Original Article

Factors affecting treatment outcome in congenital nasolacrimal duct obstruction: A retrospective analysis from South India

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Purpose: To investigate outcomes for different treatment modalities in congenital nasolacrimal duct obstruction (CNLDO) in an Indian population. **Design:** Retrospective, interventional, case series. **Materials and Methods:** In an institutional setting, case records of patients with CNLDO from January 2008 to 2012, were reviewed, and data on patient demographics, clinical presentation, and treatment details (sac massage, probing, and/or dacryocystorhinostomy) were recorded. Success of treatment was defined as complete resolution of symptoms and negative regurgitation on pressure over lacrimal sac (ROPLAS) area. **Results:** Two hundred and ninety-eight eyes of 240 patients with a mean age of 22.2 ± 26.14 months (median = 12 months, interquartile range = 17) were analyzed. Sac massage (n = 226) was successful in 67 eyes (30%). Multivariable logistic regression analyses showed that children with mucoid ROPLAS were almost 6 times more likely (odds ratio [OR] = 5.55 vs. clear ROPLAS, 95% confidence interval [CI] = 2.35–13.09, $P < 0.001$) to experience failure of sac massage. Overall probing (n = 193) was successful for 143 (74%) eyes. Multivariable logistic regression showed that older children were 25% more likely to experience probing failure (OR = 1.25 for every 6 months increment in age, 95%, CI = 1.09–1.42, P = 0.001). **Conclusion:** Sac massage is successful in only a third of our patients and those with mucoid ROPLAS are more likely to experience failure. Probing is successful in three-quarter of our subjects, and its success declines with a progressive increase in age. Lower socioeconomic status, poor general health, and recurrent respiratory infections are unique to our population and may influence outcomes.

Key words: Congenital nasolacrimal duct obstruction, dacryocystorhinostomy, probing, sac massage, success rate

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Congenital nasolacrimal duct obstruction (CNLDO) is a common condition affecting 20% of infants in their 1st year of life[1] and occurs due to the failure of canalization of nasolacrimal duct.[2] Spontaneous resolution occurs in the majority of the cases by 1 year of age.[1,3] Interventions routinely employed to overcome CNLDO range from conservative approaches such as lacrimal sac massage (referred as "sac massage" hence forth) to more intrusive methods such as probing with or without intubation, balloon catheterization, silicone tube intubation, and dacryocystorhinostomy (DCR). Affected children up to 1 year of age are typically treated conservatively with digital sac massage which has been reported to have a high success rate (77–95%).[3-7] Probing of the nasolacrimal duct is generally attempted after a child is more than 1-year-old[4-6] and is generally quite effective with success rates ranging from 77% to 97% after 1st time application. Controversy still persists regarding the effectiveness of early (<1 year) and late (>3 years) probing.[8,9] External DCR is performed in complex CNLDO cases such as those with craniofacial anomalies, Down syndrome, or in children typically beyond 3 years of age who have previously experienced unsuccessful sac massage and probing.

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Our study primarily aims at evaluating the success rates of sac massage, probing(s), and external DCR, either sequentially or in isolation as necessary. A secondary objective was to evaluate the factors affecting the success of different treatment modalities.

Materials and Methods

Retrospectively, case records of all patients presenting between January 2008 and January 2012, with the diagnosis of CNLDO were retrieved from the medical records department using standard ICD-9 coding. Our Institutional Review Board approved the study. Diagnosis of CNLDO was based on presenting symptoms such as watering, discharge, swelling, and redness noticed since or shortly after birth. Acute dacryocystitis was diagnosed by the presence of acute onset swelling of the lacrimal sac area along with pain, redness, and tenderness. Cases with a history of multiple recurrences and remissions of pain and swelling were diagnosed as chronic dacryocystitis. Mucocele was defined

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as the presence of asymptomatic swelling of the lacrimal sac area. Fistula was characterized by an abnormal opening around the sac area with or without discharge. Patients with a minimum follow-up of 3 months from the day of presentation were included in the study. Children presenting with punctal agenesis acquired NLDO due to trauma or craniofacial anomalies, and excessive tear production from a non-CNLDO induced etiology such as allergic conjunctivitis and congenital glaucoma were excluded. The following variables were recorded from patient's record, after obtaining informed consent from the patients' legal guardian: Laterality, age at presentation, gender, presenting symptoms, viz., watering, discharge, swelling, dacryocystitis, mucocele, pyocele, ROPLAS area, syringing in older children, treatment modality (sac massage, probing, and DCR), duration of treatment, age at the time of probing or DCR, and follow-up duration. In cases with simultaneous or sequential bilateral presentation, each eye was considered as an independent case to avoid selection bias.

