Effect of age on primary balloon dacryocystoplasty and probing success in congenital nasolacrimal duct obstruction

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Abstract

Purpose To compare the success rates of balloon dacryocystoplasty (BDP) and probing as a primary procedure in congenital nasolacrical duct obstruction (CNLDO) and investigate the effect of age on both procedures.

Methods A total of 135 patients (171 eyes) with simple and incomplete complex CNLDO were included in this retrospective study; complete complex CNLDO cases were excluded. The success rates for primary BDP (118 eyes) and for probing (53 eyes) were compared overall and among the age groups; Group 1 (12–24 months old), Group 2 (25–36 months old), and Group 3 (> 36 months old).

Results Mean age of the patients was 41.5 ± 27.2 months for primary BDP, and 21.8 ± 10.8 months for probing (p < 0.001). Overall success rates for primary BDP and probing were 81.1% (43/53) and 76.3% (90/118), respectively (p = 0.481). Success rates for BDP and probing among age groups were 93.8% and 85.3% in Group 1 (p = 0.360), 93.3% and 50.0% in Group 2 (p = 0.012), and 63.6% and 27.3% in Group 3 (p = 0.052), respectively. Cox regression analysis showed that the median ages were 18 months for probing and 36 months for primary BDP. The Poisson regression model showed that for every 1-month increase in patients’ age, the success rate of probing decreased by 9.7%.

Conclusion Probing success decreased to a point where different treatment options such as primary BDP can be discussed with the patients’ parents after 18 months of age. The success of BDP decreased after 36 months, while it maintained a high success rate between 24 and 36 months as primary treatment.

Keywords Probing · Primary balloon dacryocystoplasty · Congenital nasolacrical duct obstruction · Age · Effect · CNLDO

Introduction

Congenital nasolacrical duct obstruction (CNLDO) is a clinical condition characterized by epiphora, crusting on the lashes, and mucopurulent secretions. A large-scale cohort study showed that CNLDO occurs in one out of nine newborn children, making the condition a public health problem [1].
The resolution rate for CNLDO with medical management, such as topical antibiotics and Crigler massage, is approximately 75–90% [2, 3], which does not differ from the resolution rate with early probing before the age of 12 months [3, 4]. Due to these similar resolution rates, probing has been recommended for patients with persistent symptoms after the first year of life [3]. Although probing is accepted as the first-line treatment for persistent CNLDO, controversial reports have discussed the procedure’s optimal timing and resolution rates with patients’ advancing age. While some authors reported a significant decrease in success rates for late probing [2, 5–7], in contrast, others found that age did not significantly affect success rates [4, 8, 9].

Balloon dacryocystoplasty (BDP) is an alternative treatment option for CNLDO in addition to nasolacrimal intubation and dacryocystorhinostomy. BDP is generally used as a second-line treatment in primary probing failure cases, with a 74–94% reported success rate [10]. In addition, some authors have declared that BDP offers a good outcome when used as a primary treatment for CNLDO, especially among older children and different obstruction types [11–16]. To the best of our knowledge, only two studies in the literature compare probing and BDP as primary treatments in CNLDO [17, 18]. However, the efficacy of BDP compared to probing as a first-line procedure has yet to be determined, and future studies are expected to address this issue [19].

Therefore, the purpose of our study is to compare the results of probing and primary BDP in patients with different age groups, to investigate at what age the success rate of primary probing reduces, and to determine the optimal timing of BDP as a first-line treatment.

Materials and methods

This single-center retrospective study included 135 simple and incomplete complex CNLDO patients (171 eyes) of whom probing or BDP was applied as a primary procedure between 2011 and 2018 in Marmara University School of Medicine Hospital, Department of Ophthalmology. The study protocol was approved by the Institutional Review Board of Marmara University School of Medicine (No. 09.2015.210), and the study was performed following the Declaration of Helsinki principles. In addition, before the interventions, all of the patients’ legal guardians routinely provided written informed consent to participate in the study and the use of medical information in the study analysis.

