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Primary Treatment of Nasolacrimal Duct Obstruction with Nasolacrimal Duct Intubation in Children Less than Four Years Old

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Abstract

Purpose—To report the outcome of nasolacrimal duct intubation as the primary treatment of congenital nasolacrimal duct obstruction (NLDO) in children less than 4 years of age.

Methods—182 eyes of 139 children receiving intubation with planned tube retention for 2 to 5 months were enrolled in a prospective, non-randomized observational multicenter study (19 sites). Children were aged 6 to <45 months at the time of surgery, with no prior nasolacrimal surgical procedure, and had at least one of the following clinical signs of NLDO: epiphora, mucous discharge and/or increased tear lake.

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Results—Treatment success was defined as absence of epiphora, mucous discharge and increased tear lake at the outcome visit one month after tube removal. The surgical outcome was assessed in 150 eyes (82% of cohort). The proportion of eyes treated successfully was 91% (95% confidence interval = 86% to 95%). The outcome dye disappearance test was normal in 125 (86%) eyes, indeterminate in 13 (9%), and abnormal in 7 (5%) of the 145 eyes tested. Monocanalicular tubes were used in 74% of cases. The tube was removed prior to the planned minimum retention time of months in 61 eyes (41%). For 23 eyes the early removal was due to inadvertent displacement by the patient.

Conclusion—In children 6 to <45 months of age, nasolacrimal duct intubation in a non-randomized and non-comparative trial was a successful primary treatment of NLDO in about 90% of cases not lost to follow up.

Introduction

Congenital nasolacrimal duct obstruction (NLDO) is a common ocular condition in young children. Some cases will resolve spontaneously or with massage early in life.[1–5] For those children whose obstruction does not spontaneously resolve, studies of primary surgical management have found probing to be successful in 70% to 97% of cases[3, 6–9] with many reports around 90%.[3, 6–8] In spite of success with probing, some clinicians have felt that temporary intubation of the nasolacrimal drainage system should be performed under the belief that higher success rates would result, especially in older children or in those having the procedure under general anesthesia.

Nasolacrimal intubation involves probing the nasolacrimal duct followed by placement of a silicone tube stent in one or both canaliculi. This procedure has been popular since its introduction in the late 1960s for the treatment of persistent NLDO after failed probing.[3, 10–22] Intubation has also been used by clinicians for primary treatment of NLDO in older children or when the duct feels tight during probing.[11, 15, 23–25] Increasing experience with the technique and the introduction of monocanalicular intubation have led to the use of intubation as a primary procedure for NLDO in younger children.[16, 26, 27] Success rates from 79% to 96% have been reported for intubation as a primary procedure in retrospective case series.[24, 26–28]

We conducted a prospective non-randomized study of primary surgical treatment of congenital NLDO in children from 6 to 48 months of age in whom a surgical procedure was planned. The timing of the procedure and choice of surgery were determined by the clinician caring for the child. Herein, we report the outcomes for children who underwent nasolacrimal intubation as primary treatment of NLDO with planned tube retention of 2 to 5 months. Outcomes for patients receiving nasolacrimal duct probing or balloon catheter dilation are reported separately.[7]

Methods

This study, supported through a cooperative agreement with the National Eye Institute of the National Institutes of Health, was conducted by the Pediatric Eye Disease Investigator Group at 19 clinical sites. The protocol and Health Insurance Portability and Accountability Act (HIPAA) compliant informed consent forms were approved by the respective institutional review boards. The parent or guardian of each study patient gave written informed consent. The protocol, available at http://public.pedig.jaeb.org, is summarized below.

The eligibility criteria included children aged 6 to <48 months with NLDO who underwent nasolacrimal intubation in one or both eyes. Other major eligibility criteria included onset of NLDO symptoms and/or signs prior to 6 months chronological age, presence of epiphora, increased tear film, and/or mucopurulent discharge in the absence of an upper respiratory

infection or ocular surface irritation, no prior nasolacrimal duct surgery (including probing, nasolacrimal intubation, balloon catheter dilation, or dacryocystorhinostomy), and Down syndrome not present. Surgery was to be performed within 30 days of enrollment.

