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ORIGINAL ARTICLE

Should Silicone Lacrimal Stenting be a Better Choice for Primary Endoscopic Powered Dacryocystorhinostomy?

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Abstract

Objective: To compare endoscopic dacryocystorhinostomy (EnDCR) with and without silicone lacrimal stenting through subjective (patients') and objective (surgeons') outcome parameters. **Methodology**: Following defined selection criteria, EnDCR was performed on patients with primary chronic dacryocystitis with post-saccal stenosis. Every alternate patient had silicone lacrimal stenting (group A: no stenting; group B: with stenting); stents were removed at three months. At six months (minimum follow-up period), patients' responses on symptom relief (through a five-point score) and naso-endoscopic evaluation (visualization of rhinostome; presence of granulations and synechiae; lacrimal drainage patency by estimating methylene blue flow pattern) were compared between the groups. **Results**: Each group had 20 patients. There was no statistically significant difference in group-wise follow-up periods. Five-point score at six months revealed 85% and 95% of patients in groups A and B, respectively, experienced "success"; among them, 60% and 75% were "symptom-free". The majority (75%) in group B experienced no discomfort from stenting. Naso-endoscopy revealed 80% patients in group A and 65% in group B had well-delineated rhinostome, albeit with granulations in 25% and 50%, respectively. Spontaneous dye flow was achieved, respectively, in 75% and 90%. The difference in none of the subjective and endoscopic parameters achieved statistical significance. None had synechia; fibrosis was seen in the four patients with no dye flow even with pressure/massaging. **Conclusion**: There was no statistically significant difference in EnDCR with and without silicone lacrimal stenting in the overall outcome of symptomatic improvement and endoscopic assessment of the surgical site.

Keywords Endoscopic dacryocystorhinostomy · Lacrimal stenting · Silicone stent · Rhinostome · Lacrimal drainage

Level of Evidence 2b.

Introduction

Endoscopic dacryocystorhinostomy (EnDCR) is the gold standard operation for chronic dacryocystitis with post-saccal stenosis. The procedure, however, is not without complications, which are predominantly due to the surgical technique itself. These include failure to preserve the medial wall of the sac and leaving bare bone around the rhinostome leading to tissue trauma, poor healing, granulations, neo-osteogenesis, bone remodeling, and synechia [1, 2]. In fact, stenosis of the rhinostome is a major complication that can follow both endoscopic and external approaches, necessitating revision surgery. Among the modifications suggested to reduce the incidence and extent of rhinostome stenosis,

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bicanalicular silicone lacrimal stent is one of the most widely practised techniques. In recent times, there has been a considerable body of work on EnDCR with stenting [3–7], although admittedly, proper indication and long-term results of stent placement require further, periodic evaluation. The present study investigates, through a rigorously carried out methodology, the outcome of EnDCR with silicone stenting in terms of success and complications, and compares the data with those of EnDCR without stenting. The study thereby re-explores the rationality and suitability of placing stent in EnDCR in a primary, uncomplicated clinical setting.

Materials and Methods

Study Set-Up

This comparative study was conducted in a tertiary care teaching institute during January 2019 to June 2020. Patients with epiphora were subjected to probe test and lacrimal syringing. Those with a hard stop (probe test) and with slow/delayed regurgitation from the upper punctum (lacrimal syringing), signifying primary chronic dacryocystitis with post-saccal stenosis were considered. The patients were the primary attendee in the department of Otorhinolaryngology and Head-Neck surgery, but those who opted for EnDCR were also referred from the department of Ophthalmology. They were recruited for surgery during January-December 2019, and were followed up for a minimum period of six months, up to June 2020.

