Primary vs Secondary Endoscopic Dacryocystorhinostomy for Acute Dacryocystitis With Lacrimal Sac Abscess Formation: A Randomized Clinical Trial

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IMPORTANCE Endoscopic dacryocystorhinostomy (EN-DCR) is emerging as the preferred procedure in the management of nasolacrimal duct obstructions. However, its safety and long-term efficacy in the setting of acute dacryocystitis with lacrimal sac abscess have not been well studied.

OBJECTIVE To compare outcomes of EN-DCR as primary treatment with EN-DCR as a secondary treatment after percutaneous drainage of lacrimal sac abscess in acute dacryocystitis.

DESIGN, SETTING, AND PARTICIPANTS This randomized clinical trial was conducted from October 1, 2012, to October 31, 2015, at a tertiary ophthalmic center. The assessors of success at postoperative year 1 were masked to the procedures received by the participants. All surgical procedures were performed by 2 oculoplastic surgeons with different levels of EN-DCR experience. Eligible participants had acute dacryocystitis and lacrimal sac abscess presenting within 2 weeks of onset, who were 18 to 90 years of age. Analysis was of the intention-to-treat population.

INTERVENTIONS Patients were allocated by block randomization to receive either percutaneous drainage of lacrimal sac abscess followed by EN-DCR after the acute episode subsided (control group) or primary EN-DCR within 2 weeks of presentation (intervention group). Both groups received a course of empirical systemic antibiotics (amoxicillin and clavulanic acid, 375 mg, to be taken 3 times a day for 1 week).

MAIN OUTCOMES AND MEASURES Primary outcomes were time from presentation to documentation of symptom resolution and recurrence within 3 months.

RESULTS Thirty-two patients were randomized equally into 2 treatment arms (control and intervention). The mean (SD) age of patients was 61 (13) years, and there was a predominance of women (27 [84%]). The mean (SD) time to symptom resolution was 13.8 (5.8) days in the intervention group compared with 31.7 (27.1) days in the control group (mean difference, 17.9; 95% CI, 3.71-32.01; P = .02). The mean (SD) time to surgery in the intervention group was shorter at 11.9 (6.3) days compared with 45.6 (30.1) days in the control group (mean difference, 33.6; 95% CI, 17.92-49.33; P < .001). Recurrences occurred once in the control group and did not occur in the intervention group. No differences in operation time and complications between the 2 groups were identified. The anatomical and functional success was 87.5% (14 of 16 cases) in both groups at postoperative year 1.

CONCLUSIONS AND RELEVANCE Primary EN-DCR in acute dacryocystitis with lacrimal sac abscess results in faster resolution compared with secondary treatment. No differences in recurrence, safety, or outcomes at postoperative year 1 were noted between the 2 treatment groups.

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Acute dacryocystitis is a painful, debilitating condition characterized by a suppurative inflammation of the lacrimal sac. It is usually a secondary bacterial infection in the presence of nasolacrinal duct obstruction (NLDO) of various origins.\textsuperscript{1,2} In a US-based study, this condition was found in 71.3\%\textsuperscript{3} to 83.3\%\textsuperscript{4} of middle-aged women, with a quoted incidence of 2.4\%\textsuperscript{5} among patients with lacrimal system disorders. Presentation varies from mild overlying preseptal cellulitis to frank lacrimal abscess and even vision problems or life-threatening conditions, such as sepsis, orbital cellulitis, and superior ophthalmic thrombosis.\textsuperscript{6,7} Despite the various approaches described in the literature for the management of this condition, an evidence-based treatment modality has not yet been well established.

The secondary treatment for acute dacryocystitis with abscess formation consists of warm compresses, systemic antibiotics, and percutaneous abscess drainage, followed by external dacryocystorhinostomy when acute infection has subsided.\textsuperscript{3} This treatment strategy, however, has several limitations. Because the underlying pathology of NLDO is not corrected in the initial stage, there may be prolonged or recurrent infection. Percutaneous abscess drainage may result in unsightly cutaneous scar and fistula formation. In addition, surgical intervention in 2 stages may increase patient discomfort and the number of hospital visits.

The objective of this randomized clinical trial is to compare the clinical outcomes of endoscopic dacryocystorhinostomy (EN-DCR) as a sole primary treatment with EN-DCR as a secondary (or conventional) treatment after percutaneous drainage of lacrimal sac abscess in acute dacryocystitis.