Enrollment and Surgery

At the enrollment visit, each of three clinical signs of NLDO (epiphora, increased tear film, and mucous discharge) was assessed by the surgeon as either present or absent. A Dye Disappearance Test without topical anesthesia was performed and the results classified after 5 minutes as normal, abnormal, or indeterminate, based on a simplification of a scheme proposed by MacEwen and colleagues.[29] Standard drawings of the Dye Disappearance Test findings were used for comparison. In brief, no retained fluorescein in the tear film or only a very thin meniscus of fluorescein-tinted tear were considered normal, while a thick meniscus of fluorescein-tinted tear was considered abnormal. An indeterminate result was minimally increased tear film or retained fluorescein in the tear. Also at this visit, the patient's parent completed a written questionnaire on symptoms and health-related quality of life[30] described later.

Nasolacrimal duct intubation consisted of dilation of at least one punctum and the placement of a monocanalicular or bicanalicular tube. Probing prior to passage of the tube, the type and brand of tube used, the performance of inferior turbinate infracture, and the method of securing the tube (if secured) were at investigator discretion. We did not record the punctum used for monocanalicular tubes.

The surgeon was asked to characterize the obstruction as simple or complex based on feel during passage of the probe, with simple defined as a single obstruction which was easily passed. The prescription of peri-operative and post-operative antibiotics and steroids were at investigator discretion. All procedures were performed under general anesthesia.

Follow Up Examinations

The protocol stipulated that the tube should remain in place for 2 to 5 months and should then be removed by the surgeon while the child was awake or under conscious sedation. The study outcome examination was timed for 1 month (±1 week) from the date of tube removal. The timing of tube removal was recorded for all patients using a best estimate of the time when the tube removal was not performed by the surgeon.

At the outcome examination, the child's parent completed the questionnaire (described later) before the child was examined. Once the questionnaire was completed, a certified and trained examiner who was not the surgeon evaluated each study eye for the presence or absence of the three clinical signs of NLDO (epiphora, increased tear film, and mucous discharge). Based on this examination, treatment success for the analysis was the absence of all three signs. Patients who had one or more signs at the outcome examination or had additional nasolacrimal duct surgery prior to the outcome examination were classified as treatment failures. A Dye Disappearance Test was also performed. Information on occurrence of punctal damage, punctal slitting, nosebleeds, dacryocystitis, pyogenic granuloma formation, corneal abrasion, or other postoperative complications was recorded.

Parental Questionnaire

A quality of life questionnaire (available at http://public.pedig.jaeb.org) was completed at baseline and at the outcome visit.[30] The questionnaire consists of 23 eye-specific symptom-related items that are averaged to create a symptom score for each affected eye, and 8 patient-level items that are averaged to create a measure of the impact of NLDO on the parent's and

child's health-related quality of life (HRQOL). Scores for both the symptom and HRQOL scales range from 0 to 4 with a higher score indicating worse symptoms or worse HRQOL.

Statistical Analysis

The proportion of eyes with treatment success based on clinical signs assessment, both overall and within subgroups of interest, and a 95% confidence interval were computed using logistic regression with generalized estimating equations to adjust for correlation between eyes of patients affected bilaterally.[31] Baseline characteristics of patients completing follow-up were compared to those not completing follow-up and differences between these 2 groups of 15% or more are reported in the results.

Results

Baseline Characteristics

Nasolacrimal duct intubation was performed as primary treatment for NLDO in 182 eyes of 139 patients. Patient age at surgery ranged from 6 to 45 months with a mean of 19 months. Most patients (68%) had onset of symptoms of NLDO within the first month of life. Nearly all eyes (95%) had increased tear film as a sign of NLDO; epiphora (85%) and mucous discharge (64%) were less frequent. Additional baseline characteristics are reported in the Table.

A monocanalicular tube was placed in 135 (74%) of the procedures and a bicanalicular tube in 47 (26%). Tubes were not secured in the nose for 106 (58%) of cases and secured in 76 (42%). Of the tubes secured, 36 (47%) were monocanalicular and 40 (53%) were bicanalicular. The proportion of tubes secured with a nasal mucosal suture versus simple tying in the nose was not recorded. At the time of surgery, the nasolacrimal duct obstruction was characterized as simple in 137 (75%) of eyes and complex in 45 (25%) of eyes. Inferior turbinate infracture was performed in 33 (18%) of eyes.

