Endoscopic dacryocystorhinostomy with and without bicanalicular silicone tube in patients with a small lacrimal sac: a comparative study

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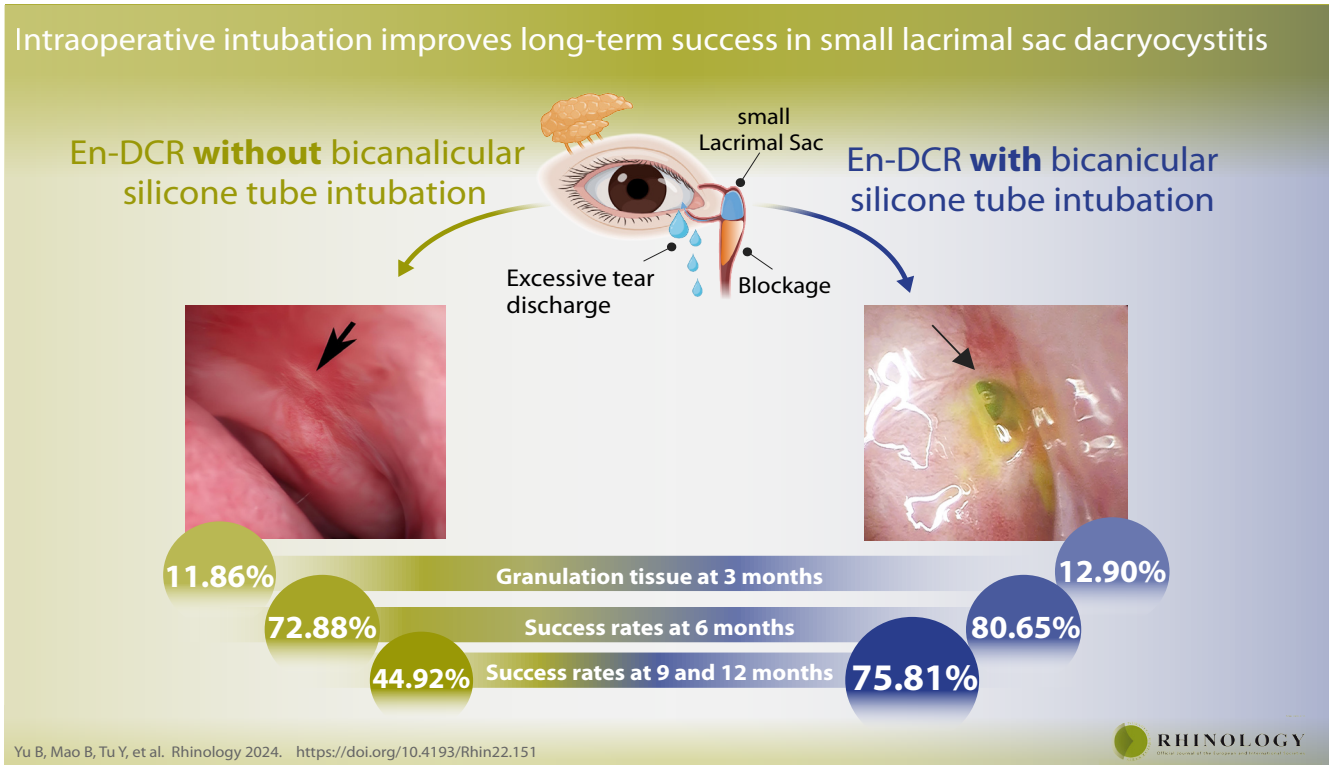
Rhinology 62: 5, 623 - 630, 2024
https://doi.org/10.4193/Rhin22.151



