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Office probing for treatment of nasolacrimal duct obstruction in infants

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Abstract

Purpose—To determine whether demographic or clinical factors are associated with the outcome of office-based nasolacrimal duct probing for the treatment of congenital nasolacrimal duct obstruction (NLDO).

Methods—In two multicenter prospective studies, 384 eyes of 304 children aged 6 to <15 months with NLDO underwent a nasolacrimal duct probing performed in the office using topical anesthesia. Treatment success, defined as no clinical signs of NLDO (epiphora, increased tear lake, or mucous discharge) and no reoperation, was assessed 1 month after probing in one study and 6 months after probing in the other study. Data from both studies were pooled to evaluate associations between baseline characteristics and treatment success.

Results—Office probing was successful in 75% of eyes overall (95% CI, 70%–80%). The procedure was less successful in eyes of children with bilateral NLDO compared with unilateral NLDO (63% vs 80%; relative risk = 0.78 [95% CI, 0.66–0.92]) and in eyes that had 2 or 3 clinical signs of NLDO compared with one (71% vs 83% relative risk = 0.88 [95% CI, 0.81–0.96]). Treatment success did not appear to be related to age, specific clinical signs of NLDO, prior treatment, or research study.

Conclusions—Performing nasolacrimal duct probing in the office successfully treats NLDO in the majority of cases in children aged 6 to <15 months. The success rate is lower with bilateral disease or when more than one clinical sign of NLDO is present.

Congenital nasolacrimal duct obstruction (NLDO) is one of the most common ocular conditions of infancy, occurring in an estimated 1% to 20% of infants.[1–4] Most cases resolve spontaneously or after lacrimal sac massage,[5–9] although surgical treatment is considered for

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patients whose symptoms persist past 6 month of age. One treatment option is to perform the probing in the office setting using topical anesthesia and infant restraint. Such office-based probing is most often used in children less than 1 year of age[10–13] because older infants may be too strong to be sufficiently restrained for the procedure to be performed safely in the office.

We report outcomes of office-based probing in infants aged 6 to <15 months who participated in one of two large multicenter prospective studies. Using the data from both studies, we investigated whether clinical and demographic factors are related to the likelihood of office probing success.

Methods

The two studies were supported through a cooperative agreement with the National Eye Institute of the National Institutes of Health and were conducted by the Pediatric Eye Disease Investigator Group (PEDIG) at 24 academic and community-based ophthalmology practices. The protocols and Health Information Portability and Accountability Act of 1996–compliant informed consent forms were approved by the respective institutional review boards. The parent or guardian of each study subject provided written informed consent. The studies are listed on www.clinicaltrials.gov under identifiers NCT00315289 and NCT00780741. The protocols are available on the PEDIG website (www.pedig.net, accessed 3/30/12); relevant aspects are summarized herein.

Subject Selection

The first research study[10] (study A) was a nonrandomized prospective study that enrolled 718 children between 6 and 48 months of age who were undergoing any type of primary procedure for treating unilateral or bilateral NLDO (probing, nasolacrimal intubation, or balloon catheter dilation), either in a surgical facility or office setting. The current analysis includes the 193 subjects from this study who underwent office probing before 15 months of age (4 children older than 15 months underwent office probing). The second research study[5,14] (study B) was a randomized trial that enrolled 220 children 6–10 months of age who had unilateral or bilateral NLDO. Subjects were assigned to receive either immediate office probing or 6 months of observation followed by deferred probing under general anesthesia in a surgical facility if symptoms persisted. The current analysis includes the 111 subjects from this study who were assigned to and underwent immediate office probing.

In addition to the age ranges described above, major eligibility criteria for both studies included onset of NLDO symptoms prior to 6 months of age, presence of at least one sign of NLDO (epiphora, increased tear lake, and/or mucous discharge in the absence of an upper respiratory infection, ocular surface irritation, or glaucoma) and no prior nasolacrimal duct surgery. Prior NLDO treatment with nasolacrimal sac massage, topical antibiotics, topical steroids, or systemic antibiotics was permitted.

Treatment

Office probing procedures were performed using topical ocular surface anesthesia and infant restraint. The surgical procedure consisted of dilation of at least one lacrimal punctum and the passage of a probe into the nose. Patency was to be confirmed with metal on metal probe contact, visualization of the probe beneath the inferior turbinate, irrigation with saline in the office inciting a swallow reflex, or recovery of fluorescein-colored saline from the nose after irrigation through the nasolacrimal duct. Postoperative medications were at investigator discretion in study A. In study B, antibiotic/steroid eyedrops (tobramycin/dexamethasone 0.3%/0.1%) were used for 1 week postoperatively.

