

Balloon catheter dilatation versus probing as primary treatment for congenital dacryostenosis

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ABSTRACT

Aim To compare the success rate of balloon catheter dilatation of the nasolacrimal duct with probing and irrigation as primary treatment for congenital dacryostenosis.

Methods Charts of all children who were operated on for the first time for congenital dacryostenosis during the years 2004 to 2006 were analysed and the outcomes compared. Surgical success was defined as absence of epiphora and mucous discharge, and of increased tear lake, at the last visit.

Results 68 children (114 eyes) underwent balloon catheter dilatation and 37 children (60 eyes) had probing. Children who had balloon dilatation were significantly older: mean age 55.98 ± 113.6 (range 9.0–728.0) months as opposed to 18.5 ± 6.5 (range 7.0–60.0) months, $p < 0.01$). After a mean follow-up time of 15.4 (range 4–32) months, 102 of 114 eyes were defined as successfully treated following balloon catheter dilatation (89.5% success rate) compared with 52 of 60 eyes following probing (86.7% success rate, $p = 0.581$). Five of six patients (80%) in which the #00 probe could only hardly be inserted into the nasolacrimal duct because of firm bone resistance failed in the probing group, as opposed to only 2/10 (20%) in the balloon catheter group ($p = 0.03$).

Conclusion Children who had balloon catheter dilatation had a slightly better success rate than those who had probing; however, this difference was statistically significant only for patients who had a relatively narrow nasolacrimal bone duct.

controls that had probing. They found that balloon dacryoplasty was successful in 90% of patients as opposed to an 86% success rate for probing ($p = 0.2$). This study had several limitations: the sample size was small, the follow-up time was relatively short and different between the balloon catheter and probing groups (3 and 9 months, respectively), and each group was operated on by a different surgeon.

The aim of this study was to compare balloon catheter dilatation with conventional probing and irrigation for the treatment of congenital dacryostenosis by evaluating long-term results in a large group of patients treated by one surgeon.

METHODS

This retrospective study included all children who were operated on for the first time by the senior author (Y M) due to dacryostenosis between 2004 and 2006. Patients from both the Paediatric Ophthalmology Service in Assaf Harofeh Medical Center, Zerifin, Israel, and from the operating surgeon's private practice were enrolled. Diagnostic criteria for dacryostenosis were a history of frequent tearing or purulent discharge and positive dye-disappearing test.

Balloon catheter dacryoplasty and conventional probing were offered to all parents; however, since during that time the cost of the balloon catheter was not reimbursed by the Israel Ministry of Health, parents who elected to use the balloon catheter had to pay for it, and this might have influenced their decision.

Surgical technique

Balloon catheter

For dacryoplasty we used the LaciCath balloon catheter (Quest Medical, Allen, Texas, USA). This catheter has a 2 or 3 mm silicone balloon assembled near its tip. The silicone balloon can be inflated using hydrostatic pressure to a maximal width of 2 or 3 mm while inside the lacrimal system, thus allowing dilatation of the lacrimal duct and valves. We used the 2 mm balloon for children younger than 30 months and the 3 mm balloon for children older than 30 months. All children who underwent balloon catheter were treated pre-operatively for 3 days with oral antibiotics (amoxicillin, 30 mg/kg per day) and with dexamethasone 0.1%–phenylephrin 0.12%–neomycin 0.5% eye drops (Dexefrin; Fischer Pharmaceuticals Ltd, Tel Aviv, Israel). During the surgery i.v. ampicillin (50 mg/kg per dose) and dexamethasone sodium phosphate (2 mg/kg per dose) were administered. After the operation oral prednisone 1 mg/kg and oral amoxicillin treatment was continued for 3 days, and the dexamethasone

Congenital dacryostenosis is a common disorder affecting 6% of all newborn infants.¹ In most children the epiphora resolves by the age of 1 year with the help of conservative measures such as topical massage and local antibiotic treatment.² It is widely accepted that if the epiphora persists beyond the age of 1 year, surgical treatment is indicated.³ Balloon catheter dilatation of the nasolacrimal duct is a relatively new treatment for congenital dacryostenosis first described by Becker *et al.*⁴ This treatment involves probing of the distal nasolacrimal duct with a catheter on which a 2–3 mm width silicone balloon is assembled. After insertion of the catheter, the balloon is inflated under hydrostatic pressure, which allows maximal dilatation of the duct and of the valve of Hasner. We have found only one study in the literature that compared the results of probing with the results of balloon dacryoplasty as primary treatment for congenital dacryostenosis. Gunton *et al.*⁵ retrospectively paired 29 eyes that had balloon catheter dilatation with 29 eyes of age-matched

0.1%—phenylephrin 0.12%—neomycin 0.5% eye drops three times per day together with nose decongestant spray twice per day were given for 1 week.

