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Balloon dilatation for treatment of congenital nasolacrimal duct obstruction

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PURPOSE. *To evaluate the safety and effectiveness of balloon dacryocystoplasty in the treatment of congenital nasolacrimal duct obstructions.*
METHODS. *Balloon dacryocystoplasty was attempted in 25 eyes of 21 patients. The procedure was performed successfully in 24 eyes of 20 patients, age range 21-72 months. Nineteen eyes had no previous procedure. The mean age of this group was 43.9 months (range 36-72 months). Five eyes had failed probing of lacrimal system. The mean age of this group was 22.2 months (range 21-24 months). The authors performed balloon dacryocystoplasty under endoscopic guidance. Clinical success was defined as complete remission of epiphora within follow-up period of 7-34 months (mean 25.2 months).*
RESULTS. *The authors performed balloon dacryocystoplasty in 24 eyes. The first procedure was successful in 20 of them and the clinic success rate was 83.3%. The technique was repeated in the one eye that recurred and as it ended successfully, the clinic success rate increased to 87.5%. In 17 of the 19 eyes (89.4%) in which balloon dacryocystoplasty was performed primarily, and in 4 of 5 eyes (80%) in which balloon dacryocystoplasty was performed secondarily after unsuccessful probing, the procedure was clinically successful. There was intermittent epiphora in 3 eyes (15%) and these were considered as recurrence.*
CONCLUSIONS. *This experience shows that balloon dilatation is a safe and effective treatment of congenital nasolacrimal duct obstruction as a primary procedure in children over 36 months of age and as a secondary procedure after failure of lacrimal system probing. As a result, balloon dacryocystoplasty can be an alternative treatment in older children and can be preferred to silicone intubation and dacryocystorhinostomy performed after unsuccessful probing. (Eur J Ophthalmol 2005; 179-85)*

KEY WORDS. *Balloon dacryocystoplasty, Probing, Silicone intubation, Congenital nasolacrimal duct obstruction*

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INTRODUCTION

Congenital nasolacrimal duct obstruction (CNLDO) is the most common disease of childhood affecting the lacrimal drainage system; its rate is between 6 and 20% in the newborn period, which is the result of the membranous obstruction of the Hasner valve (1-3). Congenital nasolacrimal duct obstructions can result with spontaneous resolution in early term or probing and silicone intubation can be required. Although different views have been reported, most studies have concluded that the success rate of probing and silicone intubation decreases with age and especially silicone intubation has some complications (4-16).

Less invasive treatment modalities with higher success rates are desirable. Becker et al were the first to perform balloon dilatation to the lacrimal drainage

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system, performed their operation in adult patients in 1989 and in affected children in 1991 (17, 18), and consequent studies were performed by other authors (19-22). In this study we investigated the efficiency of balloon dacryocystoplasty (BDCP) performed primarily for patients over 3 years of age with congenital nasolacrimal duct obstruction and secondarily for cases with unsuccessful probing.

MATERIALS AND METHODS

Balloon dilatation of the congenital nasolacrimal duct obstruction was attempted in 25 eyes of 21 patients presenting with epiphora between 2000 and 2002. The procedure was performed successfully in 24 eyes of 20 patients, age range 21-72 months. This technique could not be performed in one case who was 11 years old.

The diagnosis of CNLDO was clinical, as evidenced by epiphora beginning during the first few weeks of life, recurrent mucopurulent discharge, and cresting and reflux of contents of the lacrimal sac on pressure. The fluorescein dye disappearance test was used to confirm the diagnosis if the clinical signs did not corroborate the history. The dye disappearance test was performed by placing one drop of 2% fluorescein dye in each conjunctival cul-de-sac. After 5 minutes, the conjunctival cul-de-sac was examined for the presence of dye. Patients with complicating factors, such as congenital dacryocystocele, acute dacryocystitis, dacryocutaneous fistula, history of trauma to the nasolacrimal system, punctal or canalicular abnormalities, and craniofacial abnormality were not included in the study.

Balloon dilatation was performed under general anesthesia with endotracheal intubation in all cases. The cottonoid soaked in adrenaline (1/100,000) solution was placed in the region of inferior turbinate for 5 minutes. In all cases first the punctum was dilated and then the degree of obstruction was established with lacrimal lavage performed under endoscopy. We used the following instruments for BDCP procedure, listed in Figure 1A.