Patients with lid problems (ectropion, entropion, lid laxity, ptosis, lagophthalmos), history of ipsilateral DCR, acute dacryocystitis [with lacrimal sac abscess/pyomucocele, skin inflammation, draining fistula in the lacrimal region], predominantly purulent regurgitate on syringing, punctal stenosis, symptoms suggesting malignancy or mass lesion (neoplastic/granulomatous), post-traumatic bone deformity, pre-existing primary bone diseases affecting the nose and orbit, co-existent systemic morbidities like diabetes mellitus and auto-immune endarteritis, and those with clinical features suggesting primary or secondary atrophic rhinitis, acute/acute-on-chronic rhinosinusitis and allergic rhinitis were excluded from the study. This list also included patients lost to follow-up. Those presenting with bilateral chronic dacryocystitis were operated only on the side with dominant symptoms, or according to their choice when the distress was comparable on both sides.

The study was approved by the Institutional Ethical Committee. Informed consent in writing was obtained from each patient prior to his/her inclusion in the study. Investigations and interventions were strictly according to the principles stated in the declaration of Helsinki 1964 and its subsequent revisions.

Prior to surgery, all patients were prescribed co-amoxiclav in appropriate dosage for seven days, and topical antibiotic medication in the affected eye. All surgeries and subsequent evaluations at follow-up were performed by the authors themselves as a team who followed identical surgical principles and follow-up protocol. The authors had comparable experience in EnDCR, and had been practising the procedure for at least eight years.

Surgical Procedure

All patients were operated under general anesthesia. Adequate nasal decongestion was achieved with cotton pledgets soaked with diluted 1:1000 adrenaline (3 ml adrenaline in 30 ml normal saline). The endoscopic surgery console system consisted of 4 mm 0 and 30 degree endoscopes (Karl Storz SE & Co. KG; Tuttlingen, Germany) and three-chip camera with high-definition monitor system (Stryker; Kalamazoo, Michigan, USA). Septal deviation significant enough needing correction, and the anatomic disposition of the middle turbinate, axilla and agger nasi were noted.

A posterior-based mucosal flap was raised following the surgical steps and dimensions described by Wormald PJ [2]. The lacrimal bone was identified at its junction with the frontonasal process of maxilla, and was peeled off. The exposed frontonasal process was next completely removed, including the area where it articulated with the skull-base, by powered drilling (endo-nasal drill bur for Straightshot® M5 microdebrider handpiece and Integrated Power Console System; Medtronic; Minneapolis, Minnesota, USA). The agger nasi cell, when present and large enough, was opened up. This was irrespective of the patients' symptomatology. The reasons for opening up of the agger cell was because when large, it caused hindrance to the endoscopic vision, and also because agger signified pneumatization of the lacrimal sac bed (frontonasal process of maxilla and lacrimal bone), and the purpose of drilling was to expose the entire medial wall of the sac completely, without any bony overhang. The medial wall of the lacrimal sac was next infiltrated with diluted adrenaline solution before incising. The lower puncta was then dilated, and a Bowman's probe (Karl Storz SE & Co. KG; Tuttlingen, Germany) was inserted to tent the medial wall of the lacrimal sac. With a 30º endoscope, the medial wall of the lacrimal sac was incised with a disposable keratome in a horizontal H-shaped manner, with the vertical limb of the incision made at the peak of the tent. The anterior and posterior flaps thus created were excised with 45º upturned Blakesley forceps (Karl Storz SE & Co. KG; Tuttlingen, Germany), and the lateral wall of the lacrimal sac was flushed with the lateral nasal wall. The cavity

of the lacrimal sac was irrigated with normal saline; this was followed by lacrimal syringing whereby free flow of normal saline was ensured.

Every alternate patient was chosen for silicone stenting (group B). Those who were not, were considered as group A. In group B, one end of the silicone tube (Medtronic, Jacksonville, Florida, USA) was inserted through the upper punctum and the other end through the lower one. Both ends were then taken outside the nasal cavity and a knot was applied which was pushed back close to the lateral wall of the lacrimal sac. Several such knots (4–6 in number) were made, care being taken not to make them too tight.

Finally, the posterior-based mucosal flap so long tucked between the septum and middle turbinate was retrieved, cut into two incomplete halves, and were trimmed appropriately to cover any bare bone. Antibiotic-impregnated Merocel® nasal pack (Medtronic; Minneapolis, Minnesota, USA), was inserted and kept in-situ for 24 h.