Before surgery, the nose was packed with a tampon soaked in diluted epinephrine (1:10 000) solution. The puncti were dilated and a #00 probe was inserted through the upper punctum, through the lacrimal sac and duct and into the nose. The probe was felt with a metal on metal sensation in the nose using #2 probe and retrieved out of the lacrimal system. The balloon catheter was passed through the superior punctum, canaliculus, sac and into the nasolacrimal duct down to the nasal floor. Presence of the catheter in the nose was confirmed. The inflation was performed according to the manufacturer's protocol (Quest Medical, Inc., LacriCATH Procedures, <http://www.lacricath.com/procedure/>). Briefly, the balloon was inflated for 90 s, deflated, inflated for additional 60 s, deflated again, withdrawn 5 mm, and the inflation/deflation procedure was repeated. Fluorescein was used to irrigate the lacrimal system and recovered in the nose with a flexible clear feeding tube used as a suction catheter.

Probing and irrigation

No pre- or intra-operative treatment was given. The puncti were dilated and #00 probe was inserted into the nasolacrimal duct and then a #0 probe and #1 probes were inserted if possible. The duct was irrigated with fluorescein-stained saline. Post surgery, children were treated for 1 week with dexamethasone 0.1%—phenylephrin 0.12%—neomycin 0.5% eye drops (Dexefrin; Fischer Pharmaceuticals Ltd) three times per day and with nasal decongestant spray twice per day.

All procedures were performed under general anaesthesia. If a #00 probe could not be inserted, all procedures were aborted and a silicone tube was implanted instead. If a #00 probe could be inserted with difficulty into the naso-lacrimal duct because of a narrow bone canal, the patient was noted as having 'bony resistance' to probing. Patients from both study groups were followed in the clinic with their first visit scheduled for 2 weeks following the procedure. Surgical success was defined as complete resolution of signs of dacryostenosis (epiphora, mucous discharge and increased tear lake) at the last visit. Children who had frequent epiphora and/or had recurrent infections or purulent discharge despite surgery were classified as treatment failure. Some of these children had additional surgery, usually silicone tube implantation.

Statistical analysis

In order to compare categorical variables between the two procedure types, the χ^2 test as well as the Fisher's exact test were applied. The comparison of the procedure types for quantitative variables was carried out using the independent samples t test and the non-parametric Mann–Whitney test. In order to adjust for intra-subject correlations between operated eyes, some statistical tests were applied both to the weighted data and the unweighted data.⁶ When the data were weighted, a weight of

0.5 was assigned to eyes whose subjects were operated on both eyes, and a weight of 1.0 to eyes whose subjects were operated on one eye only. All tests applied were two-tailed, and a p value of 5% or less was considered to be statistically significant.

RESULTS

Study group characteristics are reported in table 1.

Sixty-eight children (114 eyes) had balloon catheter dilatation and 37 children (60 eyes) had conventional probing and irrigation. Children who had balloon catheter dilatation were significantly older than the children who had probing: mean age 55.98 ± 113.6 (range 9.0–728.0) months as opposed to 18.5 ± 6.5 (range 7.0–60.0) months, $p < 0.01$. In the balloon catheter group, after a mean follow-up of 15.4 (range 4–32) months, 12 eyes (10.5%) were classified as treatment failure due to persistent signs of dacryostenosis (89.5% success rate). Overall balloon catheterisation failure in patients with bilateral dacryostenosis was 10 of 92 eyes (10.8%) and two of 22 eyes (9.0%) in patients with a unilateral problem. Three eyes of two patients with bilateral involvement needed additional surgery after failed catheterisation.

In the probing group, which had statistically similar mean follow-up time (17.3 (range 5–32) months, $p = 0.44$), eight eyes (13.3%) were classified as treatment failure (86.7% success rate). All probing failures were among patients with bilateral dacryostenosis (eight of 46 eyes (17.3%)). Two eyes of two patients with bilateral involvement needed additional surgery after failed probing. There was no statistically significant difference in the success rate between the balloon and probing groups ($p = 0.581$). Hard bony intraoperative resistance was noted in 10 eyes in the balloon catheter group, and two of them failed the procedure (20%). In contrast, six patients in the probing group had bony resistance, and five were classified as failure (80%, Fisher's exact test $p = 0.03$). Age was not a significant factor with regard to outcome in each of the groups. No complications were noted in both groups.

DISCUSSION

Probing of the lacrimal duct has been considered to be the standard treatment for congenital lacrimal duct obstruction for many years, as it is simple to perform, quick and effective.^{2–5} Although advocated by some,^{7–8} alternative treatments, such as silicone tube insertion, are not usually recommended for primary treatment: silicon tube insertion may cause complications and necessitate an additional procedure for removal of the tube. Balloon dacryoplasty, however, first reported by Becker *et al*,⁴ maybe an alternative treatment to conventional probing as it is simple to perform and does not necessitate implantation of foreign materials such as silicone tubes.

