Balloon Catheter Dilation and Nasolacrimal Duct Intubation for Treatment of Nasolacrimal Duct Obstruction After Failed Probing

Pediatric Eye Disease Investigator Group*

**Objective:** To compare the outcomes of balloon catheter dilation and nasolacrimal intubation as treatment for congenital nasolacrimal duct obstruction after failed probing in children younger than 4 years.

**Methods:** We conducted a prospective, nonrandomized, multicenter study that enrolled 159 children aged 6 months to younger than 48 months who had a history of a single failed nasolacrimal duct probing and at least 1 of the following clinical signs of nasolacrimal duct obstruction: epiphora, mucous discharge, or increased tear lake. One hundred ninety-nine eyes underwent either balloon catheter nasolacrimal duct dilation or nasolacrimal duct intubation. Treatment success was defined as absence of epiphora, mucous discharge, or increased tear lake at the outcome visit 6 months after surgery.

**Results:** Treatment success was reported in 65 of 84 eyes (77%; 95% confidence interval, 65%-85%) in the balloon catheter dilation group compared with 72 of 88 eyes (84% after adjustment for intereye correlation; 74%-91%) in the nasolacrimal intubation group (risk ratio for success for intubation vs balloon dilation, 1.08; 0.95-1.22).

**Conclusion:** Both balloon catheter dilation and nasolacrimal duct intubation alleviate the clinical signs of persistent nasolacrimal duct obstruction in a similar percentage of patients.


**CONGENITAL NASOLACRIMAL DUCT OBSTRUCTION (NLDO)** is a common condition of infancy and early childhood. Most cases resolve spontaneously or after lacrimal sac massage. In children in whom blockage does not resolve spontaneously, probing of the nasolacrimal duct (NLD) is generally a successful surgical treatment. We found in a prospective observational study of 955 eyes treated with probing as an initial procedure in children aged 6 to 36 months that 78% of eyes were successfully treated. In patients in whom initial probing is unsuccessful, a second procedure is usually recommended.

Surgical procedures to treat persistent NLDO after failed probing include repeat probing, NLD intubation, and balloon catheter dilation. There is no preferred practice for the management of NLDO. Several case series have reviewed the outcomes of repeat probing to treat persistent NLDO, with success ranging from 25% to 69%. These varied results for a second probing led to the introduction of NLD intubation more than 50 years ago. More recently, balloon catheter dilation has been used for treatment of persistent NLDO. Goldstein et al suggested that balloon catheter dilation or monolacunar intubation are equally effective choices for a second surgery after failed probing based on their results in a nonrandomized retrospective case series.

We initially designed and launched a prospective randomized study to compare balloon catheter dilation with NLD intubation for treatment of persistent NLDO after failed probing. However, we were unable to recruit a sufficient number of patients because parents were reluctant to accept randomization and most investigators preferred to perform their usual procedure. Thus, we modified our protocol to conduct a prospective nonrandomized study with the choice of treatment determined by the clinician.

**METHODS**

This study, supported by a cooperative agreement with the National Eye Institute of the National Institutes of Health, was conducted by the Pediatric Eye Disease Investigator Group.
at 39 clinical sites. Investigators were predominantly pediatric ophthalmologists, although a few oculoplastic subspecialists also participated. The protocol and informed consent forms complied with the Health Insurance Portability and Accountability Act of 1996 were approved by the respective institutional review boards. The parent or guardian of each study patient gave written informed consent. The complete protocol is available at http://public.pedig.jaeb.org.

The study included children aged 6 months to younger than 48 months in whom balloon catheter dilation or NLD intubation was planned as a second surgical procedure for the treatment of NLDO within 30 days. Major eligibility criteria included onset of NLDO symptoms before 6 months of age; presence of at least 1 sign of NLDO (epiphora, mucopurulent discharge, or increased tear lake in the absence of upper respiratory infection or ocular surface irritation); previous failed single primary probing procedure to treat NLDO; no history of discharge, or increased tear lake in the absence of upper respiratory infection or ocular surface irritation); previous failed single primary probing procedure to treat NLDO; no history of nasal discharge, balloon catheter dilation, or NLD intubation; no history of NLD intubation, balloon catheter dilation, more than 1 probing, or dacrocystorhinostomy; and absence of Down syndrome. In addition, children with craniosynostosis, Goldenhar syndrome, clefting syndromes, hemifacial microsomia, or any midline facial anomaly were excluded.