Reoperations in study B were performed at the surgeon's discretion provided they occurred at least 6 weeks after the initial surgery. Because study A had only 1 month of follow-up after the initial surgery, any reoperations occurred after the study had ended.

Follow-up

Outcome examinations were conducted by study-certified examiners at 1 month (±1 week) after surgery in study A and at 6 months (±2 weeks) after surgery in study B. At each visit, the presence or absence of each of 3 clinical signs of NLDO (epiphora, increased tear lake, and mucous discharge) was assessed.

Statistical Methods

Probing success was defined as the absence of clinical signs of NLDO (epiphora, increased tear lake, or mucous discharge) on clinical examination and not having undergone reoperation. The analysis used the outcome assessed one month after surgery in study A and the outcome assessed 6 months after surgery in study B, and included only subjects who had completed the specified visit. The proportion of eyes with office probing success and a 95% confidence interval was calculated using logistic regression with generalized estimating equations to adjust for the correlation between eyes of subjects with two study eyes.[15] The analysis was performed both stratified by study and pooling data from both studies.

The associations of office probing success and baseline demographic and clinical characteristics were assessed pooling 1-month data from study A and 6-month data from study B, as a stratified analysis found similar associations in the two studies for all factors except gender. Relative risks and 95% confidence intervals were estimated using Poisson regression models with robust variance estimation[16] using the factor of interest, laterality, number of baseline clinical signs of NLDO, and study as covariates, and using generalized estimating equations to adjust for the intereye correlation between outcomes in eyes from subjects with bilateral NLDO.[15]

Data was analyzed using SAS version 9.3. (SAS Institute Inc, Cary, NC).

Results

Study A

The 193 subjects (243 eyes) in study A had a mean age of 9.8 months (range, 6.1–14.4) at the time of office-based nasolacrimal duct probing; 103 (53%) were female and 150 (78%) were white (e-Supplement 2, available at jaapos.org). Fifty subjects (26%) had bilateral NLDO and 160 (83%) had received prior treatment with nasolacrimal sac massage and/or antibiotics. No complications were reported for any office probing.

A total of 185 subjects (96%) completed the outcome visit 1 month after surgery. Treatment success, defined as the absence of clinical signs of NLDO (epiphora, increased tear lake, or mucous discharge) on examination and no reoperation, was reported for 164 of 234 eyes (72%; 95% CI, 66%–78%; Table 1). Subject-level treatment success (requiring success in both eyes in bilateral NLDO cases) was reported for 129 of 185 subjects (70%; 95% CI, 63%–76%).

An additional analysis limited to subjects 6 to <10 months of age (mean age, 8.3 months) showed treatment success in 89 of 124 eyes (75%; 95% CI, 66%–82%).

Study B

The 111 subjects (141 eyes) in study B had a mean age of 7.7 months (range, 5.9–9.9) at the time of office-based nasolacrimal duct probing; 44 (40%) were female and 87 (78%) were white (e-Supplement 2). Thirty subjects (27%) had bilateral NLDO and 91 (83%) had received prior treatment with nasolacrimal sac massage and/or antibiotics. In addition to the initial office probing procedure, 5 subjects were reoperated before the 6-month postoperative visit. No complications were reported for any probing procedures.

The 6-month postsurgical visit was completed by 99 subjects (89%). Treatment success, defined as the absence of clinical signs of NLDO (epiphora, increased tear lake, or mucous discharge) on examination and no reoperation, was reported for 98 of 126 eyes (80%; 95% CI, 71%–86%) 6 months after surgery (Table 1). Subject-level treatment success (requiring success in both eyes in bilateral NLDO cases) was reported for 78 of 99 subjects (79%; 95% CI, 70%–86%).

Overall Success

With data from both studies pooled, the success rate of office probing was 75% (95% CI, 70%–80%).

Predictive Factors

After pooling data from both research studies, office probing was less likely to be successful in eyes from subjects with bilateral NLDO compared with those with unilateral disease (63% vs 80%; relative risk = 0.78 [95% CI, 0.66–0.92]) and in eyes that initially had 2 or 3 clinical signs of NLDO compared with those with only one sign (71% vs 83% relative risk = 0.88 [95% CI, 0.81–0.96]) (Table 2). The likelihood of treatment success did not appear related to any of the other baseline characteristics that we evaluated: age, presence of specific clinical signs of NLDO, prior treatment with massage or topical antibiotics, or which research study the subject participated in.