In our hands, balloon dacryoplasty had excellent results, with a success rate of 89%. These results of primary treatment for congenital dacryostenosis are similar to those reported by Lachmund *et al* (90%),⁹ Yuskel *et al* (89.4%),¹⁰ Chen *et al* (79%),¹¹ Leuder *et al* (82%),¹² Tao *et al* (82%)¹³ and Repka *et al* (82%).¹⁴

The overall success rate of simple probing in our study was slightly lower (86%) than balloon dacryoplasty, but similar to the rates previously reported by Ciftci *et al* (76%)¹⁵ Casady *et al* (77%)¹⁶ and Repka *et al* (78%).¹⁷

One explanation for difference in success rate between the treatment groups in our study may be the pre-, intra- and postoperative treatment that we used. Children who underwent balloon dacryoplasty were treated systemically and topically with steroids and antibiotics before and after surgery with the

Table 1 Study group characteristics

	Probing and irrigation	Balloon catheter
Patients, n (eyes)	37 (60)	68 (114)
Sex: female, n (%)	18 (48.6)	35 (51.5)
Laterality, bilateral, n (%)	23 (62.1)	46 (67.6)
Laterality, unilateral, n (%)	14 (37.8)	22 (32.3)
Age at surgery (months)	18.5 ±	55.98 ±
(mean ± SD, range)	6.5 (7.0–60.0)	113.6 (9.0–728.0)

addition of nasal decongestants. In contrast, children who underwent probing received postoperative treatment composed only of topical steroids, antibiotics and nasal decongestants. As shown by Paulsen *et al*,¹⁸ bacterial inflammation may have a significant role in causing swelling of the mucous membrane with reactive hyperaemia and temporary occlusion of the lacrimal passage. Prevention of inflammation in the immediate peri-operative period may therefore influence the results. In addition, as shown by Narioka *et al*,¹⁹ the use of adrenergic agents such as epinephrine, in addition to the prevention of bleeding and oedema, may cause dilatation of the lacrimal duct that may help in preventing re-stenosis. Although the use of systemic steroids in the postoperative period following balloon dilatation was not shown to influence the results in one report,²⁰ we decided to continue using this regimen in order to prevent postoperative oedema.

We acknowledge the fact that this difference in peri-operative treatment between groups may cause bias; however, since systemic treatment is uniformly not advocated following probing, we decided not to change this well-established convention. A prospective standardised comparative study using similar medication for both groups may be needed to overcome such potential bias.

It is accepted that older children have a less favourable outcome of probing²¹ and this was explained to the parents before surgery. We believe that this was the reason for the age difference between groups in our study: parents of older children elected the balloon catheter option significantly more than parents of younger babies. However, age was not a significant factor with regard to the success rate in each of the study groups, and this is similar to observations reported in other studies.^{5 11}

Our observations were very similar to those from the study conducted by Gunton *et al*,⁵ who described that balloon dacryoplasty was successful in 90% of patients as opposed to a success rate of 86% for probing. In our study, we compared a large series of patients who were all operated on by one surgeon, with a longer follow-up time. Although patients were not randomised for each group, the bias of treatment assignment was based on the parents' decisions and not on medical staff opinion. In fact, this treatment selection bias in our study was in favour of successful results of the probing group: most parents of relatively young patients, whose outcome is reported to be better, chose probing as primary treatment, while parents of older patients tended to choose the balloon dacryoplasty as their preferred treatment modality. The fact that the balloon catheter group achieved similar results despite this bias might further support the efficacy of this treatment option.

An interesting observation was that in 5/6 patients (80%) in which the #00 probe was inserted with difficulty because of a narrow nasolacrimal bone duct failed the procedure, while only 20% of those who had this difficulty in the balloon catheter group were classified as failure ($p=0.03$). This difference may imply that the inflation of the balloon catheter inside a relatively narrow nasolacrimal duct may assist in dilating it, thus improving the outcome in this subset of patients.

One concern of many parents when choosing the balloon catheter option was whether this treatment carries additional risk in comparison to simple probing. Theoretically this may be true, as the procedure is more time-consuming and necessitates systemic treatment. However, we encountered no complications in our study in both methods. Furthermore, of hundreds of reported procedures of balloon dacryoplasty in the literature, there is only one report of complication: orbital emphysema that

resolved without damage.²² In addition, it has been shown that no permanent tissue damage is caused by the catheter in histological studies.²³

Another concern regarding this procedure is the cost of the balloon catheter, which may be a heavy burden on the health-care system. As previously described by Lueder,¹² in almost all of our cases we managed to use the same catheter for both eyes, thus saving 50% of the cost. Despite that, the high cost of the device was a limiting factor for its use by many patients.

In conclusion, both probing and balloon catheter dilatation of the tear duct are safe and effective procedures as primary treatment for congenital dacryostenosis. We found that balloon catheter dilation had a slightly better outcome, but this difference was statistically significant only for patients who had a relatively narrow nasolacrimal bone duct.

Competing interests None to declare.

Ethics approval This study was conducted with the approval of the Assaf Harofeh Medical Centre Ethics Review Board.

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