct obstruction or chronic dacryocystitis. 50 patients underwent external DCR and 50 patients underwent external DCR with

AM. The surgeries were performed by a single surgeon trained in Orbit and Oculoplasty.

All symptomatic epiphora cases diagnosed with primary acquired lacrimal sac or nasolacrimal duct obstruction or chronic dacryocystitis 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, entropion, ectropion, lower lid laxity, suspicion of malignancy, radiation therapy were excluded from the study.

A detailed ocular and systemic history was 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.

All patients received a course of antibiotics starting one day prior to surgery for 5 days.

100 patients were randomised into 2 groups of 50 each, group I patients underwent External DCR, group II patients underwent external DCR with AM.

Technique of DCR

Informed consent was taken from all patients.

Ribbon gauge soaked in 4% xylocaine and adrenaline 1:2,00,000 was used to pack the nasal cavity and surgery was performed under local anaesthesia. A straight incision of 1 to 1.5cm in length was made medial to medial canthus, starting at the level of medial canthal ligament. The orbicularis muscle fibres are separated with blunt dissection and cat's paw retractors are used to retract the wound. The periosteum overlying the anterior lacrimal crest is exposed. The periosteal incision is made just medial and inferior to the bony insertion of medial canthal tendon.

The osteotomy measuring approximately 10-15mm in diameter was created with citelli's punch. With the help of 11 number Bard Parker blade, first lacrimal sac and then nasal mucosa were opened in H shaped fashion to form larger anterior and smaller posterior flaps. Both the posterior flaps of sac and nasal mucosa are excised.

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.

In the present study only anterior flaps of nasal mucosa and lacrimal sac were sutured by interrupted sutures by 6/0 vicryl suture material. Subcuticular

sutures were put to close the wound. Antibiotic drops were instilled into eye, antibiotic ointment applied to operated site and dressing done.

Duration of surgery was measured from the incision on the skin to the end of closure of skin incision by suturing.

All patients were given systemic oral antibiotics and analgesics for 5 days. Antibiotic eye drops were advised for 6 times daily for 3 days. Nasal pack was removed after 24 hours. Nasal decongestant drops were instilled 5 drops 3 times a day for 3 days. Sutures were removed on 7th day. Lacrimal sac syringing was done on 1st, 2nd postoperative day.

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.

Statistical analysis was done by student t test, chi square test of proportion and percentage.

Observation & Results

Present study involved 100 cases, comprising 50 cases in external dacryocystorhinostomy (Group 1, DCR Group) and 50 cases in external dacryocystorhinostomy with AM(Group 2, DCR with AM). (Table 1)

Table 1: Number of eyes in each group

Group 1 External Dacryocystorhinostomy	Group 2 External Dacryocystorhinostomy with Amniotic Membrane	Total
50	50	100

Age distribution of the patients: Out of 100 patients studied, the maximum number of cases 28[=28%] belonged to 41-50 years age group [13=26% in group 1 and 15=30% in group 2]. This was followed by 24[=24%] belonging to age group 51-60 yrs [13=26% in group 1 and 11=22% in group 2]. There were 18[=18%] cases in age group 61-70 yrs [8=16% in group 1 and 10=20% in group 2]. 14[=14%] cases belonged to age group of 21-30yrs [7=14% in group 1 and 7=14% in group 2]. 12cases [=12%] belonged to age group of 31-40yrs [7=14% in group 1 and 5=10% in group 2], 2 cases [=2%] were in age group 71-80 yrs [2=4% in group 1 and no patients in group 2]. 2 cases [=2%] were in age group 81-90 yrs [no patients in group 1 and 2=4% in group 2]. Youngest patient

studied was 22 years old and oldest was 83 years old. (Table 2)

Table 2: Age distribution

Age in Years	Group I		Group II		Total	
	No.	%	No.	%	No.	%
21-30	7	14	7	14	14	14
31-40	7	14	5	10	12	12
41-50	13	26	15	30	28	28
51-60	13	26	11	22	24	24
61-70	8	16	10	20	18	18
71-80	2	4	0	0	2	2
81-90	0	0	2	4	2	2

Sex distribution of the patients: There were 38[=38%] male patients [18=36% in Group 1 and 20=40% in group 2], 62[=62%] female patients [32=64% in Group 1 and 30=60% in group 2]. (Table 3)

Table 3: Sex distribution

Sex	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Male	18	36	20	40	38	38
Female	32	64	30	60	62	62

Laterality of symptoms: In Group 1 out of 50 eyes operated 27[=54%] were right and 23[=46%] were left side. In Group 2 out of 50 eyes operated 26[=52%] were right and 24[=48%] were left eyes. Thus in total 53[=53%] were right and 47[=47%] were left eyes. (Table 4)

Table 4: Laterality of symptoms

Laterality	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Right side	27	54	26	52	53	53
Left side	23	46	24	48	47	47