Methods

This randomized clinical trial was conducted at a single tertiary eye hospital in Hong Kong (Hong Kong Eye Hospital) from October 1, 2012, through October 31, 2015. It is registered with the Centre for Clinical Research and Biostatistics—Clinical Trials Registry of the Chinese University of Hong Kong (http://www2.ccrb.cuhk.edu.hk/web Identifier: CUHK_CCT00350). It was approved by the Research Ethics Committee of the Hong Kong Hospital Authority and was conducted in accordance with the Declaration of Helsinki.\textsuperscript{8} All patients provided written informed consent before the screening investigations. See the Supplement for the trial protocol.

We identified consecutive patients (n = 33) with acute dacryocystitis, defined as painful lacrimal sac distention with marked medial canthal inflammation, who presented to the hospital during the study period. We included all patients with acute dacryocystitis and lacrimal sac abscess formation presenting within 2 weeks of symptom onset and who were between 18 and 90 years of age and fit for operation under general anesthesia. We excluded all cases with a history of dacryocystorhinostomy or maxillofacial surgery; trauma, neoplasm, or congenital anomalies of the lacrimal drainage system; immunocompromised state; poor cooperation for operation or endoscopic examination; and failure or refusal to give consent. The recruitment flowchart is shown in Figure 1.

All surgical procedures were performed at the Hong Kong Eye Hospital by 2 oculoplastic surgeons with different levels of experience; 1 (H.K.Y.) had performed more than 500 EN-DCR operations (surgeon A), and the other (A.C.W.) had performed approximately 50 EN-DCR operations independently (surgeon B). We also compared the surgical outcomes for the 2 surgeons.

Randomization and Masking

Participants were allocated by block randomization into 2 blocks according to the operating surgeon (A or B) in a ratio of 1:1 by computer-generated random numbers of 0 (representing the control group) and 1 (representing the intervention group). The random numbers in the computer-generated sequence were placed in sequentially numbered, opaque, sealed envelopes in blocks. These envelopes were stored in a box, which was kept and managed by a designated clerical staff at the Hong Kong Eye Hospital. With consent from the participant to enter the study, the oculoplastic surgeon in charge of the patient called the designated clerical staff member to obtain the randomization code and offered treatment accordingly.
Masking was not possible for the participant and the surgeon in view of the differences in treatment modality used. However, the assessors (one of whom was E.Y.L.) of anatomical and functional success at postoperative year 1 were masked to the initial procedures offered.

**Interventions**

Patients in the control group received percutaneous lacrimal abscess drainage under local anesthesia on the same day of presentation after randomization (and then received EN-DCR later). A course of empirical systemic antibiotics was given. The drainage site was laid open, followed by regular dressing of the wound until the infection subsided. Repeated percutaneous drainage of lacrimal abscess was performed if the infection failed to resolve. Approximately 1 month after acute dacryocystitis subsided, EN-DCR was arranged as a secondary treatment of the underlying nasolacrimal duct obstruction.

Patients in the intervention group received early EN-DCR only as a primary treatment for acute dacryocystitis. Due to logistics and the public hospital setting, early surgery was arranged as soon as possible (within 2 weeks of presentation and randomization). A course of empirical systemic antibiotics was given to all cases until signs of the infection subsided.

All EN-DCR operations were performed under general anesthesia using the mechanical method, including bone punches and drill, for osteotomy. The nasal mucosal flap was preserved whenever possible, allowing mucosa-to-mucosa apposition and aiming at complete sac marsupialization with healing by primary intention. In both groups, topical application of mitomycin C (0.4 mg/mL for 5 minutes) was used to enhance ostium patency. Bicanalicular intubation with silicone tubes was done in all cases. Nasal packing with gelfoam soaked in triamcinolone acetate (40 mg/mL) was done at the end of the procedure.

Patients were followed up at day 1 of presentation, week 1 of presentation, and at postoperative day 1, week 1, month 1, month 3, month 6, and year 1. Additional visits as required were separately arranged and documented. The primary outcomes measured included the (1) time to resolution of symptoms, defined as the duration from the day of presentation to the day of documented resolution of symptoms (including complete resolution of pain, medial canthal swelling, associated cellulitis, and fever), and (2) recurrence of acute dacryocystitis within 3 months. The secondary outcomes evaluated included the (1) efficacy of EN-DCR (including anatomical success, defined as a well patent ostium and positive dye test in the nasal cavity during endoscopic examination at postoperative month 12, and functional success, defined as an absence of subjective epiphora at postoperative month 12) and (2) safety of EN-DCR conducted in our trial, documenting the incidence of complications observed. All postoperative follow-up and assessment of success were performed by oculoplastic specialists who were masked to the initial procedures offered to the patients.

