Endoscopic Dacryocystorhinostomy With Ologen Implant

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Abstract

Objective: To compare the effectiveness of endoscopic dacryocystorhinostomy with ologen implant versus endoscopic dacryocystorhinostomy with silicon tube implantation.

Background: Chronic dacryocystitis is an inflammatory disorder of the lacrimal sac that is mostly accompanied by partial or total nasolacrimal duct obstruction. Watering and discharge are the most common symptoms, however some cases can escalate to serious ocular and extraocular complications. It can result in severe ocular morbidity and loss of productivity at work, as it can temporarily obscure vision, prevent a person from concentrating on their task, and be socially uncomfortable. The goal of this research is to find a way to reduce recurrence after DCR surgery.

Methods: We conducted a prospective controlled study to evaluate effectiveness of endoscopic dacryocystorhinostomy with ologen implant versus endoscopic dacryocystorhinostomy with silicon tube implantation. A total of 40 patients underwent primary endoscopic DCR surgery in Menoufia University Hospital from march 2020 till march 2021. A total of 20 cases did endoscopic DCR using ologen implant (group A) and the other 20 cases did endoscopic DCR using silicon tube (group B).

Results: The success rate, which was evaluated by MUNK score and syringing test, was compared between both groups also rate of complications like epistaxis, implant complications and post surgery synechiae was compared. Success rates was 75% in ologen group and 85% in the other group. Epistaxis, infection and post surgery synechiae were statistically in significant between the two groups but implant complications was more in ologen group than the other group.

Conclusion: Endoscopic DCR with ologen implantation is not superior to endoscopic DCR with silicon stenting due to the challenging ologen implantation procedure and the high cost relative to silicon stenting.

Introduction

Endoscopic DCR procedures were developed in the 1980s and 1990s[1]. The endoscopic approach eliminates the necessity for a cutaneous incision and allows the surgeon to dissect and marsupialize the lacrimal sac more precisely[2]. With success rates equivalent to the external technique, endoscopic DCR has gained favor as a treatment for nasolacrimal duct obstruction[3,4].

However the debate continues with regard to external DCR versus endoscopic DCR. The advantages of external DCR are the direct visualization of the lacrimal sac and lack of need for expensive instrumentation. Disadvantages of external DCR include medial canthal scar and disruption of the orbicularis which may lead to abnormal tear pump, and increased post-op morbidity due to the skin incision[5].

Endoscopic DCR (endo-DCR) has the advantages of no external incision and scar, no disturbance of tear pump anatomy, and the capacity to examine, diagnose, and treat endonasal pathology like septal deviation or middle turbinate hypertrophy. The cost of instrumentation, the steep learning curve of endonasal procedures, and the difficulty of suturing the lacrimal sac-nasal mucosal flaps are all disadvantages of endoscopic DCR. Despite these drawbacks, success rates of up to 94 percent have been reported with enhanced instrumentation and technological developments[6].

Ologen is a porcine collagen implant that is biodegradable and porous. It affects the fibrosis process by regulating secreted extracellular matrix deposition and influencing fibroblast migratory patterns[7].

The purpose of this work is to compare the effectiveness of endoscopic dacryocystorhinostomy with Ologen implant versus endoscopic dacryocystorhinostomy with silicon tube implantation.

Patients And Methods

This is a prospective comparative randomized study .It was conducted on 40 patients undergoing primary endoscopic DCR surgery in Menoufia University Hospital,in the period from January 2019 to September 2021.Patients were divided into two groups:

Ologen group (a) : underwent endoscopic DCR using ologen implant (20 cases)

Silicon tube group (b) : underwent endoscopic DCR using silicon tube implantation (20 cases) .

All patients underwent a complete ophthalmological examination (vision ,IOP,fundus exam)and also evaluation of the lacrimal system prior to surgery, which will involve probing and sac syringing to determine lacrimal system patency. Syringing confirms nasolacrimal duct occlusion, as evidenced by resistance to saline flow and regurgitation from the opposite punctum. All patients will have a conventional diagnostic rigid nasal endoscopy in addition to a thorough clinical assessment and routine blood tests. This method allows for the evaluation septal deviation as well as any other nasal or sinus pathologic abnormalities.

Any patient with canalicular obstruction, a lacrimal sac tumour, a dacryolith, or traumatic obstruction was **excluded**. In patients with chronic dacryocystitis or when acute inflammation has subsided, the operation is performed. After all patients have been informed about the surgical operation and its effects, informed permission is acquired.