1) A 20-gauge soft plastic sheath (1.1 mm in diameter and 33 mm long) supported intraluminally with a guiding metal probe

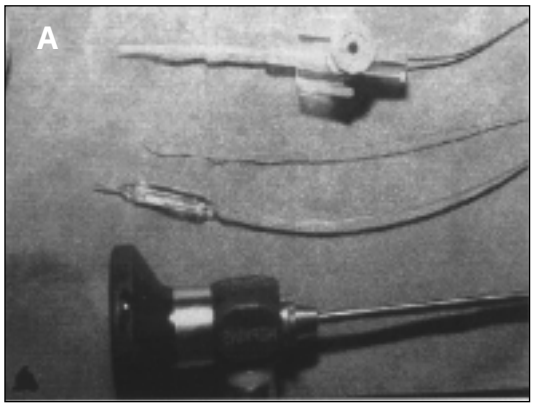
2)A 0.016-in steerable guide wire (Stubbie, Target Therapeutics, Fremont, CA): 175 cm long, with the distal 3-cm platinum tip tapering to 0.013 in.

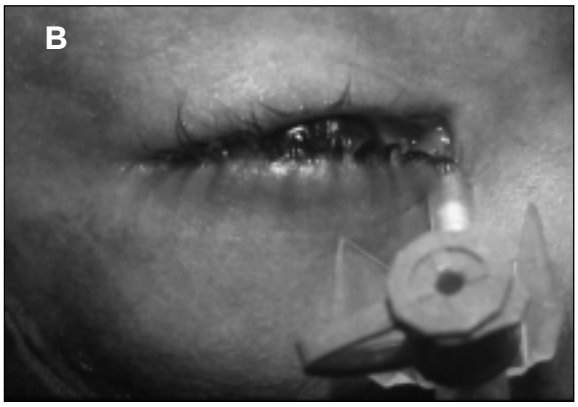
3) Monorail coronary balloon angioplasty catheter (Schneider, Zurich, Switzerland): 3 mm in diameter and 2 cm long.

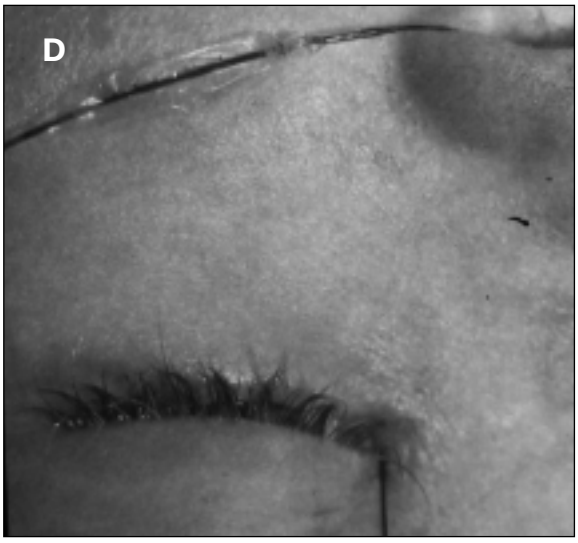
4) A 0-degree nasal endoscope.

For the BDCP, a 20-gauge soft plastic sheath supported intraluminally with a guiding metal probe was introduced through the superior canaliculus into the lacrimal system. The assembly is advanced to the level of obstruction, at which point the metal probe is retracted a few millimeters and the soft tip of the plastic sheath is gently manipulated to pass the obstruction site. After the metal probe was completely removed, saline was injected through the sheath and observed with 0-degree nasal endoscope. A 0.016-in guide wire was introduced through the sheath and advanced into the nasal cavity under nasal endoscopic guidance. A guide wire grasped and pulled out of nose. Plastic sheath was removed superiorly from the canaliculus. A deflated balloon angioplasty catheter was passed retrograde over the guide wire through the nasal aperture into distal nasolacrimal duct with endoscopic guidance and inflated with saline for 5 min at 8 atm pressure. The balloon was then deflated, pushed more proximally (lacrimal sac-nasolacrimal duct junction), and reinflated for 5 min at 8 atm pressure. The balloon could usually be palpated inferior to the medial canthal tendon in the lacrimal sac as it expanded during inflation. At the end of dilatation, the deflated balloon catheter was pulled out inferiorly through the nasal aperture and guide wire superiorly. For the last three cases, 2-0 Prolene sutures were used instead of guide wire (Fig. 1, B-E). The procedure was followed by irrigation of the lacrimal drainage system with saline through the inferior and superior canaliculus. The path of saline was observed to verify the patency with nasal endoscopy. All these procedures were performed by D.Y. with the assistance of K.C.