The patients with epiphora, high tear meniscus, and mucopurulent discharge in the absence of conjunctivitis, trauma, or any ocular disease with onset of symptoms before the age of 6 months and the presence of mucopurulent discharge with lacrimal massage in the clinical examination were evaluated as CNLDO. The diagnosis was confirmed by performing a fluorescein dye disappearance test in contradictive cases by instilling one drop of 2% fluorescein solution in the lower conjunctival fornix and observing if the dye clears from the lacrimal lake. The cases in which the fluorescein dye did not clear in 5 min were evaluated as an obstruction.

The types of obstruction were determined according to the probing results of the patients by retrospective evaluation of the surgical notes. While the complete complex CNLDO was defined as the obstruction that the probe could not reach the nasal cavity, and metal-to-metal contact could not be received due to a firm bony obstruction during the procedure; the simple and incomplete complex CNLDO was defined as the obstruction of which the metal-to-metal contact at the inferior meatus could be achieved, and the patency was open with an irrigation–aspiration test [5]. The patients with a complete complex CNLDO, dacryocystocele, craniofacial abnormality, any genetic syndrome, a history of acute dacryocystitis, a history of prior intervention, and a follow-up of fewer than six months were excluded from the study.

In our clinical practice, we routinely perform probing or primary BDP as a first-line procedure for CNLDO before or after the age of 24 months, respectively. However, although the BDP procedure is within the scope of reimbursement according to our public health insurance system, the balloon catheter used in the procedure (LacriCath, Quest Medical, Allen, Texas, USA) would not have been available at all times in our hospital. Between 2014 and 2016, there were an excess number of balloon catheters with a limited expiration date, forcing us to apply BDP for the patients before 24 months of age. However, there was limited access to balloon catheters outside the given date period, which also forced us to apply probing after the age of 24 months. This changing
availability of balloon catheters has collectively enabled the comparison of the two treatment modalities in different age groups without any voluntary intervention for selection.

All procedures were performed by the same surgeon (EÇ) under inhalation anesthesia with a laryngeal mask in the operating room. For the probing procedure, after dilating the upper punctum, a Bowman’s probe (no. 0 or 00) was inserted vertically to the punctum and advanced through the canaliculus on the horizontal plane. After reaching the nasal wall, it was rotated 90° to a vertical position and advanced through the nasolacrimal duct. After feeling the membrane rupture, confirmation was made by metal-to-metal contact, fluorescein-stained saline irrigation, and aspiration with a pediatric aspiration catheter placed in the lower meatus.

For patients undergoing BDP, after the probing procedure was performed, a LacriCath balloon catheter with a size of 2 or 3 mm selected according to the patient’s age (before or after the age of 24 months, respectively) was placed in the lacrimal duct in the deflated position. The catheter was pushed to the marked area at a distance of 15 mm proximally and then inflated twice, first at 8 bars for 90 s and then for 60 s, ensuring the dilatation of the nasolacrimal duct’s distal end. Next, the catheter was withdrawn to the second mark at 10 mm and inflated twice for 90 and 60 s again, ensuring the dilatation of the nasolacrimal duct’s proximal end this time. Then, the balloon catheter was deflated and removed. At the end of the procedure, the nasolacrimal duct passage was checked once more by an irrigation–aspiration test. A topical netilmicin 0.3% and dexamethasone 0.1% eye drops were prescribed in the first week after the procedure.

All patients were re-evaluated at 1 week, 1 month, 3 months, and 6 months postoperatively. A procedure was considered successful if there was no presence of epiphora upon examination with a lacrimal massage, no other clinical signs of CNLDO, and a negative fluorescein disappearance test at the 6-month follow-up visit. If these criteria were not met, the procedure was considered a failure.

The Statistical Package for the Social Sciences version 24.0 (SPSS v24.0; IBM Corp., Armonk, NY, USA) for Macintosh was used for statistical analysis. A Kolmogorov–Smirnov test was used for data distribution. Patients were divided into three groups according to their ages: Group 1, 12–24 months old; Group 2, 25–36 months old; and Group 3, older than 36 months. Qualitative variables were compared via the \( \chi^2 \) test. And, since the study population was nonparametrically distributed in terms of age, a Mann–Whitney \( U \) test was used for comparisons. The correlations were evaluated by the Spearman correlation test. A Poisson regression model was used to calculate risk ratios and 95% confidence intervals (CI). Cox regression analysis was used to determine the median age for a successful intervention. A \( p \)-value of less than 0.05 was considered statistically significant.