All patients had grade 5 epiphora according to MUNK scale ,some had mucocele and others had positive regurge test.

All study procedures will be carried out and approved by the Ethical Committee of Menoufia Faculty of Medicine and in accordance with the declaration of Helsinki.

Informed consent was obtained from all individual participants included in the study.

A 30° endoscope was used to do the surgery, and a mucosal flap was raised across the frontal process of the maxilla following local infiltration with 2% lidocaine and 1:200,000 adrenaline. To expose the lacrimal sac, bone was removed using bone nipping, Kerrisons straight and curved punches, or drilling. We removed enough bone until we could see the entrance of the common canaliculi.

The sac's medial wall was incised with a keratome, which was a simple procedure. The initial incision was made above the uncinate process attachment. The sac's medial wall was partially or entirely removed and marsupialized.

The rhinostomy's patency was confirmed by syringing. In order to locate the sac, an endo-illuminator was used.

In group (a) we used ologen implant at end of surgery to be inserted by the endoscope at site of rhinostomy.

In group (b) we used silicon tube stenting.

Ointment gauze or gel foam were used to fill the nasal cavity. All of the patients were given oral decongestants, antibiotics, and antibiotic eye drops and were discharged the next day.

Follow-up :After surgery, follow-up examinations were scheduled for 1 week, 1 month, 3 months, and 6 months. We asked patients to rate their problems on the MUNKscale at each visit.

Grade	Munk Scale
0	No epiphora
1	Epiphora requiring dabbing less than twice a day
2	Epiphora requiring dabbing 2–4 times a day
3	Epiphora requiring dabbing 5– 10 times a day
4	Epiphora requiring dabbing more than 10 times a day
5	Constant epiphora

The procedure was considered successful if the patient had grade 0 or grade 1 epiphora.

Syringing and irrigation was also done to all cases after 1 and 6 months.

Results were statistically analyzed by SPSS version 20 (SPSS Inc., Chicago, IL, USA). **Two types of statistics were done**

Descriptive terms include: percentage (%), mean, and standard deviation SD.

Analytical:-

Student's t-test: It is a single test that is used to determine whether or not a normally distributed quantitative variable has a significant difference between two groups.

Chi-Squared (χ^2): This statistic is used to compare two or more groups on a single qualitative variable.

Fisher's exact test: When the predicted count of any of the cells in a 2x2 contingency table is less than 5, Fisher's exact test is used to compare two groups on one qualitative variable.

Paired t test: The paired t test is a single test that is used to determine whether or not there is a significant difference between distinct time sequences for a normally distributed quantitative variable.

Wilcoxon signed rank test: It is the non-parametric version of Paired t test.

P value: Significant difference if ≤ 0.05 .

Results

Table (1) shows general characteristics of the studied cases,

Table (2) shows outcomes after 1 month evaluated by MUNK score and syringing: both groups shows no significant difference in epiphora outcomes 1 month post operative.

Table (3) shows outcomes after 6 months evaluated by MUNK score and syringing: both groups shows no significant difference in epiphora outcomes 6 months post operative.

Regarding early complications (epistaxis and infection) between two groups: table (4):results showed is no statistically significant difference between both groups.

Table (5) shows comparison of synechiae 6 months later between two groups, there was no statistically significant difference between both groups regarding post operative synechiae.

Regarding implant complications between two groups: table (6)

Group a had greater rate of post operative implant complications (p value less than 0.05) and this due to due to the difficult and challenging ologen implantation procedure.

Discussion

In the 1980s and 1990s, endoscopic DCR procedures were developed[1] .The endoscopic method eliminates the need for a cutaneous incision and allows the surgeon to see the lacrimal sac in exceptional detail during dissection and marsupialization[2]. The endoscopic DCR has gained popularity as a treatment for nasolacrimal duct obstruction, with success rates comparable to the external method[3,4].

Ologen is a porcine collagen implant that is biodegradable and porous. It affects the fibrosis process by regulating secreted extracellular matrix deposition and influencing fibroblast migratory patterns[7].

Our study was conducted on 40 patients undergoing primary endoscopic DCR surgery in Menoufia University Hospital.

We classified patients into two groups: group (A) who acquired endoscopic DCR using ologen implant (20 cases) and group B who acquired endoscopic DCR using silicon tube implantation(20 cases).