Balloon dacryocystoplasty was performed primarily in 19 eyes of 16 patients (the primary treatment group) and secondarily to 5 eyes of the 4 patients with unsuccessful probing (the secondary treatment group). The ages of the patients in the primary group ranged between 36 and 72 months (mean 43.9 months) and the range was 21 to 24 months (mean 22.2 months) in the secondary group. In the lacrimal lavage of the lower punctum performed under endo-







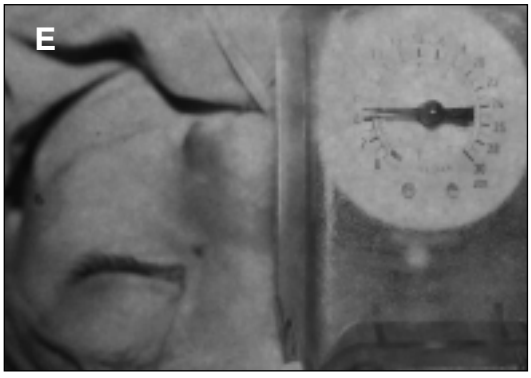


Fig. 1 - (A) *Overall view of all instruments used during balloon dacryocystoplasty.* **(B)** *Intubing the lacrimal drainage system with 20 gauge plastic sheath.* **(C)** *After moving forward the Prolene suture through the plastic sheath and removing it from the nasal cavity, extraction of the plastic cannula from the upper punctum.* **(D)** *Moving forward the deflated balloon catheter in the nasolacrimal duct over the Prolene suture.* **(E)** *Inflating the balloon in the nasolacrimal duct.*

scopic guidance before the procedure, we established that 20 eyes had no passage and 4 eyes had minimal passage with reflux of the upper punctum. Additionally, dilated lacrimal sac was present on two eyes of one patient. Except for one eye with a dilated lacrimal sac, BDCP was performed only once to all eyes included in our study. In the one eye with a dilated lacrimal sac, BDCP was repeated 6 weeks after the first procedure because of the recurrence of symptoms. All cases were followed up for 7 to 34 months (mean 25.2 months).

After the procedure, prednisolone acetate 1 mg/kg of body mass was administered intravenously. Topical tobramycin 0.3% and prednisolone acetate 1% eye drops every 2 hours were started on the first day and continued four times a day for 10 days. Oral ampicillin was administered to all patients for 7 days after the procedure.

Follow-up examinations were performed at first day, first weeks, first month, and then every 3 months after BDCP. At each follow-up visit, parents were questioned regarding the presence of symptoms and the child was examined for epiphora, crusting, swelling in the area of lacrimal sac, and regurgitation on pressure over the sac.

Clinical success was defined as complete remission of epiphora within the follow-up period of 7-34 months (mean 25.2 months) and continued remission at least for 4 months. If the first attempt at BDCP did not succeed, it was repeated.

RESULTS

Balloon dacryocystoplasty procedure was technically successful in 24 of 25 eyes; in one eye (the case who was 11 years old) the obstruction of the nasolacrimal duct could not be passed. The technical success rate of our study was calculated as 96%. In 20 of the 24 eyes the BDCP was successful after the first operation and the clinical success rate was 83.3%. In one patient with bilateral dilated lacrimal sac, after bilateral primer BDCP was performed the technique was repeated 6 weeks after the first procedure as the disease recurred in one eye. As the reoperation was successful, the clinical success rate increased to 87.5% (21 of 24 eyes).

After the follow-up period of 7-34 months (mean 25.2 months), 17 of the 19 eyes (89.4%) in which BDCP was performed primarily, and in 4 of 5 eyes (80%) in which BDCP was performed secondarily after unsuccessful probing, the procedure was clinically successful. The 3 eyes (15%) with intermittent epiphora were considered as recurrence.

Four of the 24 eyes included in our study had partial obstruction. In all 4 eyes (100%) the procedure resulted in success. In 17 of the 20 eyes (85%) with complete obstruction, the procedure was found to be successful. No major complications were observed in our study. However, in one case there was a mild swelling localized in the region of the lacrimal sac, which resolved spontaneously in 3 days.