Results

There were 44 patients (53 eyes) and 91 patients (118 eyes) who had undergone primary BDP and probing for simple and incomplete complex CNLDO during the study period, respectively. Nine patients (20.5%) in the BDP group and 27 patients (29.7%) in the probing group had bilateral disease, and the mean ± standard deviation (SD) follow-up time for all cases was 57.3 ± 18.8 (range 6–116) months. Clinical characteristics of the patients are given in Table 1.

The mean age of the patients was 41.5 ± 27.2 (range 12–120) and 21.8 ± 10.8 (range 12–60) months in the BDP and probing groups, respectively (\( p < 0.001 \)). The overall success rate of primary BDP was 81.1% (43 of 53 eyes), whereas the overall success rate of probing was 76.3% (90 of 118 eyes, \( p = 0.481 \), Table 1). There was no significant correlation between success rates and bilaterality (\( p = 0.234 \)), and there were no complications noted for either group.

Success rates for primary BDP and probing among the age groups were, 93.8% and 85.3% in Group 1 (\( p = 0.360 \)), 93.3% and 50.0% in Group 2 (\( p = 0.012 \)), and 63.6% and 27.3% in Group 3 (\( p = 0.052 \)), respectively (Table 2). Additionally, for probing, the success rate was better in Group 1 than Group 2 (\( p = 0.003 \)) and 3 (\( p < 0.001 \)), and for primary BDP, success rates were better in Group 1 (\( p = 0.033 \)) and 2 (\( p = 0.041 \)) than Group 3 (Table 2).

A likelihood ratio \( \chi^2 \) test indicated that the full model offered a significant improvement in fit over a no-predictors model (\( p < 0.05 \)). A Poisson regression model showed that age significantly predicted success for the probing group (\( p = 0.042 \)) but not for the BDP.
The incidence rate ratio indicated that the success rate of probing decreased by 9.7% (95% CI 9.5–9.9) for every 1-month patients’ age. A Cox regression analysis showed that the median ages were 18 months (95% CI 16.5–19.4) for probing and 36 months (95% CI 29.8–42.2) for primary BDP, and the log-rank difference was statistically different between these groups (p < 0.001, Fig. 1).

Discussion

In this study, we analyzed the results of primary BDP and probing for persistent simple and incomplete complex CNLDO at different age groups to identify the optimal age at which to use BDP as a first-line treatment. This study showed that the overall success rates of both procedures were similar in simple and incomplete complex CNLDO. Still, the age group evaluations revealed that the primary BDP offers better success after 24 months of age.

The success rate of probing was decreased by 9.7% for every 1-month increase in patients’ age, and the median timing for successful probing was found to be 18 months in simple and incomplete complex CNLDO in this study. Similarly, a large cohort study by Sathiamoorthi et al. [2] showed that probing’s success rates decreased with increasing age and reported a resolution rate of 89% following primary probing in 289 eyes with a lower resolution rate after 15 months. Recently, Swierczynska et al. [7] showed that probing success rates decreased dramatically with increasing age and one-third of operations ultimately failed after patients reached 24 months of age regardless of the obstruction type. In our study, the probing success rate was significantly decreased after 24 months, falling to a rate of 27% in patients older than 36 months (Group 3). However, the study’s strict complete success criteria and the limited number of patients in Groups 2 and 3 should be considered while interpreting these high failure rates.

