• Clinical Research •

# Outcomes of lacrimal sac hydrostatic pressure application in congenital nasolacrimal duct obstruction

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## Abstract
● **AIM:** To assess the success rate of lacrimal sac hydrostatic pressure application (HPA) maneuver, a conservative office procedure for treatment of congenital nasolacrimal duct obstruction (CNLDO).

● **METHODS:** The medical records of pediatric patients, 36mo old or younger, diagnosed with CNLDO between the years 2016-2022, were retrospectively reviewed. In all children, HPA was performed by a pediatric ophthalmologist. Success was defined as the resolution of epiphora and discharge within 48h of the intervention.

● **RESULTS:** A total of 281 eyes (194 patients) with CNLDO underwent HPA. Follow-up data were available for 261 eyes (179 patients, 50.3% male) and these patients were included in the analysis. The mean follow-up time was 11.6±13mo. Ninety-seven patients (54.2%) had unilateral nasolacrimal duct obstruction, while 82 patients (45.8%) had bilateral CNLDO. The mean age at the time of HPA was 5.8±5.9mo. Complete resolution of symptoms was achieved in 102 (39.1%) eyes. Patients 6mo old or younger at the time of HPA had a significantly higher success rate compared to patients older than 6mo (43.7% *vs* 30.9%, $P$=0.04). Younger age at the time of pressure application was associated with a higher resolution rate of CNLDO (OR 0.93, $P$=0.004). Sex assigned at birth, prematurity, laterality of the obstruction and type of symptoms (epiphora, discharge) were not correlated with success. A second HPA was performed in 46 eyes, with resolution of symptoms in 12 eyes (26.1%).

● **CONCLUSION:** Hydrostatic pressure applied on the lacrimal sac by an experienced ophthalmologist or an experienced pediatrician may be an effective treatment for CNLDO. We recommend HPA as an initial active conservative approach in all pediatric patients with CNLDO, especially those younger than 6mo.

● **KEYWORDS:** congenital nasolacrimal duct obstruction; Crigler method; lacrimal surgery; ocular hydrostatic pressure application; pediatric ophthalmology

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## INTRODUCTION

Congenital nasolacrimal duct obstruction (CNLDO) is an ocular condition affecting 6%-20% of infants less than one year old. The patients typically present with symptoms of persistent epiphora and discharge beginning at the neonatal period[1-3]. The most common cause of CNLDO is a distal mechanical obstruction caused by an obstructive membrane at the valve of Hasner, with other less common causes including abnormalities in the nasal bony structure development, narrowing of the distal part of the nasolacrimal duct and proximal obstruction in the Rosenmüller valve area[4]. Premature infants have a higher prevalence of CNLDO, likely due to the distal membrane's patency happening late in intrauterine development[2,4-6].

While spontaneous resolution rates are high and range between 78.4%-96%[1,7-8], the symptoms of CNLDO can cause discomfort and interfere with the infant's quality of life. Parents tend to seek medical care at pediatric clinics, searching for treatments to relieve the child's symptoms. Pediatricians can recommend conservative treatment or refer them to an ophthalmologist[1]. The conservative approach is the recommended one for most patients, specifically younger patients, and it includes observation, lacrimal sac massage performed by the parents and hydrostatic pressure application (HPA) performed by an experienced ophthalmologist or an experienced pediatrician. The use of antibiotic eyedrops is common, although controversial, and currently not

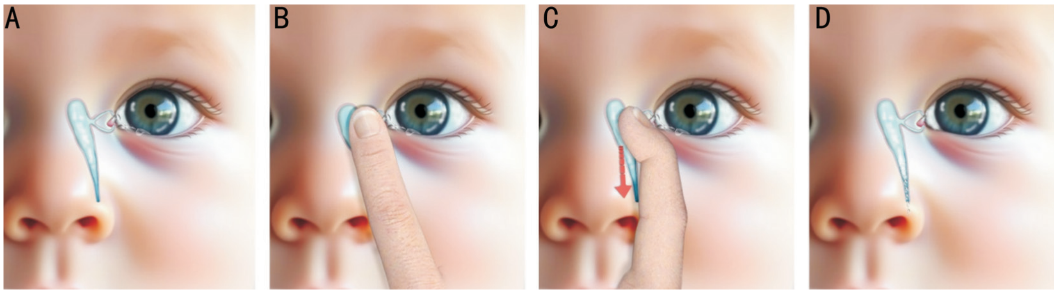


**Figure 1 Hydrostatic pressure application (HPA) technique** A: The anatomy of the nasolacrimal drainage system; B: The physician's forefinger finger is placed on the area overlying the lacrimal sac; C: The finger is pressed inwards and downwards. The arrow shows the motion of the compressed fluid within the nasolacrimal duct; D: The obstructing membrane at the valve of Hasner is ruptured, and the accumulated fluid can now drain into the inferior nasal meatus.