**Statistical Analysis**

Statistical analyses were performed using SPSS, version 16.0 (IBM). Group means were compared with an independent, unpaired, 2-tailed t test or Wilcoxon rank sum test. Success rates and complication rates were evaluated using chi-squared test or Fisher exact test. Pearson correlation coefficient was used to determine the degree of correlation. Tests of whether coefficients differed significantly from zero were conducted at the 5% significance level (2-tailed). Adjustments were not done for multiple analyses. A 2-sided P < .05 was used to indicate statistical significance. This analysis was of the intention-to-treat population.

**Results**

Thirty-two patients fulfilled the eligibility criteria and consented to join the trial from October 1, 2012, through October 31, 2015. The mean (SD) age of patients was 61 (13) years, and there was a predominance of women (27 [84%]). There was a documented preexisting NLDO in 14 of the 16 control group patients (88%) and in 11 of the 16 intervention group patients (69%). Patients were followed up from presentation to at least postoperative year 1, when the anatomical and functional success was assessed. No differences in baseline characteristics, such as age, sex distribution, laterality of involvement, and preexisting NLDO (as shown in Table 1), were identified between groups.

All patients, regardless of group, presented to our unit within 2 weeks of acute dacryocystitis onset and started a course of oral antibiotics (amoxicillin and clavulanic acid, 375 mg, to be taken 3 times a day for 1 week).

The mean (SD) time to surgery in the intervention group was shorter at 11.9 (6.3) days compared with 45.6 (30.1) days in the control group (mean difference, 33.6; 95% CI, 17.92-49.33; P < .001). One case in the intervention group received surgery at 20 days from presentation, beyond the planned time frame of 2 weeks. This delay was due to the operation being cancelled once and then rescheduled because of the patient’s high blood pressure at preoperative assessment.

The mean (SD) time to symptom resolution was 13.8 (5.8) days in the intervention group compared with 31.7 (27.1) days in the control group (mean difference, 17.9; 95% CI, 3.71-32.01; P = .02). Ten cases (63%) in the control group achieved symptom resolution with only percutaneous abscess drainage and antibiotic coverage at a mean (SD) of 23.5 (10.5) days. The remaining 6 cases required definitive EN-DCR to achieve complete symptom resolution, bringing up the mean (SD) total resolution time in the control group to 31.7 (27.1) days. One patient in the control group experienced an episode of cystitis within 3 months. These secondary outcomes evaluated using chi-squared test or Fisher exact test. Pearson correlation coefficient was used to determine the degree of correlation. Tests of whether coefficients differed significantly from zero were conducted at the 5% significance level (2-tailed). Adjustments were not done for multiple analyses. A 2-sided P < .05 was used to indicate statistical significance. This analysis was of the intention-to-treat population.
recurrent dacryocystitis while awaiting EN-DCR, prolonging the symptomatic period to 120 days. In the intervention group, all patients reported immediate relief of pain and distension on postoperative day 1. In both groups, self-reported or self-documented resolution of medial canthal swelling (if any) after surgery occurred between postoperative day 1 to day 5. No patients had residual medial canthal swelling beyond postoperative week 1. Figure 2 shows a box plot demonstrating the difference between days to resolution of symptoms between the intervention group (I) and the control group (0).

Bicanalicular intubation with silicone tube was successfully done in all cases. There was no significant difference in time from intubation to removal of silicon tube between both groups, with a mean (SD) of 34.1 (6.2) days in the intervention group vs 33.9 (5.7) days in the control group (mean difference, −0.2; 95% CI, −4.49 to 4.12; P = .93).

One case in the control group had recurrent lacrimal sac loculation 1 week after EN-DCR that required bedside aspiration for decompression. This patient did not have any further recurrence, and the ostium remained well patent at the postoperative year 1 follow-up. There were no cases of recurrence in the intervention group. Anatomical and functional success was 87.5% (14 of 16 cases) in both groups.

Four eyes of 4 patients (2 patients in each treatment group) had failed EN-DCR. In the intervention group, the 2 failed cases had scarred ostium at postoperative month 3. In the control group, 1 case had a granuloma covering the ostium at postoperative month 1; the granuloma was removed, but the patient subsequently developed scarring and stenosis at postoperative month 3. The other control case had a stenosed ostium at postoperative month 6. None of the failed cases opted for reoperation in view of mild residual tearing and no recurrence of acute dacryocystitis.