Complications

Complications reported to occur during surgery were one torn inferior turbinate and one nosebleed which required packing. The patient with the nosebleed had occasional nosebleeds post-operatively. The other post-surgical complication reported was a corneal abrasion due to the tube.

Tube Removal

Tubes were removed prior to the planned minimum retention time of 2 months in 61 eyes (41%). Of these, early tube removal was done by the patient in 13 eyes (21%), by the investigator or other clinician for displaced tubes in 10 eyes (16%), by the investigator for properly positioned tubes in 17 eyes (28%), and by someone else, usually a parent, in 21 eyes (34%).

For the 150 eyes that have follow-up, tube removal was performed with the child awake in 146 (97%). The sedation status for 3 eyes of 3 children is unknown (tube removed by another physician). In 1 eye the tube was removed during another procedure under general anesthesia.

Visit Completion

The one-month post tube removal outcome visit was completed for 112 (81%) of the 139 patients (82% of 182 eyes enrolled). The outcome examination occurred within the protocol window (4 to 6 weeks from tube removal) for 84 (57%) eyes, was prior to the window for 9 (6%) eyes, and was after the window for 54 (37%) eyes. For those children out of window, 36

of 54 exams were performed within one month, with the latest exam occurring 9 months after tube removal. The clinical signs outcome was assessed by a certified examiner other than the surgeon in 96% of cases.

Thirty-two eyes (18%) were lost to follow up before the 6 month outcome exam. These eyes differed from those completing follow-up with respect to age at surgery (34% less than 1 year old versus 13% for completers), laterality (28% bilateral versus 53% for completers), and whether tubes were secured in the nose (72% secured versus 35% for completers). They did not differ with respect to other baseline and surgery characteristics.

Primary Outcome

Treatment was classified as successful when all three clinical signs of NLDO (epiphora, mucous discharge, and increased tear lake) were absent, and no additional surgery was required prior to the outcome visit. These conditions were met at the outcome visit in 137 of the 150 eyes (91%; 95% confidence interval: 86 to 95%). Of the 12 eyes judged to be treatment failures due to presence of one or more clinical signs of NLDO, 7 had increased tear lake as the only sign, 2 eyes had both increased tear lake and epiphora, 1 eye had both increased tear lake and mucous discharge, and 2 eyes had all three signs. One other eye underwent additional surgery prior to the outcome exam and was considered a treatment failure.

Treatment failed in 6 (10%, 95% CI: 5 to 20%) of the 61 eyes in which the tube was removed prior to the planned minimum retention time of 2 months including 5 of the 32 eyes (16%, 95% CI: 7 to 32%) in which the tube was removed prior to one month, and failed in 6 (7%, 95% CI: 3 to 14%) of the 86 eyes in which the tube was removed after 2 or more months. Intubation failed in 1 of 19 eyes of patients aged <12 months (5%, 95% CI: <1 to 30%), 7 (8%, 95% CI: 4 to 14%) of 99 eyes of patients aged 12 to <24 months, and in 5 (16%, 95% CI: 7 to 33%) of 32 eyes of patients aged 24 to 45 months. Bicanalicular intubation failed in 3 of 39 eyes (8%, 95% CI: 3 to 21%), while monocanalicular intubation failed in 10 of 111 eyes (9%, 95% CI: 5 to 16%). Intubation failed in 5 of 71 eyes (7%, 95% CI: 3 to 16%) in patients with unilateral NLDO and 8 of 79 eyes (10%, 95% CI: 5 to 18%) in patients with bilateral NLDO; in 9 of 112 eyes (8%, 95% CI: 4 to 15%) with simple obstruction, and 4 of 38 eyes (11%, 95% CI: 4 to 26%) with complex obstruction; and in 2 of 30 eyes (7%, 95% CI: 2 to 24%) with inferior turbinate infracture performed and 11 of 120 eyes (9%, 95% CI: 5 to 16%) without inferior turbinate infracture.

Dye Disappearance Test

The Dye Disappearance Test performed during the outcome exam was normal in 125 (86%) eyes, indeterminate in 13 (9%), and abnormal in 7 (5%) of the 145 eyes in which it was performed. Of the 128 eyes with an abnormal Dye Disappearance Test at baseline that also had a Dye Disappearance Test at outcome, at outcome it was normal in 110 (86%), indeterminate in 11 (9%), and abnormal in 7 (5%).