Discussion

We found a 75% success rate in a prospective evaluation of office-based nasolacrimal duct probing in 360 eyes of 304 children who were between 6 and <15 months old and participated in one of two prospective studies[5,10,14] conducted by our research network. We are unaware of other prospective studies of office probing with which to compare this overall result. The success rate of 75% in our study is somewhat lower than that of a recent retrospective study that found an 82% success rate in 136 office probings in children aged 6–12 months old,[13] and an earlier retrospective study that found an 89% success rate in 823 office probings in children aged 7 to 12 months.[11]

Our 75% success rate with office probing is slightly less than the 80% success rate we found previously in 691 probings performed in a surgical facility under general anesthesia in patients aged 6 to 48 months in the two studies described herein (study A[10] and study B[5,14]) (relative risk of success for office vs facility probing = 0.90; 95% CI, 0.82–0.98). Although both office probing and facility probing are effective procedures that have minimal risk of complications,[5,10,14] several other factors can influence the choice of treatment approach. With office probing, parents may be concerned about discomfort despite the use of a topical anesthetic, and the potential for adverse psychological effects from the use of restraint. Some parents and clinicians may view the procedure as unnecessary given that 66% of NLDO cases persisting to 6 to <10 months of age will resolve with 6 months of observation and nonsurgical management.[17] Alternatively, immediate office probing provides faster

resolution of symptoms than observation followed by deferred facility probing (in patients with unilateral NLDO),[5] and it usually avoids the need for general anesthesia.[5,14]

Office probing was less successful in eyes of children with bilateral NLDO (63% compared with 80% in unilateral cases). This finding might be explained if children with bilateral NLDO are more likely to have atypical nasolacrimal duct system anatomy. However, we did not find that bilateral cases had a lower success rate than unilateral cases when the probing was performed in a surgical facility under general anesthesia; analysis of our previous data on the 691 facility probings performed in the two studies described here (study A[10] and study B[5,14]) showed similar rates of treatment success in eyes from bilateral versus unilateral cases (78% vs 83%, relative risk = 0.94; 95% CI, 0.86–1.02). Compared with bilateral office probings, we found a slightly higher rate of success with bilateral surgical facility probings (relative risk = 1.27; 95% CI, 1.08–1.51), and with unilateral probings in the office (relative risk = 1.30; 95% CI, 1.10–1.53) or with unilateral probings in a facility (relative risk = 1.36; 95% CI, 1.15–1.60). One reason for the reduced success rate of probing bilateral versus unilateral cases in the office setting (63% vs 80%) could be that when the child is conscious, the increased time required to probe a second eye might lead to a more hurried procedure being performed on each eye. Although it is possible that performing a probing in a conscious, yet restrained, child could mean there is less control of the operative field and consequently an increased incidence of complications, including inadvertent false passage or other damage to the nasolacrimal duct system, no such complications were reported in the 384 office probings performed in our studies and no unusual anatomy was reported in the 5 reoperations.

We found a slightly lower likelihood of success in children who prior to the procedure had two or three clinical signs of NLDO (epiphora, increased tear film, mucous discharge) compared with those with only one clinical sign (71% vs 83%). Given that nearly all children with only one clinical sign had only increased tear film, it is likely that such cases represent less severe disease that is more successfully treated by probing.

Office probing success was not related to age in children 6 to <15 months old. We are unaware of other studies evaluating probing success by age within this narrow age range. However, the absence of an age effect is consistent with two retrospective studies that evaluated office probing in wider age ranges. One study found a similar success rates in patients 6–12 month of age and patients >12 months (89% vs 87%)[11] and the other study found similar success rates across a wider age range, reporting success in 82% of 6 to 12 month olds, 79% of 13–18 month olds, and 78% of a small number of children ≥19 months of age.[13] Our previous prospective study,[10] in which most probings (about 75%) were performed under general anesthesia, found similar rates of success among patients 6 to <12 months, 12–<24 months, and 24 to <36 months. Lastly, a prospective study limited to probings under general anesthesia found success rates decreased with each successive year between 5 months and 60 months of age.[18]

There are several differences between the two studies. First, the primary outcome was measured at different time points. Study A assessed office probing outcomes 1 month after surgery, as this is generally considered sufficient time to determine whether a probing procedure is successful.[13,18–20] Study B assessed outcome at a later time point because the primary objective of the trial was to compare early office probing versus late facility probing treatment strategies, which required a later time point at which to compare both treatment groups. Also, the study population was slightly older in study A, and there may have been other, unmeasured baseline characteristics that differed between the two studies. Nevertheless, pooling the data for an overall estimate of success was considered reasonable given that (1) the success rates did not differ by study, (2) both studies assessed outcome at

least 1 month after surgery, and (3) in spite of any differences that might exist between the two study populations, we did not expect that the relationship of baseline factors to outcome would differ by study.