Group (a) included 20 cases with the mean age of 52.5 ± 12.12 and group (b) also included 20 cases with mean age of 54.35 ± 9.71 . Group (a) included 10 males and 10 females but group (b) included 8 males and 12 males. Eight cases were operated on their right side and 12 cases were operated on their left side in group a while 12 cases were operated on their right side in group b and 8 cases were operated on their left side.

The effect of ologen was studied in group A cases, in group B cases silicone tubes were used as stent and were removed after 6 months. The follow up period ranged from 6 months to 1 year.

Many methods or evaluation of the success of DCR operations were used in previous studies. In this study. At each visit we asked the patients to grade their complaints according to MUNK scale.

The procedure was considered successful if the patient had grade 0 or grade 1 epiphora. **Shams et al**[8], and **chin et al**[9]. also used this scale.

Syringing and irrigation was also done to all cases after 6 months as a measure of the anatomical success.

In this study the overall success rate of endoscopic DCR was 80% which is lower than the previous studies due to small sample size.

Harugop et al. conducted a prospective study on 290 patients with success rate of 93.3 %. EnDCR without intubation was performed in 240 cases and EnDCR procedures were performed with lacrimal intubation in 50 cases[10].

Raghuwanshi et al. conducted a prospective study with 90 patients who had epiphora due to NLD obstruction and were treated with endonasal DCR without stent during a three-year period. Overall, the outcomes were deemed satisfactory (88.88 percent success rate) [11].

Yuce et al. used a limited sample size (28) of patients with full stenosis of the nasolacrimal duct who were treated with endonasal dacryocystorhinostomy under endoscopically controlled conditions with silicon stenting. Approximately 97 percent of the patients were symptom-free, with only 3% reporting no improvement after surgery[12].

Regarding success rate in group a where we used ologen implant to maintain patent osteotomy, it was 75%, this was due to difficult fixation of ologen at osteotomy site that predisposed to ologen loss postoperatively.

This was in contrast to **Marey et al.**, who hypothesised that using Ologen implants in external DCR operations could reduce symptomatic epiphora without exposing patients to further intra-operative or post-operative problems[13].

However, because the follow-up time was brief and the sample size was small, more research is needed to confirm the impact of Ologen in external or endoscopic DCR operations.

Regarding success rate in group b using silicon tube was 80%:85%

Silicone tubing is used for three reasons: 1) to keep the neo-ostium open; 2) to prevent or correct canaliculus synechia; and 3) to avoid the risks of other methods like mitomycin c treatment.

Our findings were similar to those of **Harugop et al.** [10], who studied 290 patients, 240 of whom received endoscopic DCR without tube and 50 of whom received endoscopic DCR with tube, and found a success rate of 93.3 percent in EnDCR without intubation and 96 percent in EnDCR with intubation when the patients were reviewed three months after the procedure. The success rate is determined by creating a large intranasal stoma with appropriate bone removal around the stromal area, lowering the risk of postoperative stenosis and adhesions.

Our findings are similarly consistent with those of **Al-Qahtani et al.** [14], who studied 173 patients who underwent endoscopic DCR. There were 67 men and 106 women among the patients. In 92 patients, a silicon stent was employed, while in 81 individuals, no stent was used. The average postoperative follow-up period was 12 months. With silicone tubing, the success rate was 96 percent (89/92), while without tubing, it was 91 percent (73/81). There was no statistically significant difference between these two groups (p 0.117). The mean operative time was 23 minutes (range, 14–35 minutes) for endoscopic DCR without stent and 35 minutes for endoscopic DCR with stent (range, 24–48 minutes).

Raghuwanshi et al. conducted a clinical prospective analysis of 90 patients with a diagnosis of nasolacrimal duct obstruction and found different results. Without the use of a stent, the overall results were judged to be satisfactory (88.88) percent success rate. By avoiding the use of a stent, not only was the expense of the treatment reduced, but it also reduced the patient's anxiety and the need for follow-up visits from far-flung rural places[11].

Regarding implant complications there was higher incidence of complications in group a using ologen and less complications with silicon tube group due to difficult fixation of the ologen implant at osteotomy site.

Our findings contrast with those of **Smimov et al.**, who observed that following primary EN-DCR, the overall success rate was 89 percent (41/46) at the 6-month follow-up. All of the unsatisfactory outcomes were identified in patients who had silicone tubing inserted due to further complications. EN-DCR surgery with silicon tubing had a success rate of 78 percent (18/23), whereas surgery without tubing had a success rate of 100 percent (23/23) [15].