Follow-Up and Subsequent Evaluation

During the follow-up period, gentle digital massaging was advised (repetitive circular movements with the pulp of the index finger placed over the lacrimal fossa, medial to the medial canthus), 10 rounds at a time, four times/day, for three months. Irrigation with isotonic normal saline was also advised for a minimum of three weeks. Minimum follow-up period for each patient was six months, although naso-endoscopy and subjective point-based evaluation were performed periodically at one, three and six months, and subsequently bi-annually for patients within the scope of the study period. Stents were removed at three months. No lacrimal syringing was attempted in either group.

Assessment at six months (the minimum follow-up period) was considered for the final outcome analysis for both objective and subjective evaluation. A subjective evaluation in a five-point scale was made depending upon the patients' responses regarding the outcome of the surgery, that is, relief from epiphora. Patients' responses varied from "symptom-free", "significantly improved", "slightly improved", "no improvement", and "worse". The five-point score was constructed in the same order, the highest point assigned to "symptom-free" (score 5), and the least point to "worse" (score 1). Scores 3–5 were considered as "success", and 1–2 as "failure". Besides, an objective assessment was also carried out based on the endoscopic findings at six months. Observations were made on: (a) whether the rhinostome could be clearly seen; (b) presence of granulations and/or synechiae at the rhinostome site; and (c) whether the lacrimal drainage was patent, by estimating the flow pattern of methylene blue at syringing (spontaneous free flow, flow only on pressing or massaging the lacrimal sac region, or no flow). An objective checklist was maintained during the endoscopic evaluation, and appropriate responses were recorded.

Outcome of both the subjective and objective analyses were compared. Additionally, any outcome or complication exclusive to stenting, like opened knots, granulations at the opening of the common canaliculus etc., were specifically noted.

Statistical Analysis

The variations were analyzed as percentage of the two groups. Student's t-test was used to compare the mean of the groups like age, sex and follow-up period. Comparisons of the subjective and objective outcome between the groups were performed by chi-square test. P values < 0.05 were considered statistically significant. All calculations were carried out in multiple Windows Excel spreadsheets (Microsoft Corporation; Redmond, Washington, USA), using SPSS (Statistical Package for Social Sciences) software version 22 (IBM Corporation; Armonk, New York, USA).

A level of evidence of 2b has been assigned to this study, following guidelines provided by the Oxford Centre of Evidence-based Medicine [8].

Results

Patients were included in an alternative manner such that there were 20 patients each in group A (no stent given) and group B (stenting done). The study cohort overall had a mean age of 44.25 ± 16.44 years (range: 18–73 years). The mean age was 42.25 ± 16.63 years (range: 18–72 years) for group A, and 46.25 ± 16.42 years (range: 19–73 years) for group B. The difference was not statistically significant ($p = 0.765$; student's t-test; degrees of freedom [DF] = 3.8). There was an evident female preponderance overall (67.5%) and intra-group (70% in group A; 65% in group B), the difference not being statistically significant ($p = 0.114$; Pearson's χ^2 test, DF = 1). Irrespective laterality of involvement, 60% patients had dacryocystitis predominantly on the right that actually required surgical intervention. The difference between the groups in this regard (65% and 55% in groups A and B, respectively) was not statistically significant ($p = 0.417$; Pearson's χ^2 test, DF = 1).