Among the 134 eyes meeting clinical criteria for success that had a follow-up Dye Disappearance Test, it was normal in 92%, indeterminate in 7%, and abnormal in 1% whereas among the 11 eyes not meeting success criteria that had a follow-up Dye Disappearance Test, the percentages were 18%, 36%, and 45% respectively.

Questionnaire Data

At baseline, the mean symptom score based on the questionnaire was 2.8 points (range: 0.7 to 4.0) and the mean HRQOL score was 2.2 points (range: 0.3 to 3.8). The mean symptom score improved by 2.3 points (range: −0.1 to 3.8 points) among treatment successes and 1.7 points (range: −0.1 to 3.6 points) among treatment failures, and the mean HRQOL score improved

by 1.8 points (range −0.5 to 3.5) among treatment successes and by 0.0 points (range −1.4 to 1.3) among treatment failures.

Discussion

We have conducted a prospective evaluation of primary surgical treatment of congenital NLDO in children 6 to 45 months of age. In this non-randomized study the investigator choose the procedure that they would perform, simple probing, nasolacrimal intubation, or balloon catheter dilation. We found the success rate of nasolacrimal intubation to be 91% (95% confidence interval: 86 to 95%). A similar success rate was found when normal Dye Disappearance Test was used as the outcome measure. About three quarters of patients were treated with monocanalicular intubation and the remainder with bicanalicular shunts with no difference in success rates.

Our success rate is less than that recently reported by Engel and colleagues for monocanalicular intubation as primary treatment for congenital NLDO.[27] They reported a retrospective case series of 635 patients (6 to 104 months – median age = 15.2 months) in whom they found an overall success rate of 96%. Two smaller retrospective series have been published which included a large proportion of primary procedures for congenital NLDO. In one study 50 eyes were treated with monocanalicular intubation (36 as primary treatment) with an overall success rate of 79%,[26] while in the other study 50 eyes were treated with bicanalicular intubation (26 eyes as primary treatment) with an overall success rate of 86%.[32] Some previous reports have described lower success rates with increased age at the time of treatment[20, 27, 33] while others have not found an age effect.[24, 34] The number of treatment failures in our study was too small for a meaningful statistical assessment of an age effect.

Premature removal of the tube was common in our study, and was more often due to intentional removal by the investigator or parent rather than dislocation by the patient. We had too few failures with early removal to determine if it was associated with a lower success rate, but there was a suggestion that tubes removed in the first 4 weeks had a slightly worse outcome. This issue has been the subject of earlier reports. Engel and colleagues found no impact on the chance for success from premature loss of the tube in their large series of primary intubations.[27] Most reports on the optimum duration of tube retention have come from retrospective studies of intubation performed as a second or third procedure. Migliori and Putterman found that retention for only 6 weeks was sufficient for a satisfactory outcome.[16] Lim and colleagues found that there was a significant decrease in success with retention of the tubes beyond twelve months.[24] Conversely, other authors have found that retention for 6 months or more is preferable for an improved chance of success.[26, 33]

Complications of nasolacrimal duct intubation in this study were uncommon, with one nosebleed, one torn inferior turbinate, and one corneal abrasion. However, other investigators have reported complications including canalicular slitting, migration of the tubes or footplate, pyogenic granuloma formation, cellulitus, corneal/conjunctival abrasion, and corneal ulcer.[26, 27, 35, 36]

Nasolacrimal intubation is performed in a surgical facility under general anesthesia and requires a single-use intubation set. The tubes currently cost the facility between US$60 and US$100. Balloon catheter dilation is also performed in a facility where the device costs the facility $306 for unilateral and $555 for bilateral dilations (LacriCath Catalog Price List, 8/2007). For children older than one year, a probing is also typically performed in a surgical facility with similar costs other than the intubation set. However, in younger children, probing is sometimes performed in the office with the potential for increased savings. Nasolacrimal tubes may be removed in the office or in a facility with sedation. In the latter instance, that

would add substantially to the cost of the procedure. Perhaps surprisingly, nearly every tube in this study was removed without sedation. This is likely in part due to the high proportion of monocanalicular tubes that were used.

There are a number of strengths to our study. We utilized prospective data collection with investigator certification and outcome assessment performed by a certified examiner other than the operating surgeon at a uniform time interval following tube removal. We recruited a large number of patients and utilized a large number of investigators which may increase the generalizability of our findings.