recommended routinely[9-10]. If the conservative approach is unsuccessful and the symptoms persist at the age of one year, surgical intervention is recommended[11].

The technique of HPA on the lacrimal sac was first described by Crigler[12]. The maneuver aims to distribute the pressure exerted by the accumulated fluid in a manner that causes the distal membrane to rupture and the obstruction to resolve. The few studies describing the efficacy of HPA vary in their methodology. In most, the pressure application was performed daily by the parents[13-19], while only in a single study the procedure was performed by a physician in the clinic[20]. Moreover, in several studies success was defined as the resolution of CNLDO symptoms with no defined time range from the procedure[13-19], hindering the distinction between actual success of the intervention and spontaneous resolution.

The role of HPA, when performed by a physician, in promoting resolution of CNLDO, shortening symptom duration and reducing the need for surgery may not be consistently emphasized in practice. Our study aims to assess the success rate of the lacrimal sac HPA maneuver for the treatment of CNLDO and to raise awareness among physicians to its potential benefits.

## PARTICIPANTS AND METHODS

**Ethical Approval** The research adhered to the tenets of the Declaration of Helsinki and the study protocol was approved by the Institutional Review Boards of Wolfson Medical Center (No.0084-21-WOMC) and Maccabi Healthcare Services (No.0036-21-MHS). Informed consent was waived due to the retrospective nature of the study.

**Study Setting** In this retrospective study, the medical records of all pediatric patients diagnosed with CNLDO between the years 2016-2022 were reviewed. Patients were treated by a single experienced pediatric ophthalmologist (Spierer O) either at the Pediatric Ophthalmology Unit at Wolfson Medical Center or at the senior author's clinic at Maccabi Healthcare Services. Patients treated with HPA on the lacrimal sac were identified, and the success rate of the intervention was assessed.

**Patient Population** Patients included in the study were 36mo or younger at the time of HPA. The diagnosis of CNLDO was made based on a medical history of epiphora and/or discharge symptoms beginning at the neonatal period as reported by the parents, with clinical signs of nasolacrimal duct obstruction: high tear meniscus, ocular discharge and abnormal fluorescein dye disappearance test. Patients with other ocular morbidity such as strabismus or congenital cataracts and patients presenting with dacryocystitis, dacryocystocele or punctal agenesis, were excluded.

**Hydrostatic Pressure Application Technique** The HPA was performed in the clinic using the following technique: While the infant's head was held by the parent, the physician placed his forefinger on the area overlying the lacrimal sac and the common canaliculus, in a position that would block the canaliculus and prevent regurgitation of fluids through it. The physician then firmly pressed the edge of the forefinger downwards, causing the compressed fluid within the lacrimal sac to transmit the pressure to the sac's walls and to the nasolacrimal duct, ultimately rupturing the membrane at the valve of Hasner, the weakest point (Figure 1). In a follow-up visit, repeated HPA was performed in some patients who did not achieve resolution after the first intervention.

**Success Definition** The success of HPA was defined as the resolution of epiphora and discharge within 48h of the intervention. The parents of patients who did not return for a follow-up visit after the procedure were contacted by telephone and asked to answer a questionnaire to learn about the outcomes of the procedure. Parents who could not be reached were considered lost to follow-up and the patients were excluded from the study.

**Statistical Analysis** Descriptive statistics were presented as mean±standard deviation along with median and range for continuous variables. Categorical values were shown with their relative percentage. The Chi-squared or Fisher's exact test was used to compare success rates between different age groups and patient characteristics. A logistic regression model was used for possible predicting indices: child's age, sex assigned at birth, laterality of obstruction, prematurity, epiphora and discharge symptoms. The results are shown with 95% confidence intervals (CI). A two-sided *P*-value of less than 0.05 was considered statistically significant. Analyses were performed using Python programming language (Python Software Foundation, Wilmington, DE, USA).