Conclusion

To the best of our knowledge this is the first paper to evaluate efficacy of ologen in endoscopic DCR ,our result shows that endoscopic DCR with ologen implantation is not superior to endoscopic DCR with silicon stenting due to the challenging ologen implantation procedure and the high cost relative to silicon stenting, which was relatively successful in external DCR due to easy fixation of ologen in mucosal flaps.

Declarations

Compliance with Ethical Standards:

-Authorship Confirmation Statement

- All persons who meet authorship criteria are listed as authors.

-Author Disclosure Statement

- The authors have no relevant financial or non-financial interests to disclose.

-Funding Information

- No funding was received to assist with the preparation of this manuscript.

-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.

-Informed consent:

- Informed consent was obtained from all individual participants included in the study.

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Tables

Table (1): General characteristics of the studied cases.

Parameter	Group a		Group b		Total		P-value of Fischer exact
	No	%	No	%	No	%	
	20	50.0	20	50.0	50	100.0	
Age							t-test
Mean $\pm$ SD	52.5 $\pm$ 12.12		54.35 $\pm$ 9.71		53.42 $\pm$ 10.88		0.598
Gender							
• Male	10	50.0	8	40.0	18	45.0	0.751
• Female	10	50.0	12	60.0	22	55.0	
Side							
• Right	8	40.0	12	60.0	20	50.0	0.343
• Left	12	60.0	8	40.0	20	50.0	
Presenting symptoms							
• Epiphora	5	25.0	9	45.0	14	35.0	0.41
• Swelling	10	50.0	7	35.0	17	42.5	Chi square
• MPC	5	25.0	4	20.0	9	22.5	1.783
Associated pathology							
• No	15	75.0	15	75.0	30	75.0	0.287
• Deviated septum	5	25.0	3	15.0	8	20.0	Chi square
• Nasal polyp	0	0.0	2	10.0	2	0.0	2.50

Table (2): Comparison of outcomes 1 month post. operative between two groups.

Parameter	Group a		Group b		Chi square test	P-value
	No	%	No	%		
	20	50.0	20	50.0		
Epiphora 1month later						
• Grade 0	8	40.0	10	50.0	1.966	0.854
• Grade 1	6	30.0	7	35.0		
• Grade 2	1	5.0	0	0.0		
• Grade 3	2	10.0	1	5.0		
• Grade 4	2	10.0	1	5.0		
• Grade 5	1	5.0	1	5.0		
Syringing 1month later						
• Patent	15	75.0	16	80.0	0.232	0.890
• Partially block	3	15.0	2	10.0		
• Total block	2	10.0	2	10.0		

Table (3): Comparison of outcome 6 months later between two groups.

Parameter	Group a		Group b		Chi square test	P-value
	No	%	No	%		
	20	50.0	20	50.0		
Epiphora 6 month later						
• Grade 0	11	55.0	13	65.0	1.500	0.913
• Grade 1	4	20.0	4	20.0		
• Grade 2	1	5.0	1	5.0		
• Grade 3	1	5.0	0	0.0		
• Grade 4	2	10.0	1	5.0		
• Grade 5	1	5.0	1	5.0		
Syringing 6month later						
• Patent	15	75.0	17	85.0	1.125	0.570
• Partially block	3	15.0	1	5.0		
• Total block	2	10.0	2	10.0		

Table (4): Comparison of early complications between two groups.

Parameter	Group a		Group b		Chi square test	P-value
	No	%	No	%		
	20	50.0	20	50.0		
Epistaxis 1st day						
• No	14	70.0	15	75.0	0.868	0.648
• Mild	5	25.0	3	15.0		
• Moderate	1	5.0	2	10.0		
Infection 1st week						
• No infection	18	90.0	18	90.0	Fischer exact	0.698
• Positive infection	2	10.0	2	10.0		

Table (5): Comparison of synechiae 6 months later between two groups.

Parameter	Group a		Group b		Chi square test	P-value
	No	%	No	%		
	20	50.0	20	50.0		
Synechia 6month later						
• insignificant	15	75.0	17	85.0	1.125	0.570
• Moderate	3	15.0	1	5.0		
• Severe	2	10.0	2	10.0		

Table (6): Comparison of implant complications between two groups

Parameter	Group a		Group b		Chi square test	P-value
	No	%	No	%		
	20	50.0	20	50.0		
Implant complication						
• No	15	75.0	17	85.0	8.125	0.043
• Tube prolapse	0	0.0	3	15.0		
• Mass	2	10.0	0	0.0		
• Ologen loss	3	15.0	0	0.0		