Nasolacrimal probing is the generally recommended first-line treatment for persistent CNLDO after 12 months of age. However, there were controversial reports according to the time of intervention in the literature [2, 4, 7, 9]. Many surgeons prefer other procedures than primary probing for patients at older months of age. In a published questionnaire survey

| Table 1 | Clinical characteristics of the patients and overall success rates in probing and primary BDP groups |

|                        | Probing  | BDP      | p-Value     |
|------------------------|----------|----------|-------------|
| Patients/eyes, n       | 91/118   | 44/53    | –           |
| Female/male, n         | 39/52    | 24/20    | 0.202†      |
| Bilaterality, n (%)    | 27 (29.7)| 9 (20.5) | 0.256†      |
| Age as months, mean ± SD (range) | 21.8 ± 10.8 (12–60) | 41.5 ± 27.2 (12–120) | < 0.001* |
| Overall success, n (%) | 90 (76.2%) | 43 (81.1%) | 0.481†      |

Bold value indicates statistical significance

BDP balloon dacryocystoplasty, SD standard deviation

*Mann–Whitney U test, †χ² Test

| Table 2 | Success rates of probing and primary BDP according to age groups |

|                        | Group 1 12–24 months | Group 2 25–36 months | Group 3 > 36 months | p-Value* |
|------------------------|-----------------------|-----------------------|---------------------|----------|
| Probing Success/n      | 81/95                 | 6/12                  | 3/11                |          |
| Probing Success rate   | 85.3%                 | 50%                   | 27.3%               |          |
| Primary BDP Success/n  | 15/16                 | 14/15                 | 14/22               |          |
| Primary BDP Success rate | 93.8%              | 93.3%                 | 63.6%               |          |
| p-Value*               | 0.360                 | **0.012**             | 0.052               |          |

Bold value indicates statistical significance

BDP balloon dacryocystoplasty

*χ² Test

Group (p = 0.368). The incidence rate ratio indicated that the success rate of probing decreased by 9.7% (95% CI 9.5–9.9) for every 1-month patients’ age. A Cox regression analysis showed that the median ages were 18 months (95% CI 16.5–19.4) for probing and 36 months (95% CI 29.8–42.2) for primary BDP, and the log-rank difference was statistically different between these groups (p < 0.001, Fig. 1).
among 119 members of the American Association for Pediatric Ophthalmology and Strabismus, 53% of physicians preferred primary BDP or silicone tubes if probing treatment was delayed until 24 months of age [20]. Furthermore, this rate increased to 68% if probing treatment was delayed until 36 months of age [20]. In our clinical practice, we prefer primary BDP after 24 months of age rather than silicone tubes because of the possibility of focal damage to the punctum and canaliculus, extrusion of the stent, and corneal damage previously reported with silicon tubes [19].

BDP is a well-known procedure; however, there are limited numbers of studies comparing primary BDP and probing in the literature. Although statistically not significant, we found that primary BDP was slightly more successful than probing in terms of overall success rates (81.1% vs. 76.3%, p = 0.481), even though the primary BDP patients were significantly older than the probing patients (41.5 ± 27.2 vs. 21.8 ± 10.8 months, p < 0.001). Similar to our study, Goldich et al. [18] also reported no significant difference between the overall success rates of primary BDP and probing (89.5% vs. 86.7%, p = 0.548) at significantly different mean ages (55.9 ± 113.6 vs. 18.5 ± 6.5 months, p < 0.01). Additionally, the authors reported that the patient’s age had no significant effect on either surgery [18]. Gunton et al. [17] conducted a study in which the mean ages of primary BDP and probing were similar (31.1 ± 13.5 vs. 37.1 ± 25.2 months, respectively, p = 0.36). They reported no significant difference between primary BDP and probing success rates either overall (90% vs. 86%, respectively, p = 0.22) or in different age groups [17]. In contrast, we found that primary BDP yielded significantly better results than probing after 24 months of age. In Group 2 (patients aged 25–36 months), we observed a significant difference in success rates of primary BDP (93.3%) and probing (50.0%, p = 0.012). This result seems to be due to a

![Cox regression analysis for probing and primary balloon dacryocystoplasty](image)
significant decrease in probing’s success rate since no difference was observed in BDP’s success rate until patients reached 36 months (BDP, Group 1: 93.8%, Group 2: 93.3%, p = 0.963).