However, there are several limitations to our observational study. The most important is that our study was not randomized and thus there could have been selection bias with regard to patient age, timing of surgery, and investigator choice of procedure (probing, balloon catheter dilation, bicanalicular nasolacrimal intubation, monocanalicular nasolacrimal intubation). Therefore, a comparison of the results of our study among intubation, probing and balloon catheter dilation as primary procedures for NLDO should not be made. A randomized clinical trial is needed to determine which of these procedures provides superior clinical outcomes. Second, the low proportion of failures precludes an adequately-powered analysis of the impact of baseline factors on outcome. Third, follow up was incomplete for 18% of cases. If these cases had a higher proportion of failures than those that completed follow up, the success rate determined in this study could be an overestimate. Conversely, if these cases had a lower proportion of failures, the success rate could be an underestimate. Fourth, we did not study a fixed time interval for retention of the tubes, but rather recommended an interval of 2 to 5 months. Thus we cannot fully address the optimum length of time that the tubes should remain in place for the greatest chance for success. Fifth, infracture of the inferior turbinate was performed in only a minority of patients, so we cannot assess the utility of this technique. Havins has suggested that infracture favorably affects the outcome of intubation.[37] Sixth, though both bicanalicular and monocanalicular intubation were used, our numbers by technique are too small to compare these techniques. In addition a comparison would be limited by investigator selection bias. Seventh, 17% of our patients were between 6 and 12 months of age and might have spontaneously improved, slightly increasing our estimate of success. Lastly, only primary procedures were included in the study and results do not reflect the utility of nasolacrimal intubation for previously treated cases of NLDO. We are currently performing that study and results will be available in the next few years.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Baseline patient demographic and clinical characteristics

Characteristic	**N = 139 patients**
Gender: female *N (%)*	68 (49%)
Race/ethnicity, *N (%)*	
White	101 (73%)
African-American	4 (3%)
Hispanic or Latino	28 (20%)
Other	5 (4%)
Unknown/not reported	1 (<1%)
Age at onset of NLDO, in months* *N (%)*	
0 to <1	94 (68%)
1 to <6	45 (32%)
Age at surgery, in months *N (%)*	
6 - <12	24 (17%)
12 - <18	58 (42%)
18 -<24	28 (20%)
24 - <36	18 (13%)
36 - <48	11 (8%)
Mean (range)	19 (6–45)
Previous treatment with topical antibiotics *N (%)*	
Yes	108 (78%)
No	26 (19%)
Not known	5 (4%)
Previous treatment with nasolacrimal duct massage *N (%)*	
Yes	100 (72%)
No	27 (19%)
Not known	12 (9%)
Laterality of NLDO treated with intubation (by patient) *N (%)*	
Unilateral†	96 (69%)
Bilateral	43 (31%)
Type of stent (by eye) *N (%)*	
Monocanalicular	135 (74%)
Bicanalicular	47 (26%)
Tubes secured in patient's nose (by eye) *N (%)*	
No	106 (58%)
Yes	76 (42%)
Monocanalicular	36 (47%)
Bicanalicular	40 (53%)
Clinical signs	**N = 182 eyes**
Increased tear lake present *N (%)*	172 (95%)
Epiphora present *N (%)*	155 (85%)
Mucous discharge present *N (%)*	116 (64%)
Number of clinical signs of NLDO *N (%)*	
1	18 (10%)
2	67 (37%)
3	97 (53%)
Dye Disappearance Test results at enrollment *N (%)*	
Normal**	4 (2%)
Indeterminate	17 (9%)
Abnormal	159 (88%)
Not done	2 (-)
Type of obstruction *N (%)*	
Simple	137 (75%)
Complex	45 (25%)
Inferior turbinate infracture performed *N (%)*	
Yes	33 (18%)
No	149 (82%)

NLDO nasolacrimal duct obstruction

[*] Bilateral patients were classified according to age at onset in first eye.

[**] Clinical signs in patients with normal Dye Disappearance Test results included 2 patients with epiphora as the only sign, 1 patient with increased tear lake as the only sign, and 1 patient with both epiphora and increased tear lake.

[†] Six patients with bilateral NLDO got intubation in one eye and another procedure in the other eye (4 balloon catheter dilation, and 2 probing). These are counted here as unilateral intubation cases.