## RESULTS

A total of 281 eyes with CNLDO (194 patients) underwent HPA. Follow-up data were available for 261 eyes (179 patients, 50.3% male) and these patients were included in the analysis. The mean follow-up time was 11.6±13mo. Ninety-seven patients (54.2%) had unilateral nasolacrimal duct obstruction, while 82 patients (45.8%) had bilateral CNLDO. The mean age at the time of HPA was 5.8±5.9mo (median 4mo, range 0-28mo).

Of the 261 eyes that underwent HPA, 102 (39.1%) experienced complete resolution of symptoms within 48h. Patients were divided into age groups according to their age at the time of intervention: patients aged 6mo or less at the time of HPA had a statistically significant higher success rate (43.7%) compared to patients older than 6mo (30.9%, *P*=0.04; Table 1). The resolution rates in different age groups are presented in Figure 2. In a multivariate logistic regression model, younger age at the time of pressure application was associated with a higher success rate and resolution of CNLDO [odds ratio (OR) 0.93, *P*=0.004; Table 2]. Sex assigned at birth, prematurity, laterality of obstruction and type of symptoms (epiphora, discharge) were not associated with resolution following HPA.

In 46 eyes (of 37 patients, 56.8% male) in which the CNLDO did not resolve after the initial HPA, a second HPA was performed. The mean age at the time of the second attempt was 5.6±3.4mo (median 4mo, range 3-14mo), and the mean interval between the first and second HPA was 11.1±6.9wk (median 9.7wk, range 2.6-37.9wk). Twelve eyes (26.1%) had complete resolution after the second HPA. No significant difference in success rate was found in the distribution across different age groups (*P*=0.60). No adverse events, such as a procedure-related ocular infection, were observed.

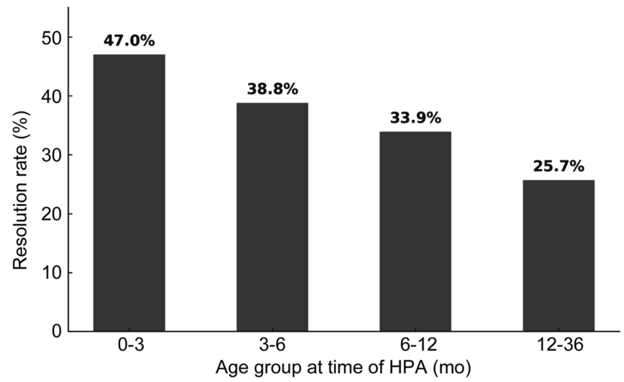


**Figure 2 Resolution rates in different age groups after the first HPA** The success rate of each age group is shown in percentages. HPA: Hydrostatic pressure application.

**Table 1 Correlation of demographic and clinical factors with CNLDO resolution following the first HPA**

| Category | No. of eyes | Success | *P* |
|---|---|---|---|
| Total | 261 | 102 (39.1%) | |
| Age | | | 0.04 |
| <6mo | 167 | 73 (43.7%) | |
| 6-36mo | 94 | 29 (30.9%) | |
| Sex assigned at birth | | | 0.29 |
| Male | 131 | 47 (35.9%) | |
| Female | 130 | 55 (42.3%) | |
| Uni/bilateral | | | 0.58 |
| Unilateral | 97 | 40 (41.2%) | |
| Bilateral | 164 | 62 (37.8%) | |
| Laterality | | | 0.48 |
| Right eye | 131 | 54 (41.2%) | |
| Left eye | 130 | 48 (36.9%) | |
| Prematurity | | | 0.77 |
| No | 247 | 96 (38.9%) | |
| Yes | 14 | 6 (42.9%) | |
| Epiphora | | | 0.27 |
| Present | 239 | 91 (38.1%) | |
| Absent | 22 | 11 (50%) | |
| Discharge | | | 1 |
| Present | 254 | 99 (39.1%) | |
| Absent | 7 | 3 (42.9%) | |

CNLDO: Congenital nasolacrimal duct obstruction; HPA: Hydrostatic pressure application.

## DISCUSSION

In this study we investigated the success rate of HPA in CNLDO and examined the association of possible predicting indices with resolution. We showed that 40% of eyes had complete resolution of symptoms within 48h of the initial HPA procedure. Patients aged 6mo or younger exhibited a significantly higher success rate than older children. A logistic regression model demonstrated a significant association between the younger age at the time of the procedure and CNLDO resolution. Although the maneuver might cause temporary discomfort, the chances of a rapid resolution following the procedure are high, as demonstrated by our results.