Abstract

Background: To establish whether bicanalicular silicone tube intubation is required during endoscopic dacryocystorhinostomy (En-DCR) for treating chronic dacryocystitis with a small lacrimal sac. **Methods**: In total, this study enrolled 264 patients diagnosed with unilateral chronic dacryocystitis with small lacrimal sacs via computed tomography-dacryocystography that underwent En-DCR from March 2016-September 2020. Patients were randomized into two treatment groups, with those in group A undergoing tubes intubation and those in group B not undergoing this procedure. The tubes were removed 3 months post-operation in group A. Surgical outcomes and related complication rates were then compared. **Results**: This study included 242 patients, including 124 and 118 in groups A and B, respectively. At the three-month follow-up time point, 12.90% of patients in group A exhibited ostial granulation tissue, with this frequency with no differences observed in group B (11.86%). At 6 months post-surgery, 80.65% of patients in group A and 72.88% of patients in group B exhibited successful surgical outcomes, with no significant differences between groups. At 9 months postoperatively, the overall effective success rate was 60.74%, and the success rate was significantly higher in group A relative to group B (group A: 75.81%; group B: 44.92%). There were no failed patient outcomes observed as of the 12-month follow-up time point. **Conclusions**: While En-DCR-based treatment of chronic dacryocystitis in those with small lacrimal sacs did not yield satisfactory outcomes with respect to the overall effective success rate, these results suggest that intra-operative intubation may improve success rates in long-term follow-up.

Key words: En-DCR, bicanalicular silicone tube, small lacrimal sac

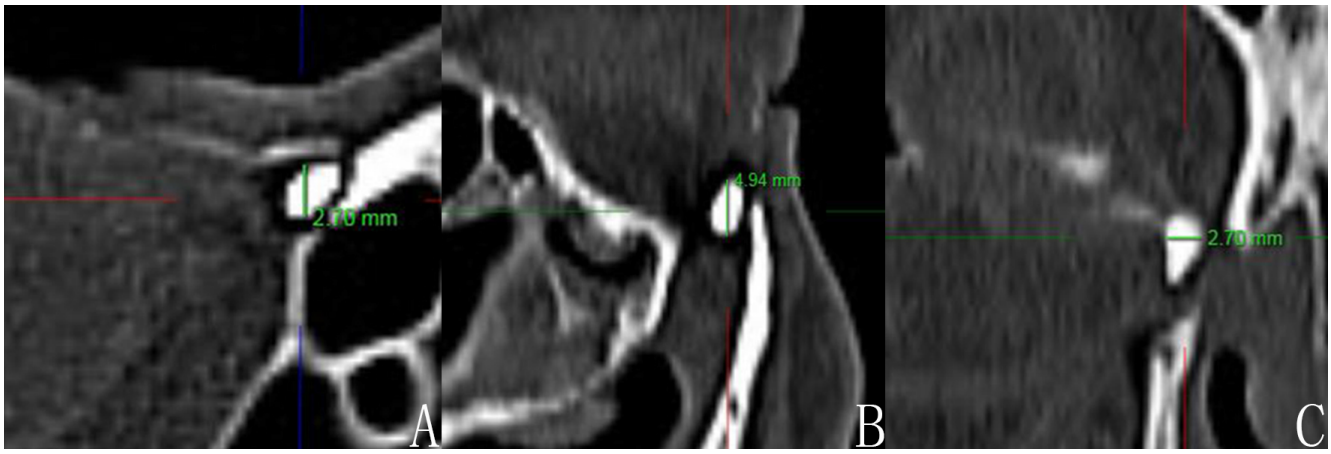


Figure 1. Measurement of the maximum dacryocyst diameters in three planes.

Introduction

Dacryocystorhinostomy (DCR) is the first-line approach to treating primary nasolacrimal duct obstruction (NLDO), and is reported to be successful in over 80% of patients [1-3]. Endoscopic DCR (En-DCR) is an increasingly popular version of this approach that offers advantages over the traditional external approach in that it avoids the need for generating cutaneous incisions and associated scarring, reduces the risk of disrupting normal lacrimal pump functionality, and expedites patient rehabilitation [4,5]. Rates of En-DCR success are reported to range from 80-96%, with some variability as a function of study-specific success criteria and follow-up durations [4,6,7]. While prognostic factors associated with DCR outcomes have yet to be fully clarified, lacrimal sac size has been shown to be an important predictor of operative success [8-11]. Specifically, En-DCR is thought to be less efficacious in patients with small lacrimal sacs relative to patients with larger lacrimal sacs, such that a small lacrimal sac may be a contraindication for DCR [8,9]. Many groups avoid utilizing silicone tube intubation in the context of chronic dacryocystitis as these tubes are inorganic and may therefore facilitate the development of persistent intranasal granulation tissue, punctal adhesions, canalicular laceration, or postoperative infections. Such intubation is generally only recommended in patients with a small lacrimal sac, a narrow upper nasal cavity, or canalicular stenosis/obstruction [12-14]. However, we are not aware of any randomized controlled trials that have assessed the relative efficacy of such silicone tube intubation in patients with small lacrimal sacs undergoing En-DCR. As such, we herein assessed whether bicanalicular silicone tube intubation can influence En-DCR outcomes in patients with small lacrimal sacs being treated for chronic dacryocystitis.