ENROLLMENT AND SURGERY

At the enrollment visit, each of 3 clinical signs of NLDO (epiphora, mucous discharge, and increased tear lake) was directly observed by the surgeon and reported as either present or absent. A dye disappearance test performed without use of topical anesthesia was performed by a certified examiner according to a protocol described previously.11

All procedures were performed using general anesthesia in a surgical facility, that is, a hospital outpatient surgical department or ambulatory surgical center. Surgery was to occur within 30 days of enrollment. With the exception of the 8 patients who were enrolled and randomized before our study design was changed (balloon dilation, n=3; intubation, n=2; and balloon dilation in 1 eye and intubation in the other eye, n=3), the choice of NLD balloon catheter dilation or intubation was at the investigator's discretion.

Balloon catheter NLD dilation consisted of dilation of at least 1 punctum, passage of a probe, and passage of a semiflexible wire probe with an inflatable balloon on the tip (LacriCATH; Quest Medical, Inc, Allen, Texas) into the nasal cavity. The size of the probe used before passage of the balloon catheter was at the investigator's discretion. A 2-mm balloon catheter was used in children younger than 30 months, and a 3-mm balloon catheter was used in children 30 months to younger than 48 months of age, as recommended by the manufacturer. The inflation protocol specified by the manufacturer in its product labeling was followed (http://www.lacricath.com/procedure/). In brief, the balloon is inflated for 90 seconds, deflated, inflated for 60 seconds, and withdrawn 5 mm; then the inflation-deflation protocol is repeated.

 Nasolacrimal duct intubation consisted of dilation of at least 1 punctum and the placement of a monocanalicular or bicanalicular tube. Probing before passage of the tube, the type and brand of tube used, and the method of securing the tube (if secured) were at investigator discretion. The protocol stipulated that the tube should remain in place for 2 to 5 months and be removed by the surgeon while the child was awake or under conscious sedation. Patency was confirmed by touching the probe or balloon catheter in the nasal cavity with a second probe, visualization of the probe beneath the inferior turbinate, retrieval of the intubation tubing from the nose, or recovery of fluorescein dye–colored saline solution from the nose after irrigation through the nasolacral system. Infracture of the inferior turbinate bone was optional. The nature of the obstruction was classified by the clinician as simple (defined as a single obstruction that was easily passed during the probing procedure) and complex (defined as a blockage or multiple blockages anywhere along the tear drainage pathway that causes more difficulty than usual with probe passage such as blockage at the valve of Hasner, tight inferior turbinate blockage, flow, canalicul problems, or multiple obstructions in the NLD). Prescription of perioperative and postoperative antibiotic and corticosteroid agents was at investigator discretion.

FOLLOW-UP EXAMINATIONS

The primary outcome visit was at 6 months (±1 month) after surgery. There was an interim visit 1 month (±1 week) after balloon catheter dilation and 1 month (±1 week) after tube removal in children who underwent NLD intubation. At both follow-up visits, a trained and certified examiner other than the operating surgeon directly observed the presence or absence of each of 3 clinical signs of NLDO (epiphora, mucous discharge, and increased tear lake), and a dye disappearance test was also performed. If symptoms of an upper respiratory tract infection and any of the clinical signs of NLDO were present at the primary outcome visit, the child returned after 1 to 3 weeks and the outcome examination was repeated.