DISCUSSION

The most common reason for CNLDO is the persistence of nasal and lacrimal epithelial cell layers at the level of Hasner's valve. Debris of epithelial cells leads to this obstruction in some patients (20). CNLDO spontaneously resolves in 80-96% of patients, thus no surgical procedure is required (2, 23, 24). Probing is preferred when there is no response to conservative therapy. However, it is frequently the procedure of choice for children with nasolacrimal duct obstruction in the first years of life and there are many different reports about the best timing of this procedure in the literature (5-8, 10, 20, 25).

Some studies reported that after 1 year of age, delaying the probing decreases the success linearly (6-8, 25). Katowitz and Welsh (25) reported the success rate of probing as 33% for patients older than 2 years of age, Havins and Wilkins (8) reported this same rate as 56% in patients over 18 months of age, and Sturrock et al (26) reported their success rate as 42% in patients over 2 years of age.

Paul and Shepherd (5) reported a different type of nasolacrimal duct obstruction seen in a subgroup of newborns and they named this type "probe-resistant" as the rate of success of probing is low. These patients do not respond to conservative therapy and thus they consist of a major proportion of the older patient group, leading to a decline in the success rate of probing. Another form of CNLDO is the atonic lacrimal sac in which the obstruction is diffuse as the lumen narrows along the whole duct (5).

In 2000, Honovar et al (7) evaluated the success of probing in the 60 cases they followed up for 24 to 186 months (mean 33 months). They concluded that although probing is a primary surgical procedure with high success rates for the patient group consisting of 2- to 3-year-olds, the success rate decreases significantly after 3 years of age. The authors cited Paul and Shepherd to explain this situation and claimed that complicated obstructions accumulate as the age increases. In this study, it was reported that the rate of tight obstructions was 12% in the age group consisting of patients 2 to 3 years old, 25% in the age group consisting of patients 3 to 4 years old, and 50% in the age group consisting of patients 4 years old and older. They reported the causes of probing failure as history of unsuccessful probing, bilateral CNLDO, dilated lacrimal sac, and tight obstructions.

As seen in the studies mentioned above, the success rate of probing is negatively correlated with the increase in age. Especially over the ages of 2 and 3 years, the success rate decreases significantly. This is the reason why we did not perform probing over 3 years of age and performed BDCP to patients under 3 years of age with recurrences after probing. Our success rate for patients over 3 years of age being 89.4% is far higher than the success rate of probing of the same age group reported in the literature. Thus this approach can be an alternative to probing in patients over 3 years of age.

Another treatment modality applied to patients with CNLDO is silicone intubation. Silicone intubation is an efficient choice of treatment in cases with unsuccessful probing and in the patient group with advanced age, and it has a temporary stent function in nasolacrimal duct (11-13). However, there are studies reporting that in silicone intubation, the rate of success increases as the time period of the silicone staying in the duct increases (14-16). Unfortunately, as this period increases, the rate of associating complications also increases.

Ruby and Lissner (13) investigated the cellular reaction on the tubes removed from the intubated patients and in their cytologic study demonstrated that as the time period of intubation increases, the inflammatory response increases. Dortzbach et al (11) reported that in the 63 cases they performed silicone tube, the rate of complications was 48%, and Anderson and Edwards (27) reported complications like nasal migration of the tube, canalicular erosion, and granuloma formation in 17 of 58 cases (29%). Ratliff and Meyer (28) reported that they had to remove the silicone tubes because of early dislocation in 7 of 40 eyes and had to repeat the silicone tubing in patients in whom epiphora continued. Ratliff and Meyer (28) stated that the success of silicone intubation depends mostly on the age of patients, and Leone and Van Gemert (16) highlighted that success of this approach decreases in patients over 4 years of age.

Complications after silicone tube intubation are loose loop formation, corneal irritation, erosion of the punctum, canalicular laceration, removal of the tube by the child, retraction of the distal silicone tube knot into nasolacrimal duct and sac, break or fall out of the tube by itself, dacryocystitis, granuloma of medial canthus, and conjunctivitis (29). Nevertheless in patients with hypertrophic inferior conchae, insertion of the tube can be technically difficult and fracturing of the conchae can be required and close monitoring of the patient is needed as long as the tube stays inserted. On the other hand, in most patients a second procedure is required for removing the tube under general anesthesia, and in patients in whom the tube could not be removed or a part of the tube is left back, the obstruction can recur and unexpected complications can come into existence (30).