The operation time for each of the 2 surgeons was comparable at 54.9 minutes per eye for surgeon A and 50.6 minutes per eye for surgeon B (mean difference, 8.19; 95% CI, −12.15 to 20; P = .39). The more experienced oculoplastic specialist (surgeon A) had a 93.8% (15 of 16 cases) anatomical and functional success rate. The oculoplastic trainee (surgeon B) had 3 cases of failed EN-DCR and a success rate of 81.3% (13 of 16 cases). The surgical outcome of patients in this study is summarized in Table 2.

Pearson correlation was performed as a post hoc analysis. The Pearson correlation coefficient for days to operation and days to symptom resolution was 0.799 (95% CI, 0.557-0.954; P < .001). Scatterplots were done separately for the control group (Figure 3A) and the intervention group (Figure 3B), highlighting the correlation between earlier operation and symptom resolution. The correlation between operation time and symptom resolution appears stronger for the intervention group (R² = 0.83) compared with the control group (R² = 0.56). However, this difference did not reach statistical significance (95% CI, −0.2 to 0.87; P = .15).

**Discussion**

The secondary treatment of acute dacryocystitis has been warm compresses with a short course of antibiotics and nonsteroidal anti-inflammatory agents followed by external dacryocystorhinostomy. The disadvantages of this secondary approach include longer time to resolution; occurrence of cutaneous fistula (documented in 2 cases [6%]); unsightly scar; prolonged and recurrent infections; and risk for failure of subsequent surgery due to scarring, intrasac synchiae, or organized granulation tissue within the lacrimal sac.10,11

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**Table 2. Surgical Outcomes of Patients**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention Group (n = 16)</th>
<th>Control Group (n = 16)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to symptom resolution, mean (SD) [range], d</td>
<td>13.8 (5.8) [2-21]</td>
<td>31.7 (27.1) [11-121]</td>
<td>.02*</td>
</tr>
<tr>
<td>Time to operation, mean (SD) [range], d</td>
<td>11.9 (6.3) [1-20]</td>
<td>45.6 (30.1) [11-120]</td>
<td>&lt;.001*</td>
</tr>
<tr>
<td>Surgeon mean operation time per eye, mean (SD) [range], min</td>
<td>48.6 (11.8) [36-75]</td>
<td>56.8 (38.1) [31-95]</td>
<td>.75*</td>
</tr>
<tr>
<td>Recurrent acute dacryocystitis within 3 mo, No. (%)</td>
<td>0</td>
<td>1 (6)</td>
<td>.98b</td>
</tr>
<tr>
<td>Time to silicon tube removal, mean (SD) [range], d</td>
<td>34.1 (6.2) [27-54]</td>
<td>33.9 (5.7) [26-47]</td>
<td>.91</td>
</tr>
<tr>
<td>Anatomical success at postoperative year 1, No. (%)</td>
<td>14 (87.5)</td>
<td>14 (87.5)</td>
<td>NA</td>
</tr>
<tr>
<td>Functional success at postoperative year 1, No. (%)</td>
<td>14 (87.5)</td>
<td>14 (87.5)</td>
<td>NA</td>
</tr>
<tr>
<td>Clinic visits, No. (%), mo</td>
<td>9.7 (1.4) [8-13]</td>
<td>20.6 (4.9) [15-30]</td>
<td>&lt;.001*</td>
</tr>
</tbody>
</table>

Abbreviation: NA, not applicable.

* Compared with an independent, unpaired, 2-tailed t test.

b Evaluated with the Fisher exact test.
In the past decade, authors have reported their positive experience with EN-DCR as the primary first-line treatment in acute dacryocystitis.\textsuperscript{10-14} The main advantage of EN-DCR as a primary procedure in acute dacryocystitis is that it provides adequate and continuous drainage of the lacrimal abscess, which leads to rapid resolution of inflammation and symptoms. By correcting the causative pathology of NLDO, the chance of recurrence is significantly reduced. In our trial, all patients in the intervention group observed a dramatic resolution of acute inflammation, most notably pain and medial canthal swelling, after EN-DCR. This result is likely due to the immediate decompression of the lacrimal sac with the relief of pressure after surgery. There was no recurrence of acute dacryocystitis in the intervention group, and 1 patient in the control group experienced an episode of recurrence while awaiting surgery. Inadequate drainage of the lacrimal sac secretions with percutaneous drainage in the secondary method may predispose the patient to prolonged or recurrent inflammation, which may promote the proliferation of fibrous or granulation tissue in the lacrimal sac and lead to complications, such as fistula formation and unsightly scar.