STATISTICAL ANALYSIS

The primary outcome was treatment success or failure 6 months after surgery based on assessment of clinical signs. Success was defined as the absence of all 3 clinical signs (epiphora, mucous discharge, and increased tear lake). Eyes that underwent another operation before a given visit were considered treatment failures for that visit. The primary analysis was a comparison of the percentage of eyes with treatment success between treatment groups. Risk ratios (RRs) and 95% confidence intervals (CIs) were calculated using Poisson regression.13 For each treatment group, point estimates for the percentage of eyes with treatment success at 6 months and 95% CIs were calculated using logistic regression. Both types of regression models used generalized estimating equations to adjust for correlation between eyes of patients in whom both eyes were operated on.20 To be included in the primary analysis, the primary outcome examination could be performed no earlier than 3 months after surgery. Confounding was assessed by evaluating factors distributed differentially between treatment groups in separate regression models with the factor and treatment group as covariates and in an overall adjusted model that included all potential confounders. Results were also obtained from an alternative analysis (last observation carried forward) using data from the interim visit to replace missing primary outcome data. Additional analyses evaluated treatment success based on dye disappearance test results at the primary outcome visit.

For the intubation group, we used Poisson regression to calculate RRs and 90% CIs to evaluate whether treatment success was related to the duration the tubes remained in place or to tube type (monocanalicular vs bicanalicular). For the analysis of tube type, we excluded a single patient who had a different tube type in each eye because this patient also had discordant outcomes, which presented difficulties with the adjustment for correlation between eyes in the same subject. Patients who underwent bilateral surgery with balloon catheter dilation in 1 eye and NLD intubation in the other eye were included in both patient cohorts; for the eye-level analyses, only the eye that underwent the specified procedure was included in the analysis. Analyses were conducted using commercially available software (SAS version 9.1; SAS Institute, Inc, Cary, North Carolina).
RESULTS

Between March 2005 and July 2007, 95 eyes in 73 subjects underwent balloon catheter dilation and 104 eyes in 90 subjects underwent NLD intubation because of NLDO that was not cured with initial probing. Four subjects in whom both eyes were operated on underwent each procedure in 1 eye. Thirty of 50 investigators performing surgery for the study (60%) performed NLD intubation exclusively, 14 (28%) performed balloon catheter dilation exclusively, and 6 (12%) performed both procedures.

BASELINE CHARACTERISTICS

The 159 patients ranged in age from 7.3 to 47.2 months (mean [SD] age, 21.0 [8.9] months). Eighty-one patients (51%) were girls, 125 (79%) were white, and 42 (26%) had bilateral disease. Six patients with bilateral disease underwent a different procedure in each eye: intubation and balloon dilation in 4 (3 of whom were randomized to this assignment) and intubation and simple probing in 2 (the eye that received simple probing was excluded from the analysis). Baseline characteristics are given by treatment group in the Table.

Table. Baseline Characteristics of Study Cohorta

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%) Surgery Type</th>
<th>Balloon Catheter Dilation</th>
<th>Nasolacrimal Intubation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Patient Characteristics</td>
<td></td>
</tr>
<tr>
<td>No. of patients</td>
<td>73</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>Female sex</td>
<td>39 (53)</td>
<td>45 (50)</td>
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<tr>
<td>Race/ethnicity</td>
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<tr>
<td>White</td>
<td>57 (78)</td>
<td>72 (80)</td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>4 (5)</td>
<td>6 (7)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>7 (10)</td>
<td>4 (4)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5 (7)</td>
<td>8 (9)</td>
<td></td>
</tr>
<tr>
<td>Age at onset of NLDO, mo</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Birth to &lt;1</td>
<td>58 (79)</td>
<td>69 (77)</td>
<td></td>
</tr>
<tr>
<td>1 to &lt;6</td>
<td>15 (21)</td>
<td>21 (23)</td>
<td></td>
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<tr>
<td>Age at primary probing, mo</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Mean (SD); range</td>
<td>13.2 (4.5); 4-25</td>
<td>14.1 (7.7); 1-44</td>
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<tr>
<td>6 to &lt;12</td>
<td>30 (41)</td>
<td>39 (43)</td>
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<td>12 to &lt;24</td>
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<td>0</td>
<td>3 (3)</td>
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<tr>
<td>Unknown</td>
<td>0</td>
<td>1 (1)</td>
<td></td>
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<tr>
<td>Age at second procedure, mo</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Mean (SD); range</td>
<td>20.7 (7.8); 7-340.8</td>
<td>21.2 (9.8); 7-47.2</td>
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</tr>
<tr>
<td>6 to &lt;12</td>
<td>5 (7)</td>
<td>13 (14)</td>
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<tr>
<td>12 to &lt;24</td>
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<td>15 (21)</td>
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<tr>
<td>36 to &lt;48</td>
<td>5 (7)</td>
<td>10 (11)</td>
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<tr>
<td>Laterality</td>
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<tr>
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<td>70 (78)</td>
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<tr>
<td>Bilateralb</td>
<td>26 (36)</td>
<td>20 (22)</td>
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<tr>
<td>Site of surgery</td>
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<tr>
<td>Ambulatory surgery center</td>
<td>50 (68)</td>
<td>31 (34)</td>
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<tr>
<td>Hospital</td>
<td>23 (32)</td>
<td>59 (66)</td>
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</tr>
</tbody>
</table>