The success of silicone intubation decreases with increase in age and there is risk of associated complications. On the other hand, our alternative treatment approach to BDCP has a higher success rate and the intraoperative and postoperative complications that may be associated with silicone intubation are avoided.

In 1991, Becker and Berry were the first to perform BDCP as an alternative surgical approach to silicone intubation for children with CNLDO (18). In another study the same authors performed BDCP to 61 eyes of 51 patients aged between 13 and 73 months (mean 26 months) and reported their success rate as 95%. In this study the rate of healing was 96% for the cases in which BDCP was performed primarily and 94% for the cases in which BDCP was performed secondary to unsuccessful probing and silicone intubation, thus the procedure is defined as efficient and safe when performed as a primary procedure in children older than 12 months and as a secondary procedure when probing and silicone intubation is unsuccessful. The

authors suggested that BDCP can be successful in cases with diffuse lacrimal stenosis in which probing was unsuccessful, as it causes dilatation along the nasolacrimal duct (20).

Cho et al (21) performed BDCP under fluoroscopy to 20 eyes of 16 patients with CNLDO aged between 12 and 78 months (mean 33 months) and determined that 15 eyes had complete obstruction at the Hasner valve, 3 eyes had complete obstruction at the lacrimal sac and at the junction of the nasolacrimal duct, and 2 eyes had partial obstruction. There were no major complications and the authors were successful in all eyes except one and concluded that no additional approach was required as there were no recurrences during the 16 months of follow-up.

Lueder performed primary BDCP to 76 patients aged between 18 and 116 months (mean 29 months) and reported success rate as 76% (37% excellent, 39% good) (31). Lueder published another study in which he performed secondary (after unsuccessful probing and silicone intubation) BDCP on 32 children aged between 11 and 141 months (mean 15 months) with persistent nasolacrimal duct obstruction and reported the rate of healing as 75% and thus concluded that BDCP in general is an efficient and safe procedure for eyes that underwent previous surgery and with persistent nasolacrimal duct obstruction (22).

Tao et al (32) performed BDCP to patients aged between 15 months and 9 years (mean 35.6 months) with success rate of 79.4% in the primary group and 74.4% in the secondary group and reported that this procedure is efficient when performed primarily in patients older than or equal to 18 months old and secondarily when probing and silicone intubation is unsuccessful.

In our study the success rate of BDCP was 89.4% when performed primarily for children older than or equal to 36 months (mean 43.9 months) and 80% when performed secondary to unsuccessful probing and these results are in accordance with the literature. However, when the ages of the primary surgery groups of the other studies and ours are compared, their patients are younger with smaller mean ages and this situation engenders the question of whether only probing would be sufficient in this age group. Taking this and the different rates of success of probing reported in the literature (5-7, 10, 20, 25) into account, we took the lower limit for primary surgery as 3 years because cases under 3 years old should be offered the chance to benefit from probing.

BDCP is defined as an efficient and safe surgical procedure that is extremely well tolerated (18-22, 31, 32). Observing no major complication in our study confirms that BDCP is a safe approach.

An important advantage of BDCP over probing and silicone intubation is its applying an efficient force to the lumen membrane. During probing and silicone intubation, the force is applied in parallel to the lumen membrane, longitudinally, and this only perforates the obstruction. During BDCP there is an efficient force along the entire nasolacrimal duct, applied directly and radially to the lumen membrane, and this leads to real dilatation. On the other hand, our performing the BDCP under endoscopic guidance, passing the region of obstruction by using plastic sheath supported with metal probes and using guide wire or 2-0 Prolene sutures, decreases the risk of false passage formation, which is the most important reason for recurrence after probing and silicone intubation. Apart from these, using 2-0 Prolene sutures instead of guide wire on the last group of cases led to a significant decrease in the cost of this approach. Continuing this study with Prolene suture instead of guide wire would be more appropriate.

BDCP is an alternative to probing over 3 years of age as its success rates are higher and an alternative to silicone intubation as its rate of both intraoperative and postoperative complication rates is lower. BDCP should be the first choice of therapy instead of other invasive procedures and approaches with high rate of complications (silicone intubation, dacryocystorhinostomy) in patients who are older and in patients with unsuccessful probing.

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