Materials and methods

This was a prospective randomized controlled study conducted in the Department of Orbital and Oculoplastic Surgery, Eye Hospital of Wenzhou Medical University from March 2016 to September 2020. The Eye Hospital of Wenzhou Medical University and the Institutional Ethics Committee (Medical Ethics Committee, Wenzhou Medical University, Wenzhou, Zhejiang, China) approved this study, which was consistent with the Declaration of Helsinki (2008). All patients provided informed consent to participate in this study.

Patients were eligible for inclusion if they had been diagnosed with anatomical NLDO and chronic dacryocystitis, had a small lacrimal sac, and elected to undergo surgical treatment. A standard preoperative assessment of eyelids and the lacrimal apparatus was conducted in all patients through a combination of probing, irrigation, and computed tomographic-dacryocystography (CT-DCG). The nasolacrimal drainage system was evaluated via CT following topical iopromide application (300 mg iodine/mL) as a radiopaque material. Prior to such contrast material application, the medial canthus was gently massaged to empty the lacrimal sac to facilitate contrast material entry into this compartment. The contrast agent was instilled into the sac through the inferior canalicular at a 1-2 drop/min rate for 2-4 minutes, until the agent overflowed from the superior canalicular. Spiral CT examinations were conducted in the horizontal plane with a Spiral CT instrument (SOMATOM Emotion 16) with a 0.75 mm/rotation table index and 1.0 mm reconstruction thickness. Images were used to reconstruct sagittal and vertical images, with maximum dacryocyst diameters in these three planes being measured by radiologists blinded to patient clinical status (Figure 1). These maximum dacryocyst diameters in the three planes were used in edge-to-edge convention, with each diameter measured three times and the average used as the final measurement. Lacrimal sacs were considered small based upon the following criteria:

1. Horizontal length ≤ 3 mm,
2. Sagittal length ≤ 3 mm,
3. Vertical length ≤ 6 mm.

Patients were excluded when they were <18 years old, had

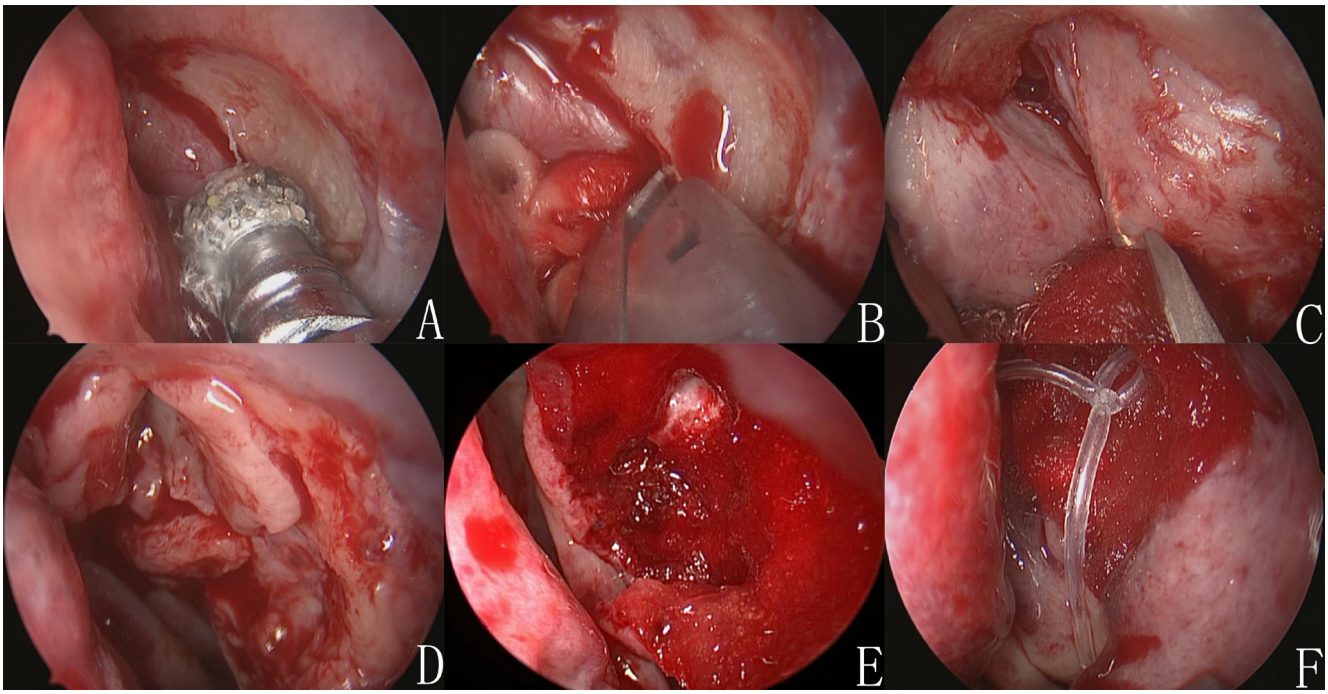


Figure 2. The maxilla and frontal process of the maxilla were thinned using a power burr (A), followed by their removal with a Kerrison rongeur (B). An incision was made in the anterior portion of the lacrimal sac using an ultrasharp 9# MVR knife (C). The sac was then fully opened, and a nasalmucosal flap was stripped and repositioned to cover the exposed maxilla (D), after which Merogel was packed around the wound (E). A bicanalicular silicone tube was inserted into the ostia of patients in group A from the superior and inferior puncta, and the tube ends were tied together within the nasal cavity (F).

undergone prior En-DCR or external DCR, suffered from severe nasosinusitis, canalicular obstruction/stenosis, primary neoplasms of the nasolacrimal system, a history of nasal trauma, or any systemic diseases associated with bleeding disorders or coagulopathy. Patients who were intraoperatively found to have a lacrimal sac size not consistent with the above criteria were also excluded, as were patients with a follow-up period of < 12 months or for whom the bicanalicular silicone tube was prolapsed within 3 months after surgery.

Preoperatively and postoperatively, patients were assessed by the same author who blinded to patient clinical status for evidence of epiphora and purulent secretions, and underwent dye tests, nasal endoscopy, and lacrimal irrigation. Patient demographic data including age, gender, and symptom duration. Patients were randomized into two groups that either did or did not undergo bicanalicular silicone tube intubation during En-DCR (groups A and B, respectively) using concealed random allocation from a computer-generated random numbers table.

Surgical procedures

En-DCR procedures were conducted under general anesthesia with a 0o 4.0-mm endonasal endoscope (Karl Storz, Tuttlingen, Germany). First, an 8-10 mm square mucosal flap above the operculum of the middle turbinate was cut using a blade, and a diamond burr attached to a micro-debrider (XPS3000; Medtronic Xomed, MN, USA) was then used to thin the underlying maxilla and frontal process of the maxilla (Figure 2A), followed by removal with a Kerrison rongeur (Figure 2B), thus exposing the lacrimal sac medial wall. The probe was then inserted from the upper punctum to expand the medial sac, enabling the opening of the sac with a curved 9# MVR knife (EdgePlus Trocar Blade, Alcon, TX, USA) (Figure 2C). Lacrimal sac volume was then assessed subjectively. Saline irrigation via the lower canalicular puncta was used to assess patency, after which the nasal mucosal flap was trimmed and repositioned to cover the exposed maxilla (Figure 2D). Two Merogel (Medtronic Xomed) pieces soaked with 5 mg/2 mL dexamethasone were then applied as a means of covering the posterior lacrimal sac flap and the surrounding 1-2 mm of the ostial wound surface (Figure 2E). In group A patients, a bicanalicular silicone tube was then inserted into the ostium from the superior and inferior puncta, with the ends of the tube being tied within the nasal cavity (Figure 2F). Patients were postoperatively treated for 2 days with methylprednisolone (10 mg/kg/day) and ceftriaxone (2.0 g/day). For three days postoperatively, lacrimal syringing with dexamethasone and tobramycin was conducted once daily. Intranasal Rhinocort Aqua Nasal Spray (AstraZeneca, DE, USA) was prescribed for the twice-daily treatment of all patients for 3 months. Silicone tubes were allowed to remain in the ostium for 3 months and were then removed. When ostial granulation tissue

Table 1. Patient characteristics and postoperative outcome for both groups.