One of our study’s important results is that the success rate of primary BDP significantly decreased after patients reached 36 months of age compared to the other age groups. Group 3’s primary BDP success rate significantly reduced to 63.6% from 93.3% (p = 0.041). A previous study about primary BDP reported the procedure’s success rate at 100% before patients reached 24 months (n = 5), decreasing to 75.9% for children older than 24 months (n = 29) (mean age 35.6 months) [12]. Still, this result was not statistically significant (p = 0.526) [12]. Another study, conducted by the Pediatric Eye Disease Investigator Group, showed that primary BDP’s failure rate was 14% for patients between 12 and 24 months old, and this rate increased to 25% for patients between 24 and 48 months old (mean age 23 months) [15]. Although the failure rate was reported to increase with patients’ age, no statistical evaluation was reported between these two groups [15]. Interestingly, in the recent research by Gazit et al. [16], it was found that the primary BDP success rate was significantly decreased after 36 months of age, quite similar to our study. This success reduction in these studies, including ours, could be explained by persistent and late-intervened CNLDO’s ability to result in increased adhesions and fibrosis in the nasolacrimal duct [6]. BDP’s effectiveness may decrease when opening these tighter adhesions for older patients.

Our study contributes to filling the literature’s gap of insufficient results for primary BDP versus primary probing at different patient ages [19]; however, it faces some limitations. In recent years, the publications about endoscopy-assisted probing have been increasing, and the fact that endoscopy was not used in this study can be considered a limitation. A recent systematic review showed that the success rate of conventional probing was 75.3%, and endoscopy-assisted probing was 95.3% [21], which is similar to the success rate of secondary BDP (74–94%) [10]. Galindo-Ferreiro et al. [22] reported the success rates of endoscopy-assisted and conventional probing over 4-year-old patients as 94.6% and 58.7%, respectively. This success difference with the use of endoscopy depends on the ability to perform interventions such as intubation in narrow occlusions, excision of trapdoor re-closure of membranous obstruction, or widening the Hasner valve with a sickle knife [23, 24]. The high success rate of BDP may be due to the fact that it alone is sufficient to open such occlusions. To the best of our knowledge, the success rate between primary BDP and endoscopy-guided probing in CNLDO has not been compared, and this issue can be addressed in future studies. In addition, a recent survey from the UK showed that while 43.9% of oculoplastic consultants were using nasoendoscopy in probing, only 12.9% of pediatric consultants were [25]. Considering that the primary treatment of a prevalent disease such as CNLDO is also applied by general ophthalmologists, it can be predicted that the overall rate of endoscopy use is lower than these rates. Therefore, the present study has illuminating aspects about these two procedures performed conventionally without using an endoscope.

In conclusion, amid the ongoing debate about the optimal timing and more favorable surgical choices for CNLDO, this study suggests that after a cut-off point of 18 months, probing success decreases to a level that other options such as primary BDP could be discussed with the patient’s parents. However, primary BDP did not provide significantly better results than probing between 12 and 24 months in CNLDO. Furthermore, while the primary BDP maintained a high success rate between 24 and 36 months, its success decreased after 36 months. Nevertheless, the BDP may be chosen as a primary treatment with an excellent success rate between 24 and 36 months of age. However, more reliable randomized prospective studies are needed to define better the first-line therapy for children in this age group.

Author contributions All authors contributed to the study’s conception and design. Material preparation, data collection and analysis were performed by SS, MOS, EÇ and VD. VD wrote the draft, and all authors commented on previous versions of the manuscript. Finally, all authors read and approved the final manuscript. Finally, all authors read and approved the final manuscript.

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Data availability Raw data were generated at Marmara University School of Medicine Department of Ophthalmology. Derived data supporting the findings of this study are available from the corresponding author (EÇ) on request.

Declarations
Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest. No conflict of interest, financial or other, exists, and this manuscript has not been published and is not under consideration for publication elsewhere.

Ethical approval All procedures performed in studies involving human participants were in accordance with the Institutional Ethics Committee of Marmara University (Istanbul, Turkey) and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Consent and approval were obtained from the Institutional Ethics Committee of Marmara University (Istanbul, Turkey) to process the data of patients’ records in this retrospective study. And also, before the interventions, all of the patients’ legal guardians routinely provided written informed consent to participate in the study and the use of medical information in the study analysis.

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