Nasolacrimal duct probing in the office setting is successful in treating clinical signs of NLDO in three-quarters of infants and young children. The success rate is lower with bilateral disease or when more than one clinical sign of NLDO is present but does not appear to be related to age within the range of 6 to <15 months.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Outcomes of office nasolacrimal duct probing[a]

	Overall N (%) [95% CI]	Study A 1 month after surgery N (%) [95% CI]	Study B 6 months after surgery N (%) [95% CI]
Eyes (all subjects)	N = 360	N = 234	N = 126
Success	262 (75) [70%–80%][b]	164 (72) [66%–78%][b]	98 (80) [71%–86%][b]
Unilateral NLDO subjects	N = 208	N = 136	N = 72
Success	166 (80) [74%–85%]	106 (78)[70%–84%]	60 (83) [73%–90%]
Bilateral NLDO subjects	N = 76	N = 49	N = 27
Success/success	41 (54) [43%–65%]	23 (47) [34%–61%]	18 (67) [47%–82%]
Success/failure	14 (18)	12 (24)	2 (7)
Failure/failure	21 (28)	14 (29)	7 (26)

CI, confidence interval.

[a]Success was defined by the study protocols as the absence of clinical signs of NLDO (epiphora, increased tear lake, or mucous discharge) on clinical examination and not having undergone reoperation.

[b]Point estimates and confidence intervals for eye-level data are adjusted for correlation between outcomes in eyes of subjects with bilateral NLDO.

Table 2

Office probing outcomes according to baseline characteristics[a]

Baseline characteristics	N eyes	Eyes with success N (%)[b]	Adjusted relative risk for success and 95% CI[c]
Total	360	262 (73)	—
Age at surgery, months[d]			
6 to <7	57	44 (77)	—
7 to <8	65	53 (82)	1.04 (0.85–1.28)
8 to <9	60	40 (67)	0.93 (0.72–1.18)
9 to <10	68	50 (74)	1.02 (0.83–1.26)
10 to <11	46	30 (65)	0.87 (0.64–1.16)
11 to <12	26	18 (69)	0.93 (0.67–1.30)
12 to <15	38	27 (71)	0.99 (0.75–1.31)
Sex			
Female	171	124 (73)	0.95 (0.84–1.07)
Male	189	138 (73)	—
Race/ethnicity			
White	278	209 (75)	—
Hispanic/Latino	42	29 (69)	0.96 (0.79–1.17)
Other	36	23 (64)	0.87 (0.66–1.16)
Laterality			
Unilateral	208	166 (80)	—
Bilateral	152	96 (63)	0.78 (0.66–0.92)
Epiphora			
Present	273	196 (72)	1.07 (0.89–1.30)
Absent	87	66 (76)	—
Mucous discharge			
Present	254	182 (72)	0.92 (0.75–1.13)
Absent	106	80 (75)	—
Increased tear film			
Present	354	257 (73)	1.03 (0.72–1.48)
Absent	6	5 (83)	—
Number of clinical signs[e]			
1	46	38 (83)	—
2 or 3	314	224 (71)	0.88 (0.81–0.96)
Prior antibiotics			
Yes	214	153 (72)	0.90 (0.78–1.04)
No	138	105 (76)	—
Prior massage			
Yes	258	185 (72)	0.93 (0.79–1.09)
No	95	74 (78)	—
Study			

Baseline characteristics	N eyes	Eyes with success N (%)[b]	Adjusted relative risk for success and 95% CI[c]
Study A	234	164 (70)	—
Study B	126	98 (78)	1.09 (0.96–1.24)

CI, confidence interval.

[a] Data are pooled across studies. For study B, success is defined as the absence of clinical signs (epiphora, mucous discharge and increased tear film) at the *6-month* visit and no prior reoperation. For study A, success is defined as the absence of clinical signs at the *1-month* visit (reoperation was not allowed). Dashes indicate reference levels.

[b] Percentages are not corrected for correlation of eyes in subjects with both eyes in the study.

[c] Relative risk compares risk between the specified level and reference level. Relative risks and 95% CIs are from Poisson regression models using the factor of interest, laterality, number of baseline clinical signs of NLDO, and study as covariates and use generalized estimating equations to account for the intereye correlation between eyes from subjects who have both eyes in the study.

[d] Adjusted relative risk per additional month of age at surgery is 0.99 (0.95–1.03).

[e] Clinical signs evaluated were epiphora, mucous discharge and increased tear lake. 91% of eyes with one clinical sign had increased tear film alone.