Characteristics	Group A	Group B	t or χ^2 Value	P Value
Mean age ± SD	56.65±13.30	56.65±14.31	-0.004	0.997
Gender (F/M)	80/44	77/41	0.014	0.904
Eye (OD/OS)	56/68	61/57	1.034	0.309
Lacrimal size horizontal (mm)	2.64±0.31	2.69±0.29	-1.481	0.140
Lacrimal size sagittal (mm)	2.61±0.32	2.66±0.30	-1.260	0.209
Lacrimal size vertical (mm)	4.55±0.61	4.57±0.60	-0.302	0.763
Duration of symptoms (M)	16.13±15.27	17.79±15.94	-0.827	0.409
Granulation tissue 3M (%)	12.90%	11.86%	0.060	0.806
Success rate 6M (%)	80.65%	72.88%	2.049	0.152
Reason for failure (6M)				
Granulation (n/%)	14	16		
Scar (n/%)	8	11		
Canalicular obstruction (n/%)	2	5		
Success rate 9/12M (%)	75.81%	44.92%	24.196	<0.001
Reason for failure (12M)				
Granulation (n/%)	16	33		
Scar (n/%)	12	27		
Canalicular obstruction (n/%)	2	5		

SD: standard deviation; F/M: female/male; OD: oculus dexter; OS: oculus sinister; mm: millimeter; M: month.

was detected upon follow-up, it was cut using direct endoscopic visualization, and Intranasal Rhinocort Aqua Nasal Spray was administered for two additional weeks.

Patient follow-up was conducted at 1 week, 2 weeks, and 1, 3, 6, 9 and 12 months postoperatively. The presence of epiphora or purulent secretions was recorded at each follow-up, and intranasal ostium patency was assessed via lacrimal irrigation and endoscopic examination.

Successful tear drainage reconstruction was defined by a lack of any epiphora or purulent secretions, with normal endoscopic dye test results, free-flowing lacrimal system irrigation, and evidence of ostial patency with a normal-looking epithelized mucosa upon endonasal endoscopic investigation. Operative failure, in contrast, was indicated by any of the following: 1) a lack of improvement in epiphora or any episodes of postoperative dacryocystitis, 2) a lack of successful lacrimal irrigation, and/or 3) the confirmation of lacrimal sac occlusion by granulation and/or scar tissue as evidenced by endoscopic visualization and abnormal endoscopic dye test results.

Statistical analyses

SPSS v 26.0 was used for all statistical testing. Demographic data were compared via independent t-tests or chi-squared tests, while success rates were compared via Pearson chi-squared tests or Fisher's exact tests. $P < 0.05$ was the significance threshold for this study.

Results

In total, 264 patients (264 eyes) were enrolled in this study, including 134 patients in group A and 130 patients in group B. Three patients in each group were intraoperatively found to exhibit canaliculus stenosis. Three patients in group A and 7 patients in group B failed to complete postoperative follow-up. Bicanalicular silicone tube prolapse occurred within 3 months after surgery in one patient in group A. Three patients in group A and 2 patients in group B were found to exhibit a lacrimal sac size not consistent with inclusion criteria. After these patients were excluded, 124 and 118 patients were enrolled in groups A and B, respectively. Patient characteristics are compiled in Table 1. There were no significant differences in the patients' age ($t=-0.004$ $p>0.05$), gender ($\chi^2=0.014$, $p>0.05$), eye ($\chi^2=1.034$, $p>0.05$), horizontal, sagittal, and vertical size of the lacrimal sac (horizontal, $t=-1.481$, $p>0.05$; sagittal, $t=-1.260$, $p>0.05$; vertical, $t=-0.302$, $p>0.05$), or symptom duration ($t=-0.827$, $p>0.05$) between groups.

The postoperative outcomes are compiled in Table 1. At the 3-month follow-up time point, 12.90% of patients in group A (16/124) exhibited granulation tissue around the ostium, with this rate being no different than that observed in group B (11.86%; 14/118) ($\chi^2=0.060$, $p>0.05$).

At the 6-month follow-up time point, success rates were comparable between the two groups (group A: 80.65%, 100/124; group B: 72.88%, 86/118) ($\chi^2=2.049$, $p> 0.05$).