The first line of treatment was based on the discretion of the treating physician. Two physicians were involved in deciding the treatment modality. Physicians were conservative in the initial period and started with sac massage in the majority of children as per our institutional practice. Probing was considered in cases with persistent symptoms even after a minimum of 3 months of complete adherence to sac massage. Primary probing or DCR, i.e. without prior sac massage was considered in a minority of subjects presenting with acute dacryocystitis and pyocele after the infection was quiescent.

Crigler's method[10] of sac massage was taught by physicians to the parents or accompanying guardians using an instructional video and were instructed to properly perform 10 strokes 4 times a day. All patients who failed to show resolution of CNLDO after a minimum of 3 months of sac massage trial were advised to undergo probing. Probing[11] and external DCR[12] were performed under anesthesia as per standard techniques. A repeated attempt to probe was made after 6 weeks, after which DCR was recommended.

Treatment success was defined as the absence of fluid on ROPLAS and complete resolution of symptoms for at least 3 months after a procedure or during the patient's last visit to the hospital, whichever was later.

Statistical analysis

Continuous variables were presented as mean ± standard deviation (SD) and/or median with interquartile range (IQR) and analyzed using the Student's *t*-test or Wilcoxon rank sum test for nonparametric variables. Categorical variables were presented as proportions, and group differences were analyzed using the Chi-square or Fisher exact test. Univariate and multivariable logistic regression analysis were performed to determine factors associated with failure of sac massage and probing separately, and results were presented as odds ratios (ORs) and 95% confidence intervals (CIs). Covariates included were age, gender, type of ROPLAS, and type of symptoms at presentation. Data entry was completed using Microsoft Excel 2010 (Microsoft Office Standard 2010) and statistical analyses were done by STATA I/C 12.0 (StataCorp., Texas, USA). The value $P \leq 0.05$ was considered statistically significant.

Results

Total of 352 eyes of 275 children were provisionally diagnosed as CNLDO during the study period. All the case records were retrieved for analysis. Out of 352 eyes, 32 eyes were excluded due to inadequate follow-up and 22 eyes due to acquired etiology of nasolacrimal duct obstruction. In the remaining 298 eyes of 240 children with CNLDO, 153 (52%) were right eyes and 145 (48%) left eyes. Mean age at the time of presentation was 22.2 ± 26.14 months (median = 12 months, IQR = 17).

Hydrostatic sac massage

Total of 226 eyes were advised sac massage, out of which 67 (30%) were successful while 159 (70%) failed and were advised to undergo probing. Mean (±SD) age of children was 16 ± 18 months (median = 12, IQR = 16) and two-third of these were ≤12 months of age (160 out of 226 eyes). The median duration of sac massage trial was 5 months. Children who experience successful resolution with sac massage were significantly younger (mean = 13.90 ± 18.25, median = 7, IQR = 14) than those who experienced failure of sac massage (17.19 ± 18.51, median = 12, IQR = 17) (P = 0.008, Wilcoxon rank sum). In children below 1 year of age, successful sac massage was achieved in a significantly greater proportion of those in the 0–6 months age group (47%) compared to those in the 7–12 months age group (24%) (P = 0.003).

At presentation, clear fluid on ROPLAS was seen in 154 eyes out of the 226 (68%) who underwent initial sac massage while the remaining 72 eyes (32%) had mucoid ROPLAS. Successful sac massage was achieved in 39% children with clear ROPLAS versus 10% children with mucoid ROPLAS (P < 0.001). There was no difference in success rates of sac massage in eyes presenting with watering alone (34%) compared to eyes with both watering and discharge (24%) (P = 0.11).

Univariate and multivariable logistic regression models [Table 1] showed that, after adjusting for age, gender, and type of symptoms, children with mucoid ROPLAS were almost 6 times more likely to experience failure of sac massage compared to those with clear ROPLAS.