Naso-endoscopy performed immediately prior to surgery revealed ipsilateral deviated nasal septum in three patients (two in group A; one in group B) that ultimately required limited endoscopic septoplasty for optimum surgical exposure. The agger nasi was prominent in 23 patients (10 in group A; 13 in group B) such that it needed to be opened

Table 1 Subjective evaluation at the end of six months post-surgery (n = 40)

	Group A (without stent) (n = 20)	Group B (with stent) (n = 20)	p-value
Subjective Evaluation	12 (60%)	15 (75%)	0.256 *
• Symptom free (score 1)	4 (20%)	4 (20%)	
• Significant improvement (score 2)	1 (5%)	0	
• Slight improvement (score 3)	2 (10%)	1 (5%)	
• Same (score 4)	1 (5%)	0	
• Worse (score 5)			
Outcome	17 (85%)	19 (95%)	0.277**
• Success	3 (15%)	1 (5%)	
• Failure			
Discomfort from stent (irritation, eyelid swelling, pain, etc.)†	-	5 (25%)	-
• Yes	-	15 (75%)	
• No			

* Pearson's χ^2 test, degrees of freedom (DF) = 1

** Pearson's χ^2 test with Yate's correction, DF = 1

† Information obtained at six months on recollection of symptoms prior to and/or at three months post-surgery, when the stents were removed

Table 2 Endoscopic evaluation at the end of six months post-surgery (n = 40)

	Group A (without stent) (n = 20)	Group B (with stent) (n = 20)	p-value
Rhinostome	16 (80%)	13 (65%)	1.536*
• Visible	4 (20%)	7 (35%)	
• Invisible			
Granulations	5 (25%)	10 (50%)	2.667*
• Present	15 (75%)	10 (50%)	
• Absent			
Methylene blue flow	15 (75%)	18 (90%)	0.652**
• Spontaneous	2 (10%)	1 (5%)	
• With pressure/massaging	3 (15%)	1 (5%)	
• No flow			
Knot opened	-	1 (5%)	-

* Pearson's χ^2 test, degrees of freedom (DF) = 1

** Pearson's χ^2 test with Yate's correction, DF = 1

up (reasons stated earlier) during drilling of the lateral nasal wall bone forming bed of the lacrimal fossa.

The mean follow-up was for 11.20 ± 3.28 months (range: 6–18 months). There was no statistically significant difference between the groups with mean follow-up of 11.34 ± 3.12 months (range: 8–18 months) in group A, and 11.05 ± 3.52 months (range: 6–18 months) in group B (p = 0.19; student's t-test, DF = 3.8). Analysis of the five-point subjective outcome score at six months (the minimum follow-up period) revealed that 85% and 95% patients in group A and B, respectively, experienced "success". However, the difference was not statistically significant (p = 0.277; Pearson's χ^2 test with Yate's correction, DF = 1). Among those experiencing "success", 60% in group A and 75% in group B declared themselves symptom-free (score 1). Majority (75%) in group B had no discomfort from the stent like irritation, eyelid swelling, pain, etc. The subjective outcome at six months follow-up is summarized in Table 1.

Endoscopic evaluation at six months post-surgery revealed that 80% patients in group A and 65% in group B had well-delineated rhinostome, although granulations were there, respectively, in 25% and 50%. These observations did not achieve statistical significance. Spontaneous dye flow was achieved in 75% patients in group A and in 90% in group B; however, the difference was not statistically significant (p = 0.652; Pearson's χ^2 test with Yate's correction, DF = 1). No synechia was encountered in any group, although fibrosis was seen in all four patients irrespective of the groups who had no dye flow even with pressure/massaging. Results of endoscopic evaluation at six months follow-up are summarized in Table 2.

Discussion

Silicone stents have been proved to be useful in EnDCR in selected indications, like in revision, infected lacrimal system (lacrimal mucopyocele, granulations),[5] and also in primary surgery [1, 6, 7]. It keeps the distal common canalicular outflow patent by preventing stenosis and synechia [1]. Recent researches on animal model have introduced more biocompatible and biodegradable materials (e.g., polylactic acid-polyprolactone-polyethylene glycol complexes) for lacrimal stent that minimize cicatrization of the canaliculi and subsequent stenosis [9]. On the other hand, a "tight" common canaliculus on lacrimal probing is considered one of the indications for stenting [10]. The stent in such a situation would keep the tightened valve of Rosenmüller guarding the distal common canalicular opening dilated. There are counter-opinions as well; several studies reported favorable outcomes in EnDCR without stenting [11, 12], and authors have reported in comparative analyses statistically significant success rates with EnDCR without stenting [13]. Bicanalicular stenting has often been implicated for causing post-operative bleed and eyelid complications like irritation, swelling, pain etc. [1]. Furthermore, prolonged duration of stenting results in microbial growth that might predispose to stenosis [4, 13], although a recent study revealed that appropriate antimicrobial therapy positively correlates with the patency of the lacrimal system in the long term [9]. Therefore it is apparent that the indications for lacrimal stenting and its short and long-term outcomes are essentially heterogeneous and are yet to be standardized.