One common concern regarding performing EN-DCR during an acute phase of inflammation in acute dacryocystitis is an anticipated increase in difficulty of operation and operating time due to the expected edematous mucosa of the lacrimal sac. However, our trial demonstrated no statistically significant difference in operation time between the 2 groups. Despite the more inflamed lacrimal sac intraoperatively, we achieved a similar-sized osteotomy, and all cases in our trial were successfully intubated with the use of a soft probe guidance. No intraoperative complications were documented in either group, including the formation of a sinus tract, false fistula, or injury to the canaliculus. The bicanalicular silicon tubes were removed at a mean (SD) of 34.0 (5.9) days, and there was no statistically significant difference in intubation time between the 2 groups.

Our study also compared the surgical success and operating time for the 2 operating surgeons and found no statistically significant difference between the surgeons, who had different levels of experience in conducting EN-DCR. These data suggest that primary EN-DCR in acute dacryocystitis with lacrimal sac abscess results in faster resolution compared with the secondary treatment. No differences in recurrence, safety, or outcomes at postoperative year 1 were noted between the groups, but the limited number of trial participants precludes determining confidently whether differences in these outcomes exist.

In this study, the mean (SD) time to complete resolution of symptoms was significantly shorter in the intervention group at 13.8 (5.8) days than in the control group at 31.7 (27.1) days (mean difference, 17.9; 95% CI, 3.7-32.0; \( P = .02 \)). This time difference echoes the results published in a recent retrospective review\textsuperscript{15} that showed a shorter time to resolution with primary EN-DCR compared with the time achieved in secondary treatment. In the intervention group, a single-stage procedure allows complete and continued drainage of inflammatory secretions from the lacrimal sac into the nasal cavity. In addition, transnasal drainage of lacrimal sac abscess allows surgical dissection to be performed through noninfected tissue planes, which can possibly minimize the risk of extending the infection into the surrounding tissues. We believe the reduced period of inflammation can also lower the risk for subsequent operations, scarring, and procedure failures.

This trial demonstrated high (87.5%) anatomical and functional success in both groups; this rate is comparable to the success rates reported by retrospective studies on the same topic.\textsuperscript{15} Despite the similar success rates between the 2 groups, the intervention group had significantly fewer clinic visits within the specified follow-up time of 12 months. Additional visits were required by the control group for drainage of pus and dressing of the external wound. Fewer clinic visits and faster resolution at an uncompromised safety and success profile make the chance of recurrence is significantly reduced. In our trial, all patients in the intervention group observed a dramatic resolution of acute inflammation, most notably pain and medial canthal swelling, after EN-DCR. This result is likely due to the immediate decompression of the lacrimal sac with the relief of pressure after surgery. There was no recurrence of acute dacryocystitis in the intervention group, and 1 patient in the control group experienced an episode of recurrence while awaiting surgery. Inadequate drainage of the lacrimal sac secretions with percutaneous drainage in the secondary method may predispose the patient to prolonged or recurrent inflammation, which may promote the proliferation of fibrous or granulation tissue in the lacrimal sac and lead to complications, such as fistula formation and unsightly scar.

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early EN-DCR in acute dacryocystitis an attractive initial option for patients.

Limitations
This trial is limited by its relatively small sample size, which may affect the power of the statistical analysis. Because this trial was a single-center study and all participants included were of Chinese descent, its widespread applicability is limited. In addition, we were not able to ascertain whether the resolution of acute symptoms was the outcome of surgery or of systemic antibiotics, which were given to all participants. In view of the difference in treatment modality, masking was not possible for the participants and the surgeons. To limit possible bias, the assessors of the anatomical and functional success at postoperative year 1 were masked to the initial procedures offered. The visit schedule in both treatment arms was not standardized because the follow-up frequency was determined by the patient’s clinical condition and the surgeon’s discretion. Due to a public hospital setting, we were not able to provide daily follow-up to all cases, which may have introduced bias in the collection of data toward the group with more frequent visits. Without a more objective mode of assessment, we relied on self-reporting of symptoms when assessing the resolution of symptoms. In addition, all EN-DCR procedures were performed under general anesthesia, and the tolerability of this procedure under local anesthesia or monitored anesthetic care was not assessed.

Conclusions
To our knowledge, we demonstrated that primary early EN-DCR is a recommendable procedure in acute dacryocystitis with long-term anatomical and functional outcomes comparable to those achieved in secondary treatment. A single-stage surgery is appealing to patients because there is no cutaneous incision and no need for wound dressing while awaiting definitive surgery. It also allows fewer outpatient visits and thus lower direct and indirect costs. Most important, faster symptom resolution facilitates earlier rehabilitation and improved patient comfort.

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Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

REFERENCES