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Primary Treatment of Nasolacrimal Duct Obstruction with Balloon Catheter Dilation in Children Less than Four Years Old

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Abstract

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

Methods—102 children (151 eyes) aged 12 to <48 months (mean 23 months) at the time of surgery, with no prior nasolacrimal surgical procedure, and with at least one of the following clinical signs of NLDO present, epiphora, mucous discharge and/or increased tear lake, were enrolled in a prospective, non-randomized observational multicenter study (20 sites). All children received balloon catheter dilation of the nasolacrimal system of the affected eye(s).

Results—Treatment success was defined as no epiphora, mucous discharge, or increased tear lake present at the outcome visit one month after surgery. The proportion of eyes treated successfully was 82% (95% confidence interval = 74% to 88%). The dye disappearance test at outcome was normal in 105 (73%), indeterminate in 15 (10%), and abnormal in 23 (16%) of the 143 eyes tested.

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Conclusions—In children 12 to <48 months of age, balloon catheter dilation as a primary treatment of NLDO was successful in about 80% of cases. Because we did not perform a randomized trial with a comparison group, we are unable to determine how this procedure's success rate compares with that of simple probing or nasolacrimal intubation in this age group.

Introduction

Congenital nasolacrimal duct obstruction (NLDO) is a common condition in young children. Most cases will resolve spontaneously or with massage early in life.[1–4] For those children whose obstruction does not spontaneously resolve, studies of primary surgical management during childhood have found probing to be highly successful with up to 97% cures.[5–9] In spite of success with probing for the initial surgical treatment of NLDO, balloon catheter dilation is an alternative introduced in the 1990s.[10–12] Some clinicians have recommended that balloon catheter dilation be performed to ensure higher success rates especially in older children.[13]

Balloon catheter dilation involves probing the nasolacrimal duct with a semi-flexible wire probe with an inflatable balloon on the tip. Success rates from 79% to 96% have been reported in several small retrospective case series.[10–13] One retrospective case series found similar cure rates for probing and balloon catheter dilation as a primary treatment in children older than 18 months.[11] An important disadvantage of balloon catheter dilation is the cost of the disposable balloon catheter compared with the reusable equipment for probing.[14]

We conducted a prospective, non-randomized multi-center 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 balloon catheter dilation as primary treatment of NLDO. Outcomes for patients receiving probing or nasolacrimal duct intubation are being reported separately.[9,15]

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 Invetigator Group (PEDIG) at 20 clinical sites. The protocol and Health Insurance Portability and Accountability Act 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 Pediatric Eye Disease Investigator Group. A Prospective Study of Primary Surgical Treatment of Nasolacrimal Duct Obstruction in Children Less Than Four Years Old. http://www.pedig.net (Accessed June 9, 2008), is summarized below.

The major eligibility criteria included age 6 to <48 months with NLDO and balloon catheter dilation of the nasolacrimal duct in one or both eyes as an initial procedure. Major criteria for an eye to be eligible 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 an ocular surface irritation; and no prior nasolacrimal duct surgery. 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 (DDT) without topical anesthesia was performed for each enrolled eye and the results classified after 5 minutes as normal, abnormal, or indeterminate, based on a simplification of a scheme proposed by MacEwen and colleagues.[16] Standard drawings of the

DDT 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 meniscus with or without retained fluorescein in the tear film. Also at this visit, the patient's parent completed a written questionnaire on symptoms and health-related quality of life (described later).

Balloon catheter nasolacrimal duct dilation consisted of punctal dilation of at least one punctum, passage of a probe, followed by passage of a semi-flexible wire probe with an inflatable balloon on the tip (Lacri-CATH – Quest Medical, Inc., An Atrion Company, One Allentown Parkway, Allen, Texas 75002-4211) into the nasal cavity. The size of the probe used prior to passage of the balloon catheter was at investigator discretion. The 2 mm diameter balloon was used for children less than 30 months of age, while the 3 mm diameter balloon was used for children 30 to <48 months of age as recommended by the manufacturer. The protocol stipulated that passage of the balloon catheter to the nasal cavity was confirmed with touching the catheter with a second probe in the nose or by direct visualization. The inflation protocol specified by the manufacturer was followed (available at Quest Medical, Inc. LacriCATH Procedures. http://www.lacricath.com/procedure/ (Accessed June 9, 2008)). In brief the balloon is inflated for 90 seconds, deflated, inflated for 60 seconds, withdrawn 5 mm, and the inflation/deflation protocol repeated. Inferior turbinate infracture was performed at investigator discretion. The surgeon was asked to characterize the obstruction as simple or complex, with simple defined as a single obstruction which was easily passed during the probing procedure. Complex was defined by protocol to be a blockage or multiple blockages anywhere along the tear drainage pathway that caused more difficulty than usual with probe passage, such as a blockage at the valve of Hasner, a tight inferior turbinate, canalicular problems, or multiple obstructions in the nasolacrimal duct. 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

There was a single study-specified follow-up visit 1 month (±1 week) from the date of surgery. At the follow-up visit, the child's parent completed the questionnaire before the child was examined. Once the questionnaire was completed, a certified, trained examiner other than the surgeon evaluated each affected 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. A DDT was also performed. Information on occurrence of punctal damage, nosebleeds, dacryocystitis, pyogenic granuloma formation, and corneal abrasion, or other post-operative complication was specifically recorded.