The present study utilizes this scope for a re-assessment and investigates the effects of silicone stenting during EnDCR on subsequent lacrimal patency. The methodology adopted here is reproducible and transparent, and expresses rigor in terms of study design construct and evaluation of results. The study deals with two defined patient groups who are homogeneous regarding their age-sex composition, and in their clinical profile. Although chronic dacryocystitis has been noted to be commonly involving the left side and female sex [14], the results in our study hinted otherwise, might be due to a comparatively lower sample strength. The differences in laterality and sex predilection however did not attain statistical significance. The study adopted surgical principles and follow-up protocol which were uniform for both groups, universally accepted, evidence-based, and reproducible. Although follow-up endoscopy was carried out periodically, the study took the liberty to consider evaluation at six months as the final outcome for analysis and interpretation. This ensured uniformity in the follow-up period, and also provided optimum time for healing, and resolution of granulation tissue, if any, following surgery and removal of stent. Moreover, the endoscopic surgeons were in similar positions of their learning curves for the procedure concerned. The study setting further ensured that the operative field remained comparable in the two groups because there were no or minimal infection (mucopurulence) in the lacrimal environment. This eliminated any possible bias in patient selection that could influence the outcome regarding healing. The study principally aimed at finding out whether lacrimal stenting actually had any benefit in the endoscopic surgical management of chronic dacryocystitis in primary, uncomplicated events, and therefore, logical patient selection through a strict set of exclusion criteria was an important determinant for its execution.

Our study revealed no statistically significant differences in the outcome parameters in patients undergoing EnDCR with and without lacrimal stenting, although the values numerically favored the former group (Tables 1 and 2). The comparable outcome can be attributed to the surgical procedure itself. The aim of surgery was to expose the lateral wall of the lacrimal sac in its entirety, following drilling off of large agger nasi cell and excision of the medial wall of the sac so that its lateral wall gets flushed with the lateral nasal wall, without any bony overhang (especially in the superior aspect) guarding the medial opening of the common canaliculus. Also, as stated previously, the surgical technique was uniform in both groups. Digital lacrimal massaging in the follow-up period might be another factor for such comparable results and an overall favorable outcome.

That limited granulations were observed in the post-operative endoscopic observations around the rhinostome in both groups A and B (25% and 50% respectively; not statistically significant; Table 2) could be explained by the mucosa-sacrificing technique adopted, potentially leaving minimal bare bone to heal by secondary intention. Granulations were relatively more in group B. Stenting itself, and microbial growth following its long-term stay might play additional role in it. However, since there was no statistically significant difference between the groups regarding the occurrence of granulations, this study cannot conclusively prove that patients undergoing stenting had a predilection for granulation tissue formation.

It should be noted that none was subjected to lacrimal syringing in the follow-up period. We in our institute prefer routine digital massage of the lacrimal fossa over periodic lacrimal syringing after surgery. In our experience, we find this practice obviates potential injury to the puncta and canaliculi, and subsequent stenosis that often follow repeated, too often syringing. It can be speculated that, given the favorable outcomes, religious digital lacrimal massaging as advised was a practical alternative for syringing and was sufficient to maintain lacrimal patency.