At the 9-month follow-up time point, the overall effective suc-

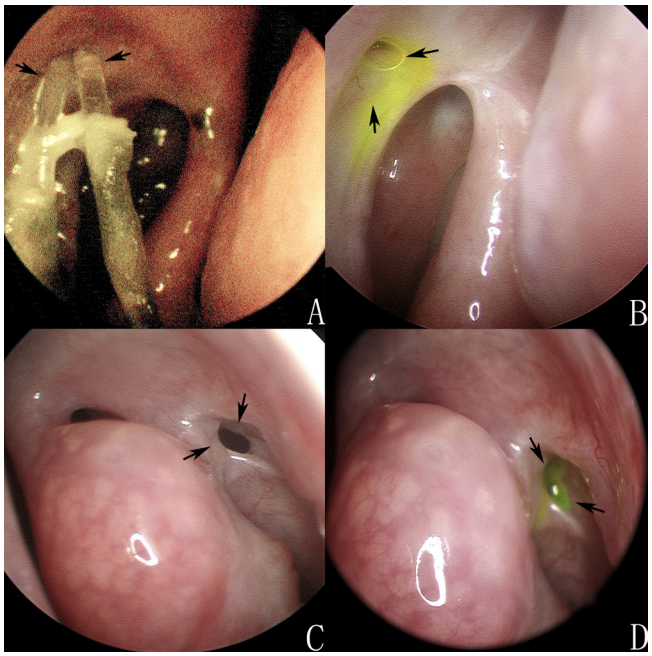


Figure 3. Representative successful cases from both groups. A case from group A. (A) Silicone tube placement in the ostium (arrow). (B) Results of the endoscopic dye test for normal function (arrow). A case from group B. (C) Evidence of ostial patency with a normal-looking epithelialized mucosa viewed through endonasal endoscopy (arrow). (D) Results of the endoscopic dye test for normal function (arrow).

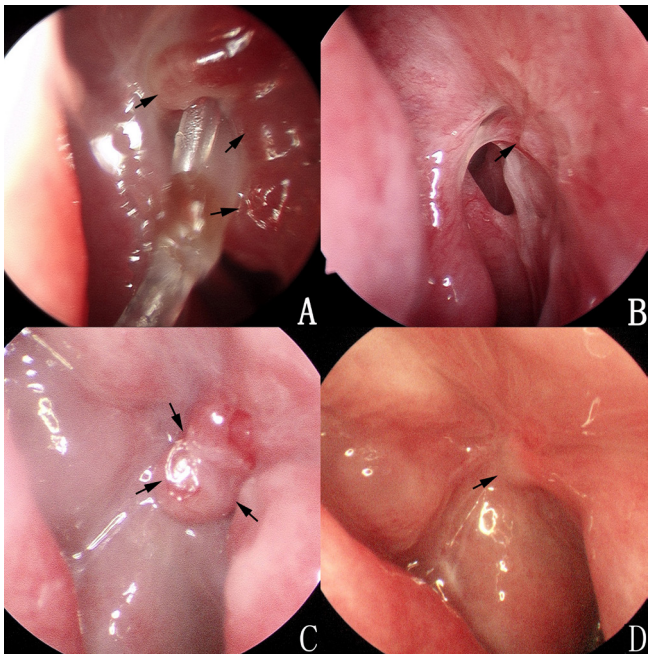


Figure 4. Representative failed cases from both groups. A case from group A. (A) The silicone tube placed in the ostium is surrounded by granulation tissue (arrow). (B) Scar synechia occluding the lacrimal sac ostium (arrow). A case from group B. (C) Granulation tissue occluding the lacrimal sac ostium (arrow). (D) Scar synechia occluding the lacrimal sac ostium (arrow).

cess rate was 60.74%, 75.81% of patients in group A (94/124) and 44.92% of patients in group B (53/118) exhibited successful surgical outcomes, with significant differences between groups (χ^2=24.196, p<0.05).

At the 12-month follow-up time point, no new failures occurred in either group. In group A, failure occurred due to granulation tissue formation at the ostium (n = 16), scar formation at the ostium (n = 12), and common canalicular obstruction (n = 2), while in group B these three causes were responsible for operative failure in 33, 27, and 5 cases, respectively (Figure 3, Figure 4).

Discussion

In this study, chronic dacryocystitis was more prevalent in middle-aged females (63 female cases between 40-65, accounting for 50.8% of the total cases in group A, and 51 female cases between 40-65, accounting for 43.2% of the total cases in group B), consistent with most other case series [1,3,6,9,14]. There were no significant differences in the patients' age, gender and eye between the two groups.