At the time of surgery, parents had been instructed to reschedule their child's follow-up visit if the child had symptoms of an upper respiratory infection (URI). If a child presented at the follow-up visit with URI symptoms, the examination was completed. If one or more clinical signs of NLDO were present, the child was rescheduled for 1–3 weeks later for an additional follow-up visit once the URI symptoms had resolved. In one patient (one eye), the additional visit was not completed, and the signs from the completed follow-up visit were used for analysis.

Parental Questionnaire

A quality of life questionnaire was completed at baseline and at the outcome visit[17] (available at Pediatric Eye Disease Investigator Group. PEDIG Forms/Questionnaires, http://public.pedig.jaeb.org (Accessed June 9, 2008)). 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 (age, laterality, type of obstruction, inferior turbinate infracture), and a 95% confidence interval were computed using logistic regression with generalized estimating equations to adjust for correlation between eyes of patients affected bilaterally.[18] Symptom and HRQOL scores were compared according to treatment success using the t-test.

Results

Baseline Characteristics

Balloon catheter dilation of the nasolacrimal duct was performed on 151 eyes in 102 patients. Patient age at surgery ranged from 12 to 47 months (mean of 23 months), with almost two-thirds of the children aged 12–<24 months. Although the study eligibility criteria allowed enrollment of patients as young as 6 months, no patients younger than 12 months were enrolled. Most patients (79%) had onset of NLDO symptoms within the first month of life. Nearly all eyes (93%) had increased tear film as a sign of NLDO at the baseline examination; 64% had epiphora and 50% had mucous discharge. Additional baseline characteristics are reported in the Table.

At the time of surgery, the NLDO was characterized as complex in 39% of eyes. Inferior turbinate infracture was performed in 16% of eyes. Patency was confirmed in 151 of 151 (100%) eyes, and the catheter tip was identified in the patient's nose in 99 of 151 eyes (66%). No complications of balloon catheter dilation were reported at the time of surgery or at the outcome examination.

The outcome visit was completed by 98 (96%) of the 102 patients (145 eyes out of 151 enrolled). Of the 145 eyes with an outcome examination, the examination occurred within the protocol window (1 month ± 1 week) for 112 (77%) eyes, was prior to the window for 4 eyes (3%), and was after the window (almost always within 8 weeks of surgery) for 29 eyes (20%). The clinical signs outcome assessment was made by a certified examiner other than the surgeon in 138 (95%) of the 145 eyes.

Primary Outcome

Treatment was classified as successful when all three clinical signs of NLDO (epiphora, mucous discharge, and increased tear lake) were absent. This condition was met at the one-month outcome visit in 120 of the 145 eyes with an outcome assessment (82%; 95% confidence interval: 74 – 88%). Of the 25 eyes (18%) judged to be treatment failures, 11 of 25 (44%) had increased tear film as the only remaining sign, 5 (20%) had both increased tear film and epiphora, 6 (24%) had all 3 clinical signs, 1 had mucous discharge only, 1 had epiphora only, and 1 had both mucous discharge and epiphora.

Balloon catheter dilation failed in 12 of 88 eyes (14%, 95% CI: 8 to 24%) of patients aged 12 to <24 months, and in 13 of 57 eyes (25%, 95% CI: 14 to 40%) of patients aged 24 to <48 months; in 14 of 92 eyes (16%, 95% CI: 9 to 25%) with simple obstruction and 11 of 53 eyes (21%, 95% CI: 12 to 35%) with complex obstruction; in 3 of 24 eyes (12%, 95% CI: 4 to 32%)

with inferior turbinate infracture and 22 of 121 eyes (19%, 95% CI: 12 to 28%) without infracture; in 12 of 49 eyes (24%, 95% CI: 14 to 38%) of patients with unilateral NLDO and 13 of 96 eyes (14%, 95% CI: 7 to 24%) of patients with bilateral NLDO; and in 14 of 93 eyes (16%, 95% CI: 9 to 25%) for which the catheter tip was identified in the patient's nose and in 11 of 52 eyes (22%, 95% CI: 12 to 37%) for which it was not identified.

Dye Disappearance Test (DDT)

The DDT at outcome was normal in 105 (73%), indeterminate in 15 (10%), and abnormal in 23 (16%) of the 143 eyes in which it was performed. Of the 116 eyes with abnormal DDT at baseline that had an outcome DDT, 88 (76%) had normal DDT at the outcome visit, 13 (11%) had indeterminate DDT, and 15 (13%) had abnormal DDT. Among the 118 eyes meeting clinical criteria for success that had DDT performed at follow-up, the DDT was normal in 85%, indeterminate in 8%, and abnormal in 7%, whereas among the 25 eyes not meeting success criteria, the percentages were 20%, 20%, and 60%, respectively.