Etiological distribution of cases: Out of 100 patients included in the study 12[=12%] patients had mucocele [4=8% in Group 1 and 8=16% in Group 2], 88 patients [=88%] had chronic dacryocystitis [46=92% in Group 1 and 42=84% in Group 2]. (Table 5)

Table 5: Etiological distribution

Diagnosis	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Mucocele	4	8	8	16	12	12
Chronic dacryocystitis	46	92	42	84	88	88

Symptomatological distribution of patients: Out of total 100 patients studied in the group 34[=34%], 18[=36%] in Group 1 and 16[=32%] in group 2 had

simple epiphora. 54[=54%] patients 28[=56%] in Group 1 and 26[=52%] in Group2 had simple epiphora with discharge. 12[=12%] patients 4[=8%] in Group 1 and 8 [16%] in Group 2 had swelling at medial canthus.(Table 6)

Table 6: Symptomatological distribution

Symptoms	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Simple epiphora	18	36	16	32	34	34
Simple epiphora with discharge	28	56	26	52	54	54
Swelling in sac area	4	8	8	16	12	12

Out of 100 cases studied 27 patients [=27%] had mild DNS [14 patients =28% in Group 1 and 13=26% in Group 2]. (Table 7)

Table 7: Ent pathology

Nasal Pathology	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Mild D.N.S	14	28	13	26	27	27

Surgical duration: The average surgical duration in group 1 was 26.32 minutes and in Group 2 was 34.28 minutes. Average mean difference between the two surgeries was 7.96 minutes. Surgical technique remaining the same in both the groups except for suturing of the AM to the periosteum surrounding the osteotomy, as well as to the posterior surface of anterior flaps. The extra time needed for surgery in Group 2 can be explained on this basis. (Table 8)

Table 8: Surgical duration (in minutes)

Average	Group I	Group II
Surgical duration	26.32	34.28

Intraoperative complications: There were 11 cases (22%) of bleeding in Group 1 and 9[=18%] in Group 2. There was injury to nasal mucosa in 2 cases [=4%] in Group 1 and 2[=4%] in Group 2. There was entry into ethmoidal air cells in 1 case [=2%] in Group 1 and 1[=2%] in Group 2. (Table 9)

Table 9: Intraoperative complications in Group I and Group II

Complications	Group 1		Group 2	
	No.	%	No.	%
Bleeding	11	22	9	18
Injury to nasal Mucosa	2	4	2	4
Entry in to Ethmoidal air cells	1	2	1	2

Post-operative complications: Epistaxis was the only major complication

- 9[=18%] patients had epistaxis in Group 1
- 8[=16%] patients had epistaxis in Group 2
- Late post operative bleeding in 2 patients [=4%] in group 1. (Table 10)

Table 10: Post-operative complications

Complications	Group I		Group II	
	No.	%	No.	%
Epistaxis	9	18	8	16
Late postoperative bleeding	2	4	0	0

Post operative irrigation patency rates: On the 1st post-operative day 48[96%] in Group 1 and 47[94%] in Group 2 were patent. 1st week 47[94%] in Group 1 and 47[94%] in Group 2 were patent. 1st month 44[88%] in Group 1 and 46[92%] in Group 2 were patent. At 3rd month 42[84%] in Group 1 and 45[90%] in Group 2 were patent. And at 6th month 42[84%] in Group 1 and 45[90%] in Group 2 were patent. (Table 11)

Table 11: Postoperative irrigation patency rate

	Group I		Group II	
	No.	%	No.	%
1 st Day	48	96	47	94
1 st Week	47	94	47	94
1 st Month	44	88	46	92
3 rd Month	42	84	45	90
6 th Month	42	84	45	90

Post-operative symptoms

Group 1: On 1st post op day all patients had scar tenderness. At 1st week 35[70%], and at 1st month 7[14%] had scar tenderness. None at 3rd and 6th months follow up. On 1st post op day all patients had mild swelling. At 1st week 17[34%], 1st month 1[2%] had mild swelling. None at 3rd and 6th month follow up. On 1st post op day all patients had epiphora. At 1st week 5[10%], 1st month 6[12%], 3rd month 4[8%], 6th month 4[8%] had epiphora. No discharge was seen on 1st day and 1st week in any patients, 1st month 2[4%], 3rd month 4[8%], 6th month 4[8%] had epiphora with discharge. (Table 12)

Table 12: Postoperative symptoms assessment in group 1

Symptoms	1 st Day	1 st Week	1 st Month	3 rd Month	6 th Month
Scar Tenderness	All	35	7	Nil	Nil
Swelling	All	17	1	Nil	Nil
Epiphora	All	5	6	4	4
Epiphora with	Nil	Nil	2	4	4