En-DCR is generally regarded as the optimal approach to treating epiphora in cases where the obstruction occurs distal to the common canaliculus. This approach relies on the generation of an anastomosis between the nasal cavity and the lacrimal sac [1,4]. While operative success rates are typically > 80% [6,7,10], these rates are significantly lower in patients with small lacrimal sacs, suggesting that this may be a contraindication for this procedure. Mannor et al. found that patients who were preoperatively found to exhibit large lacrimal sacs via dacryocystography experienced 82% postoperative success rates, whereas in patients with small lacrimal sacs the success rate was just 29% [8]. In a separate study of 134 patients, Hammoudi et al. found that a small intraoperative lacrimal sac opening was linked to a higher risk of failure relative to that associated with a large opening (71% vs. 93%) [9]. In this study, the overall effective success rate was 60.74% for patients with small lacrimal sacs, and the operative outcomes suggested that small sac size may be a negative factor associated with reduced postoperative efficacy, consistent with prior studies [8,9].

Many prior studies have failed to take lacrimal sac size into consideration, instead reporting overall operative success rates [1,5,7,12]. While a few articles have shown small lacrimal sac size to be associated with poorer operative outcomes, these studies often fail to report specific lacrimal sac size parameters. For example, Mannor et al. only reported the horizontal lacrimal sac dimension, which was preoperatively assessed via X-ray dacryocystography [8]. In their study, Hammoudi et al. defined a lacrimal sac opening as being small when a larger opening could not be made around the light probe secondary to a small, scarred lacrimal sac [9]. In their study, Lee et al. classified lacrimal sacs into three groups based upon their vertical diameter: small

(< 5 mm), medium (5 – 10 mm), and large (> 10 mm), concluding that smaller lacrimal sacs were associated with a higher risk of functional failure in patients suffering from primary nasolacrimal duct obstruction [11].

Herein, we conducted CT-DCG in all patients, and associated 3-dimensional data were taken into consideration as we believe that this approach enables the more reliable assessment of dacryocyst size and may be better able to predict operative success rates. Normal lacrimal sacs generally exhibit horizontal, sagittal, and vertical lengths of 6 mm, 6 mm, and 12 mm, respectively [5,16,17]. We considered all three of these diameters when establishing patient lacrimal sac size, with a value less than half of the normal value in all three parameters being considered indicative of small lacrimal size.

In the study, the maximum dacryocyst diameters in three planes were used in edge-to-edge convention, with each diameter measured three times and the average of the three values used as the final measurement. We admit that manual measurement of CT images is both time-consuming and laborious, and its accuracy is affected by the observer's experience. However, manual measurement is the most widely used method in the clinic as well as in studies for the quantification of CT images and is often considered a standard of reference [18]. Matsubayashi et al. conclusively demonstrated the high accuracy and reproducibility of manual measurement [19] while Chiwitt et al. assessed intra- and inter-observer repeatability by using the same CT images and found both to be satisfactory [20]. The adequate contrast between the dacryocyst and adjacent structures in CT images contributes to the accuracy of the measurement. Moreover, an experienced radiologist is able identify the boundaries of the dacryocyst accurately. Thus, we believe our manual CT measurement to be reliable.

The ostium formed during the DCR procedure will decrease in size postoperatively due to granulation tissue formation or scar tissue formation [1,4,5,9]. Ostium closure is far more likely in cases where patients exhibit a small lacrimal sac, resulting in operative failure. Additional surgical procedures such as applying mitomycin C (MMC) to the rhinostomy opening, silicone tube intubation, and corticosteroid utilization may thus be employed to improve ostium opening patency in these patients [21-25].

As an alkylating agent, topical MMC is sometimes applied to prevent fibroblast proliferation and scar hyperplasia in surgical contexts [21,26]. However, such treatment can result in complications such as glaucoma or cataracts, scleral melting, hypotony, endophthalmitis, corneal ulcers, limbal stem cell deficiencies, and maculopathy [27,28]. We thus elected not to apply MMC in the present study.