Nevertheless, in spite of the uniform and meticulous surgical techniques and post-operative care, four patients experienced failure (persistence, worsening, or return of symptoms) due to fibrosis. Fibrosis generally relates to stenting, but was found to be numerically more in group A. Because difference in outcome in the two groups did not attain statistical significance, it cannot be concluded from the present study that not providing the stent would result in a better outcome. Interestingly, at six months follow-up, endoscopic evaluation could not localize the rhinostome in 20% and 35% of subjects in group A and B respectively (Table 2). Except for the four patients who had persistence, worsening, or return of symptoms due to fibrosis, the remaining patients in this cohort where the rhinostome could not be localized did not experience “failure” (Table 1). This suggests that non-visualization of the rhinostome could be because of healthy mucosalization of the lateral wall of the lacrimal sac that did not occlude the common canalicular opening, and does not always suggest or predict failure.

There are several limitations of the present study. First, the number of patients were limited, and the elaborate and strict exclusion criteria adopted might be responsible for this. However, the study set-up being a tertiary-care teaching institute, and given the relatively short study duration, the sample strength is not negligible from the perspective of determining statistical strength and significance. Also, the rigid exclusion criteria stress on the homogeneity of the study population at the cost of the generalizability of the study outcomes. Nevertheless, the fact that there were no statistically significant differences in the outcome parameters between the groups might ultimately be related to the limited sample strength.

Second, the subjects were grouped on an alternative basis; thus there was a palpable chance factor in having the groups age and sex-matched because the methodology adopted no randomization technique. The chance factor might also play its role in not having synechia in the limited number of patients requiring septal correction prior to EnDCR. A larger sample size could have resulted in a different outcome.

Third, although the outcome instruments as described are being used in our institute as part of the follow-up assessment protocol that provide us with consistent results, there is need for their statistical validation, especially for the point-based subjective evaluation. In this context, it should be acknowledged that the minimum follow-up duration should have been extended to bring reliability to the study and to ensure reproducibility to the results. However, the ongoing coronavirus disease pandemic forced us to limit the minimum follow-up duration. Nevertheless, the results obtained are from a rigorously conducted methodology, hence they firmly show a definite trend.

Fourth, the outcome opening up of agger nasi could have had on rhinostome patency and formation of granulations was not assessed. Agger was considered here only for anatomic and surgical interest when it caused visual obstruction and/or reduced the endoscopic working space, and the effect of agger mucosa on epithelialization around the rhinostome was not assessed.

Finally, evaluation of lacrimal patency distal to the puncta during the follow-up period relied only on the mechanical property of luminal fluid transport, and did not consider integrity of the lacrimal pump system. With no provision for lacrimal scintigraphy in the present study set-up, it would not be prudent to conclude that fibrosis and/or granulations following EnDCR with/without lacrimal stenting were the only reasons for the seven patients (five in group A and two in group B; the difference not statistically significant) not achieving spontaneous dye flow on syringing.

It needs to be stressed that the present study might not be specific and universal about answering the question "whom to stent", but through an elaborate and rigorous exclusion criteria, it has attempted to explore how useful lacrimal stenting would be in patients undergoing EnDCR in a given setting of primary, uncomplicated chronic dacryocystitis. For analyzing the applicability of lacrimal setting in specific situations like mucopurulence, revision, associated comorbidities etc., other study design instruments like prospective, randomized control trials are required in a problem-specific manner. The present study essentially and deliberately deals with a niche population that is tailor-made to be well-defined and homogeneous, and therefore, the resultant restricted sample size is effectively one of its major strengths. The usefulness of lacrimal stenting has been judged here in a neutral, unbiased, homogeneous study setting, and the subsequent outcomes would add to the existing body of literature by virtue of its consistency and reproducibility.

Conclusion

Notwithstanding the numerical edge and the apparent clinical benefits of EnDCR with lacrimal stenting, this study did not reveal any statistically significant difference between EnDCR with and without stenting in terms of overall outcome of surgery (success/failure; and patency of the lacrimal system), subjective improvement of the symptom spectrum, and post-operative endoscopic assessment of the surgical site (visibility of the rhinostome and presence of granulations).

Declarations

Conflict of Interest None.

Financial Disclosure None declared.

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