Questionnaire Data

At baseline, the mean symptom score based on the questionnaire was 2.6 (range: 0.3 to 3.8) and the mean HRQOL score was 1.8 (range: 0.2 to 3.4). The mean symptom score improved by 2.0 points (range: −0.6 to 3.7 points) in 110 treatment successes and 0.7 points (range: −1.9 to 3.2 points) in 24 treatment failures ($p=0.0001$), and the mean HRQOL score improved by 1.3 points (range −1.1 to 3.2) in treatment success and by 0.2 points (range −1.4 to 2.4) in treatment failures ($p<0.0001$).

Discussion

In this prospective evaluation of balloon catheter dilation as primary treatment of congenital NLDO in 102 children 12 to 47 months of age (mean of 23 months), the success rate was 82%. This success rate is similar to previous smaller, retrospective studies of the use of the balloon catheter for primary NLDO treatment. Tao and colleagues reported a successful outcome in 27 of 34 children (79%) with a mean age of 44 months,[12] while Chen and Hsiao reported success in 57 of 72 children (79%) with a mean age of 30 months.[13] Becker and colleagues reported success in 26 of 27 (96%) children with mean age of 25 months,[10] while Gunton and colleagues reported success in 26 of 29 (90%) children with a mean age of 37.1 months.[11] Each study used different definitions of successful treatment and unmasked outcomes.

We also analyzed outcome in terms of subjective symptom score and quality of life as assessed by the parents, and the outcome of the DDT. Each of these measures improved substantially more for the successful patients compared with the failures. The DDT was normal in 73% of patients at the outcome examination.

A disadvantage of balloon catheter dilation for primary treatment is the additional cost compared to a probing. Balloon dilation is typically performed in an outpatient surgical facility with general anesthesia, with the use of more costly disposable medical equipment, which is not needed for probing or nasolacrimal intubation. The cost to a surgical facility of a balloon catheter and the inflator is $306 for a unilateral procedure and $555 for bilateral procedures (6/2007 – 2007 Atrion Catalog List Price). When compared with nasolacrimal intubation, the balloon device costs more than nasolacrimal tubes ($75 – $92), but intubation may require a separate procedure to remove the tubes either in the office or surgical facility.

There are a number of strengths to our study. We utilized prospective data collection with investigator certification and masked outcome assessment at a uniform time interval following the procedure. We recruited a large number of patients and had low (4%) loss to follow-up. A

large number of investigators participated in this study 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 or timing of surgery, investigator choice of procedure (probing, balloon catheter dilation, nasolacrimal intubation), and the setting of the surgery. It is possible that balloon catheter dilation was chosen by the investigator for more severe cases. Therefore, although the success rate of 82% is similar to the rate we found with probing (78%),[9] without randomization to remove potential selection bias, a valid comparison of outcomes with the two procedures is not possible. An additional limitation is that the sample size was too small to compare success rates among subgroups, such as age. Hence, although our data suggested an increased risk of failure with older age, we cannot say whether this was true or due to chance. Lastly, in this study we did not assess the balloon catheter dilation as a treatment for failed primary probing treatment of NLDO. Such a study is currently being conducted by PEDIG investigators and results will be available in the next few years.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Table 1

Baseline patient demographic and clinical characteristics

Characteristic	**N = 102 Patients**
Gender: Female *N(%)*	53 (52)
Race/ethnicity, *N(%)*	
White	70 (69)
African American	6 (6)
Hispanic or Latino	11 (11)
Other	4 (4)
Unknown/not reported	11 (11)
Age at onset of nasolacrimal duct obstruction (NLDO), in months* *N (%)*	
0 to <1	81 (79)
1 to <6	21 (21)
Age at surgery, in months *N (%)*	
12 - <18	34 (33)
18 -<24	31 (30)
24 - <36	25 (25)
36 - <48	12 (12)
Mean (range)	23 (12–47)
Previous treatment with topical antibiotics *N (%)*	
Yes (at least one eye)	53 (52)
No (neither eye)	35 (34)
Not known	14 (14)
Previous treatment with nasolacrimal duct (NLD) massage *N (%)*	
Yes (at least one eye)	47 (46)
No (neither eye)	37 (36)
Not known	18 (18)
Laterality of NLDO treated with balloon (by patient) *N (%)*	
Unilateral	53 (52)
Bilateral	49 (48)
Clinical signs	**N=151 eyes**
Increased tear lake present *N (%)*	141 (93)
Epiphora present *N (%)*	97 (64)
Mucous discharge present *N (%)*	75 (50)

Characteristic	N = 102 Patients
Number of clinical signs of NLDO *N (%)*	
1	45 (30)
2	50 (33)
3	56 (37)
Dye disappearance test (DDT) results at enrollment *N (%)*	
Normal**	4 (3)
Indeterminate	23 (15)
Abnormal	124 (82)
Type of obstruction *N (%)*	
Simple	92 (61)
Complex	59 (39)
Inferior turbinate infracture performed *N (%)*	
Yes	24 (16)
No	127 (84)

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

** Clinical signs in patients with normal dye disappearance test results included increased tear lake as the only sign in 2 patients, epiphora and increased tear lake in 1 patient, and all 3 signs in 1 patient.