Probing and irrigation

Initial probing (n = 193) was successful for 117 (61%) eyes. Repeat probing procedures (n = 35) were successful for another 26 (74%) eyes. The mean (SD) age of patients receiving first probing was 27.90 ± 20.13 months (median = 24 months, IQR = 13). Children who experienced the successful outcome of the first probing were significantly younger (23.58 ± 10.91 months) than those who experienced failure (34.55 ± 27.93 months, P = 0.007). Mean (SD) age of receiving repeat probing procedure was 42.22 ± 32.11 months. In children < 1 year, first probing was successful in 9/15 eyes (60%). The success rate of first probing declined with increment in age, i.e. , 74/107 (70%) between 1 and 2 years, 22/39 (56%) between 2 and 3 years, 6/12 (50%) between 3 and 4 years, and 6/15 (40%) between 4 and 5 years. None of the 5 children above 5 years experienced successful first probing.

There was no difference in success rates of first probing with respect to ROPLAS status (clear vs. mucoid; P = 0.48). A total of 133 eyes (69%) received sac massage prior to probing. Out of these 78 (59%) experienced successful first probing. Similarly, 39 out of 60 eyes (65%) experienced successful first probing when no prior sac massage was done (P = 0.40).

Table 1: Univariate and multivariable logistic regression analyses evaluating factors predicting failure of sac massage

Variable	Interval	Univariate (OR, 95% CI)	Multivariable (OR, 95% CI)
Age	6 months increment	1.07 (0.95-1.20)	1.05 (0.93-1.19)
Gender	Male versus female	0.87 (0.40-1.55)	1.08 (0.58-1.99)
ROPLAS type	Clear versus mucoid	5.93 (2.54-13.78)**	5.55 (2.35-13.09)**
Symptoms	Watering versus discharge	1.62 (0.90-2.94)	1.31 (0.41-3.05)

**P<0.001. OR: Odds ratio, CI: Confidence interval, ROPLAS: Regurgitation on pressure over lacrimal sac

Table 2: Univariate and multivariate logistic regression analyses evaluating factors predicting failure of probing

Variable	Interval	Univariate (OR, 95% CI)	Multivariable (OR, 95% CI)
Age	6 months increment	1.21 (1.08-1.37)*	1.25 (1.09-1.42)*
Gender	Male versus female	0.63 (0.35-1.16)	0.61 (0.32-1.16)
ROPLAS type	Clear versus mucoid	1.23 (0.69-2.19)	1.43 (0.77-2.69)
Symptoms	Watering versus discharge	1.24 (0.70-2.24)	-
Prior sac massage	Massage versus no massage	0.76 (0.41-1.13)	1.10 (0.59-2.06)

*P=0.001. OR: Odds ratio, CI: Confidence interval, ROPLAS: Regurgitation on pressure over lacrimal sac

Univariate and multivariable logistic regression models [Table 2] showed that, after adjusting for gender, type of ROPLAS, symptoms, and prior sac massage, older children were 25% more likely to experience failure of probing (OR = 1.25 for every 6 months increment in age, 95% CI = 1.09–1.42 with every 6 months increment in age).

Dacryocystorhinostomy

DCR procedures (n = 32) were successful for 30 (93.75%) cases (3–14 years). The median age for DCR was 54 months. Mean (SD) age for successful DCR was 7.6 ± 2.7 years. Due to very small sample size in different age groups, further statistical analysis was not performed.

Discussion

We analyzed a large cohort of children with CNLDO, who presented to us across a wide range of age groups and were treated with sac massage, probing, and DCR, either solitarily or sequentially. We found that the success rate of sac massage in our group of children was much lower than previously reported[13-16] and irrespective of age, children with mucoid ROPLAS had a significantly higher likelihood of failure of sac massage. In addition, we found that age was the only predictor of success of probing. Having a large cohort with heterogeneity in the age of presentation, type of discharge, and different initial treatment modality enabled us to evaluate multiple factors associated with outcomes of treatment across different age groups.