Discharge					
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Group 2: 1st post op day all patients had scar tenderness. At 1st week 30[60%], and at 1st month 3[6%] had scar tenderness. None at 3rd and 6th month follow up. On 1st post op day all patients had mild swelling. At 1st week 20[40%], 1st month 2[4%] had mild swelling. None at 3rd and 6th month follow up. On 1st post op day all patients had epiphora. At 1st week 5[10%], 1st month 4[8%], 3rd month 3[6%], 6th month 3[6%] had epiphora. No discharge was noticed on 1st day and 1st week in any patients. At 1st month 1[2%], 3rd month 2[4%], 6th month 2[4%] had epiphora with discharge. (Table 13)

Table 13: Postoperative symptoms assessment in group II

Symptoms	1 st Day	1 st Week	1 st Month	3 rd Month	4 th Month
Scar tenderness	All	30	3	Nil	Nil
Swelling	All	20	2	Nil	Nil
Epiphora	All	5	4	3	3
Epiphora with discharge	Nil	Nil	1	2	2

Success rate at the end of 6 months after surgery in Group 1 was 84% and in Group 2 was 90%. There was no difference in the failure rate between the two sexes. (Table 14)

Table 14: Success rate

Group	Success rate
External dacryocystorhinostomy	84%
External dacryocystorhinostomy with amniotic membrane	90%

Discussion

This prospective randomized study included 100 cases of dacryocystorhinostomy done between October 2015 and April 2016. Cases were randomized into two groups Group 1 and Group 2. Group1 containing 50 cases of external dacryocystorhinostomy and Group 2 containing 50 cases of dacryocystorhinostomy with AM. The results were compared at the end of 6 months follow up.

Chronic dacryocystitis is preferentially more common in the middle age, highest incidence is in the fifth decade but can also occur in advanced age. In our study maximum number of patients [28%] belonged to 41-50 age group. In the study by Hartikinen⁽³⁾ and others patients were in the range of 25-86 years, mean age was 64.8 years. Most studies demonstrate that 70%-83% of cases of dacryocystitis occur in females. The very striking predilection for females is due to narrower lumen of the bony lacrimal canal and a high nasal index. In the present study a female preponderance has been noticed. There were 62 female patients out of 100

patients studied(62%) and only 38% were male patients. It was also observed that failure rate is less in cases of mucocele compared to that in cases of chronic dacryocystitis. This can be due to a well defined thick sac, less infection and inflammation in case of mucoceles. Dacryocystitis has been noted to occur more frequently on left side than right.⁽⁴⁾ Arisi found that nasolacrimal duct and lacrimal fossa formed a greater angle on right side than left. This can be one of the anatomical reasons for commoner incidence of left side. Our study does not show any predilection for left sided involvement. 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⁽³⁾ et al who had observed that in 22% of ethmoidal sinuses were incorporated within the osteotomy.

There is no statistically significant difference in intraoperative complications in Group 1 and Group 2.

On an average 7.96 minutes was the mean difference in surgical duration between two groups. 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. Thus whatever extra time needed in group 2 patients can be attributed to this.

Thick bone, severe intraoperative bleeding, uncooperative patient due to reduced effect of anaesthesia are some of the causes of prolonged surgical duration.

Epistaxis was the only significant postoperative complication encountered. There was no statistically significant difference in postoperative complications in Group 1 and 2.

At the end of 6 months there were 87% asymptomatic cases (84% in Group 1 and 90% in Group 2), 7 cases with persistent epiphora(4 in Group 1 and 3 in Group 2) and 6 cases of epiphora with discharge(4 in Group 1 and 2 in Group 2). Hartikainen et al had similar observations in which 84% were asymptomatic, 2% showed watering indoor, and 15% with watering outdoor and 3% had symptoms of discharge.

We had a success rate of 84% in external dacryocystorhinostomy group and 90% 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 where as 70.5% patency in control DCR group.⁽⁵⁾ In the study by Yua Ya, Fand CT 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 mm² in

Mitomycin group and 13.2 mm² 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.^(6,7) Control group showed 10% failure, other two showing 5% failure rate.(Table 15)

Table 15: Comparative study

Study	Success rates (%)	
	Control group	DCR With AM
Present study	84	90
LIAO et al	70.5	95.5
YUA et al	83	100
YALAZ et al	90	95
KAO et al	87.5	100
Gonzalvo et al	75	100

In our study out of 100 cases total of 13 patients had failure. Out of this 8 were in group 1 and 5 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.

Limitations of the study: Larger sample size would have given a better statistical inference and a larger follow up period would have been better for the evaluation of the efficacy of amniotic membrane in maintaining the long term patency of the lacrimal passages after dacryocystorhinostomy.

Conclusion

In conclusion the success rate is higher in DCR with AM, but it is not statistically significant ($p>0.05$). In utilizing the anti-fibroblastic activity of amniotic membrane in preventing the scarring at osteotomy site in external dacryocystorhinostomy can go a long way in preventing the re-blockage and maintaining the postoperative patency of passages. Taking into consideration the long term side effects of Mitomycin C, AM can be considered as a simple and effective modification of conventional external dacryocystorhinostomy.

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