Abbreviations: Ellipses, data not available; NLDO, nasolacrimal duct obstruction.

(continued)

COMPLICATIONS

Complications were reported for a single patient in each treatment group. In the balloon catheter dilation group, 1 child with vomiting and possible aspiration during anesthesia induction was admitted for overnight observation and was released the next day without sequelae. In the NLD intubation group, 1 child had a torn canaliculus that was surgically repaired.

VISIT COMPLETION

The primary outcome visit was completed by 59 of 73 patients (81%) in the balloon catheter dilation group and 75 of 90 patients (83%) in the NLD intubation group. Primary outcome visits were completed at a mean (SD) of 6.2 (1.1) months from surgery (range, 3.0-9.5 months) in the balloon catheter dilation group and 6.5 (1.1) months (range, 5.0-9.4 months) in the intubation group. Of completed visits, the visit occurred within 6 months (±1
month) in 45 of 59 patients (76%) and 56 of 75 patients (75%) in the balloon catheter dilation and intubation groups, respectively. For patients who underwent intubation, the primary outcome visits were completed 3.7 (2.0) months after tube removal (range, 0.6-7.5 months).

**STUDY OUTCOMES**

Treatment success, defined as the absence of clinical signs of NLDO and without another operation before the 6-month visit, was reported in 65 of 84 eyes with out-

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Nasolacrimal Duct Obstruction Treatment Study Steering Committee

PEDIG Coordinating Center, Tampa

National Eye Institute, Bethesda, Maryland
Donald F. Everett.

PEDIG Executive Committee

PEDIG Data and Safety Monitoring Committee

We conducted a prospective nonrandomized study of the surgical management of persistent NLDO after probing in children aged 6 months to younger than 48 months. Balloon catheter NLD dilation and NLD intubation were successful in a similar percentage of patients with persistent NLDO—77% and 84%, respectively.

Several noncomparative series have been published for each of these procedures to treat persistent NLDO after a single probing. Balloon catheter dilation after failed probing has been reported in several retrospective case series to have success rates ranging from 53% to 95%. Nasolacrimal duct intubation after failed probing has been reported in several retrospective case series, mostly of bicanalicular intubation, to have success rates ranging from 66% to 100%. For monocanalicular intubation with the Monoka tube (FCI Ophthalmics, Issy-Les-Molineaux, France) as a secondary treatment, the only available article reported a 67% success rate. We are aware of 1 article in the English-

ASSOCIATION OF DURATION OF TUBE RETENTION AND TUBE TYPE WITH TREATMENT SUCCESS

Nasolacrimal duct tubes were removed at a mean (SD) of 2.8 (1.7) months after surgery (range, 0.0-7.0 months). These tubes were removed less than 2 months after surgery in 28 of 90 patients (31%), between 2 and 5 months in 52 patients (58%), at 5 months or later in 8 patients (9%), and after an unknown duration in 2 patients (2%). The percentage of eyes with treatment success was 90% in the 59 eyes in which tubes were left in for at least 2 months compared with 70% in the 29 eyes in which tubes were left in for less than 2 months (RR, 1.27; 99% CI, 0.91-1.79). The percentage of eyes with treatment success was similar in the 40 eyes with monocanalicular intubation and the 48 eyes with bicanalicular intubation (79% vs 87%). The RR for success with bicanalicular compared with monocanalicular tubes is 1.07 (99% CI, 0.82-1.39).