Silicone tube intubation is the most reported approach to supporting the lacrimal sac ostium in an effort to improve DCR success rates. However, some studies have suggested that such an approach can facilitate the enhanced formation of granulation tissue around the ostium, leading to higher rates of operative failure [24,25]. However, in this study, no difference was observed when comparing cases with and without silicone tube intubation with respect to the rate of granulation formation at 3 months postoperatively. This may be due to the following reasons: 1) The long-term use of intranasal rhinocort aqua nasal spray may inhibit the formation of granulation tissue. Corticosteroids exhibit anti-inflammatory, anti-mitogenic, and immunosuppressive activities that lead to their regular use in the context of DCR [7,29,30]. 2) Merogel has been shown to improve ostial patency and associated success rates for patients undergoing En-DCR by enhancing wound healing and mucosa epithelialization and thereby preventing fibrosis proximal to the ostium [30]. As such, we employed both corticosteroids and Merogel at the end of surgery for patients in the present study, with an intranasal steroid spray being prescribed twice daily for 3 months for all patients.

Similarly, in this study, no significant difference in the success rates was observed between two groups 6 months after the surgery. However, at 9 months after surgery, the success rate in group A was found to be significantly higher than that in group B and at the 12-month follow-up time point, no new failures had occurred in either group. This suggests that the postoperative follow-up time after En-DCR should be more than 9 months to assess the final effect. It also indicates that the silicone tube intubation played a role in the long-term postoperative success rate. The possible explanation may be that the degree of stoma contraction was delayed by the presence of the tube support for 3 months. The postoperative stoma requires at least 6 months to stabilize, allowing scar and granulation formation in the region of the ostium. Thus, the area available for scar formation and granulation would be greater, resulting in more extensive growth before stabilization in cases with tube intubation relative to those without tube intubation. In addition, further investigation should be undertaken on whether extending the duration of stent placement time can improve the success rate. This could be done using a controlled study to compare the postoperative efficacy of patients with intubation at 3, 6, or even 9 months after surgery to identify the optimal duration for stent placement of the small lacrimal sac.

Despite efforts to improve operative success rates, granulation tissue formation and scar tissue-mediated obstruction of the ostium were the primary causes of poor outcomes in the present study. The overall effective success rate in this study was 60.74% for patients with small lacrimal sacs, with respective success rates of 75.81% and 44.92% in groups A and B. In group A, failure occurred due to granulation tissue formation at the ostium (n = 16), scar formation at the ostium (n = 12), and common canalicular obstruction (n = 2), while in group B these three causes were responsible for operative failure in 33, 27, and 5 cases, respectively. The prominence of ostium obstruction by

scar or granulation tissue as the main cause of poor operative outcomes is consistent with prior studies [1,3,10,27,30].

There are several limitations to the present study. First, the optimal duration of intubation in patients with small lacrimal sacs was not determined. Second, a small lacrimal sac was defined as a three-dimensional structure that was half the size of the normal lacrimal sac. However, the dimension having the greatest influence on outcome remains unknown. Third, this was a single-center analysis of Chinese patients, and possible bias as it was not a double-blinded study, constraining the generalizability of our results. Further studies are needed to confirm these issues.

Our success rates were relatively low for patients with small lacrimal sacs as compared to the results of previously published En-DCR studies [5,6,23,30]. This may suggest that a small lacrimal sac may be a negative factor for En-DCR treatment. In addition, bicanalicular silicone tube intubation may represent an effective means of improving long-term success rates in patients with a small lacrimal sac undergoing En-DCR.

Conclusion

A small lacrimal sac may be a negative factor in endoscopic dacryocystorhinostomy. Bicanalicular silicone tube intubation can effectively improve the long-term success rates of the procedure in patients with small lacrimal sacs.

Acknowledgement

None.

Authors' contributions

Concept and design: BY, WW; Acquisition, analysis, or interpretation of data: BY, BM, MW, WW; Drafting of the manuscript: BY, BM; Critical revision of the manuscript for important intellectual content: all authors; Statistical analysis: BY, MW; Administrative, technical, or material support: BY, YT, WW; Supervision: BY, WW.

Funding

This work was supported by Medical and Health Science and Technology Project of Zhejiang Province (2020ZH014).

Conflicts of interest

No financial disclosures.

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Rhinology 62: 5, 623 - 630, 2024
https://doi.org/10.4193/Rhin22.151

Received for publication:
April 7, 2022
Accepted: May 27, 2024

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Assocociate Editor:
Claire Hopkins