In previous studies, hydrostatic sac massage[15] has been shown to have a success rate[3,13-17] ranging from 28% to 95%, in children older than 6 months of age. We also found that children <1 year experienced comparatively better success with sac massage compared to older children, yet this was <50%. We suspect that this was probably due to improper technique of massage instituted by parents though other factors such as infrequent follow-up, recurrent upper respiratory infections, and late initial presentation could also influence the outcome.

The type of regurgitation at the time of initial presentation can significantly affect the outcome of sac massage. The Presence of mucoid fluid on ROPLAS is suggestive of repeated or chronic inflammation of the sac, which would likely cause higher failure rates of hydrostatic sac massages. Based on this finding, it may be hypothesized that younger children with mucoid ROPLAS may benefit from early probing, however, this is speculative at present, and further study is required to confirm this phenomenon. In addition, sac massage was seen to have limited success in children beyond 1 year of age, suggesting that it can be attempted in older children with clear ROPLAS.

In our study, probing was successful in 74% cases which are similar to previous reports.[6,18,19] Median age of successful probing was 24 months, and we found that the likelihood of failure of probing increases with increasing age. Contrary to sac massage, the type of ROPLAS did not have any effect on the outcome of probing.

Sac massage remains the first line of management until 6 months of age, as was followed in our cohort. However, controversy exists between probing or sac massage as the first line of management in children between 7 and 12 months of age. Probing in <1 year of age has been less advocated due to a higher rate (78–100%) of spontaneous resolution.[20] We also found that more than half (60%) of children respond favorably to probing before the age of 1 year, which is still less than the rate of spontaneous resolution but far better than the success of sac massage (24%). Based on the above result, we believe that early probing may be beneficial in children <1 year who do not respond favorably to sac massage, and in especially those who present with mucoid ROPLAS, as they have a significantly high chance of failure to sac massage. We observed a higher success rate (70%) of probing in children with 13–24 months of age which was similar (72%) to a study conducted by Arora *et al*.,[21] but they included patients with primary probing only. Overall success of probing in children with <2 years of age at the time of probing was 68% in our study. Arora *et al*. reported similar results for the subgroup of children <2 years of age (76%), however, Limbu *et al*.[22] reported a higher success rate (90%) than ours probably due to the shorter follow-up (1 month) and smaller sample size in their study. Further, we found that

with increasing age there was a significant reduction of success rate of probing. Previous reports[4,9,23] have also suggested a negative impact of increasing age on the outcome of probing. However, in a large, prospective, nonrandomized trial enrolling children from 6 to 48 months undergoing primary probing, the Pediatric Eye Disease Investigator Group (PEDIG) investigators concluded that increasing age had no impact on the success rates of probing up to 36 months, contrary to our results.[18,21] Probable reasons for this could be regional differences in the patient population, shorter follow-up of 1 month in the PEDIG study, differences in the techniques of probing and previous sac massage done in our patients. The PEDIG group also suggested that those with milder disease respond more favorably to primary probing. However, we found that those with clear versus mucoid ROPLAS did not differ in their response to probing. Al-Faky *et al*.[24] reported that the absence of preprobing sac massage was associated with significantly higher failure rate, but in our study no such effect was seen probably due to inadequate sac massage, shorter follow-up, and different demographics of our population.[19]

The strength of our study is the heterogeneity in patient population providing an opportunity to evaluate various factors associated with treatment outcomes across various age groups. Ours is a retrospective study with its inherent limitations. Multiple confounding factors such as variable follow-up, low socioeconomic status, low literacy rate, recurrent upper respiratory infections, and minor anatomical variations could not be analyzed, which could have altered the results.

Conclusion

Sac massage, often considered as the first line of management, is successful in only a third of the patients in our study population. The type of ROPLAS is the most important factor predicting the outcome of sac massage. Probing is successful in three-quarter of our subjects, comparable to previous reports, and its success declines with a progressive increase in age. Sac massage as a primary treatment prior to probing may be successful in some older children as well and, as it does not negatively impact outcomes if probing is worth a try. Lower socioeconomic status, poor general health, and recurrent respiratory infections are unique to our population, and may influence outcomes. Measures to improve the adherence and persistence of treatment are required in our population to improve outcomes of sac massage. The hypothesis that the presence of mucoid ROPLAS in children younger than 1 year of age may benefit from early probing needs to be explored further.

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Conflicts of interest

There are no conflicts of interest.

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