COMMENT

We conducted a prospective nonrandomized study of the surgical management of persistent NLDO after probing in children aged 6 months to younger than 48 months. Balloon catheter NLD dilation and NLD intubation were successful in a similar percentage of patients with persistent NLDO—77% and 84%, respectively.
language literature\textsuperscript{18} of a retrospective nonrandomized comparison of balloon catheter dilation and monocanalicular intubation after failed probing that found 86% (36 of 42) success with balloon catheter dilation and 91% (32 of 35) success with intubation. Among intubation procedures, we examined whether tube type and duration of tube retention were related to the likelihood of success. We did not observe a difference between success rates for bicanalicular and monocanalicular intubation, a finding similar to our report on initial intubation to treat NLDO.\textsuperscript{38} We found that tubes left in place for 2 months or longer (7 months maximum) seemed to be associated with a higher success rate than tubes left in for less than 2 months (90% vs 70%); however, this finding was not statistically significant, possibly because our sample size was small. Most reports on the optimum duration of tube retention are from retrospective studies of intubation performed most often as a second or third procedure. Some authors have found that longer duration of tube retention improves the outcome,\textsuperscript{37,39} whereas others have found no effect of duration on tube retention.\textsuperscript{38,40} Our study has a number of strengths. We used prospective data collection with investigator certification and outcome assessment at a uniform interval. There were a large number of participating investigators, which may improve generalizability. However, there are several limitations as well. The most important is that our study was not randomized and, thus, there could have been selection bias insofar as choice of procedure (balloon catheter dilation or NLD intubation). However, inasmuch as most investigators performed only 1 type of procedure, selection bias would be partially mitigated. This relationship between investigator and procedure type prevents any assessment for potential investigator effects. Another limitation is our small sample size. We were able to recruit only about one-fourth of the sample size on which the randomized clinical trial had been based (320 patients per treatment group). As a result, our power for the treatment group comparison is substantially reduced. An additional limitation is that loss to follow-up was higher than optimal at 15%.

Both NLD intubation and balloon catheter dilation are performed in a surgical facility with the patient under general anesthesia. The tubes currently cost the facility between $60 and $100, whereas the balloon catheter costs the facility $306 for unilateral and $555 for bilateral dilation (LacrICATH catalog price list as of August 2007). Nasolacrimal duct tubes may be removed in sedated patients in the office or in a facility. The latter setting would add substantially to the cost of the procedure. However, in our study, only 4% were removed in a facility, essentially negating this cost in most patients.

In conclusion, balloon catheter dilation and NLD intubation were successful in a similar percentage of patients with persistent NLDO (77% and 84%, respectively). Both procedures should be considered suitable treatment for persistent NLDO after a single failed probing.


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**Archives Web Quiz Winner**

Congratulations to the winner of our December quiz, Rominder S. Momi, MD, PGY-II Resident, Section of Ophthalmology and Visual Science, Department of Surgery, University of Chicago, Chicago, Illinois. The correct answer to our December challenge was **serous macular detachment due to diabetic papillopathy**. For a complete discussion of this case, see the Small Case Series section in the January *Archives* (Nakamura M, Kanamori A, Nagai-Kusuhara A, Kusuhara S, Yamada Y, Negi A. Serous macular detachment due to diabetic papillopathy detected using optical coherence tomography. *Arch Ophthalmol*. 2009;127[1]:105-107).

Be sure to visit the *Archives of Ophthalmology* Web site (http://www.archophthalmol.com) and try your hand at our Clinical Challenge Interactive Quiz. We invite visitors to make a diagnosis based on selected information from a case report or other feature scheduled to be published in the following month’s print edition of the Archives. The first visitor to e-mail our Web editors with the correct answer will be recognized in the print journal and on our Web site and will also be able to choose one of the following books published by AMA Press: *Clinical Eye Atlas, Clinical Retina*, or *Users’ Guides to the Medical Literature*.