Crigler's first description of the HPA method was published in 1923[12], where a success rate of 100% was reported over a seven-year period, though the methodology was not detailed. Since then, various studies examined the potential advantage of HPA in resolving CNLDO. It is important to note that the terminology regarding this procedure varies in the literature, being referred to as Crigler's maneuver[16,18,20], lacrimal sac compressions[15-16,19], or lacrimal massage[14,17,19], with no

**Table 2 Multivariate logistic regression model assessing demographic and clinical factors associated with CNLDO resolution following the first HPA**

| Category | OR (95%CI) | *P* |
|---|---|---|
| Age (increment of 1mo) | 0.93 (0.88-0.98) | 0.004 |
| Sex assigned at birth | | 0.21 |
| Male | 1 | |
| Female | 1.39 (0.83-2.32) | |
| Uni/bilateral | | 0.51 |
| Unilateral | 1 | |
| Bilateral | 0.84 (0.49-1.42) | |
| Laterality | | 0.53 |
| Right eye | 1 | |
| Left eye | 0.85 (0.51-1.41) | |
| Prematurity | | 0.92 |
| No Prematurity | 1 | |
| Prematurity | 1.06 (0.33-3.36) | |
| Epiphora | | 0.45 |
| Absent | 1 | |
| Present | 0.70 (0.27-1.79) | |
| Discharge | | 0.34 |
| Absent | 1 | |
| Present | 0.45 (0.09-2.34) | |

CNLDO: Congenital nasolacrimal duct obstruction; HPA: Hydrostatic pressure application; OR: Odds ratio, CI: Confidence interval.

clear distinction between a pressure application administered in a clinical setting by a physician and a lacrimal massage performed at home by the parents. While our research presents HPA as an office procedure performed by a physician, most of the existing literature on CNLDO management has focused on parent-administered lacrimal massage, as summarized in Table 3[14-20]. These observational studies reported resolution rates ranging between 81%-96.2%[14-18]. However, many of these studies lacked standardized follow-up intervals or control groups, and presented a combined resolution rate by the age of 12mo, making it challenging to distinguish the actual effect of the massage from the naturally high rate of spontaneous resolution in CNLDO[1,7]. A recent randomized controlled trial did not show a benefit to the parent-administered lacrimal massage group compared to the control group that received topical antibiotics[19]. The authors suggested that the results could stem from an incorrect or inconsistent massage application by the caregivers, with high variations in the massage technique. To our knowledge, only one study of HPA for CNLDO administered by a physician was published, reporting a resolution rate comparable to our findings[20]. This study found a higher rate of resolution in younger patients, which is in agreement with our results.

We think it is imperative to differentiate between massages performed by the parents and HPA delivered by an experienced physician. When performed by the parents, there is no

**Table 3 Summary of the main publications regarding lacrimal sac HPA**

| Authors (y, country) | Study design | Intervention type | Population (sample size) | Definition of success | Follow-up time | Outcomes |
|---|---|---|---|---|---|---|
| Stolovitch and Michaeli[20] (2006, Israel) | Prospective | Hydrostatic pressure applied by a pediatric ophthalmologist | 742 patients (no control) | Resolution of symptoms within 2d from the intervention | Telephone within 1wk of intervention | 46% resolved after first attempt; 35% (42/120) resolved after second attempt |
| Karti *et al*[14] (2016, Türkiye) | Retrospective | Lacrimal sac massage by parents, 10 presses/time, 3×/day | 36 eyes (28 intervention, 8 control) | Improvement of epiphora and FDDT | Monthly observation until the age of 12mo | 96.2% resolved in intervention group by the age of 12mo; 77.7% resolved in control group |
| Bansal *et al*[15] (2021, India) | Retrospective | Crigler's lacrimal sac compressions by parents, 10 strokes/time, 4×/day | 795 patients (no control) | Resolution of epiphora and discharge, normal tear meniscus and FDDT | Follow-up intervals not indicated | 81% resolved by the age of 1y; no difference between age groups at time of initiation |
| Lekskul *et al*[16] (2022, Thailand) | Retrospective | Lacrimal sac compressions by parents, 10 strokes/time, 4×/day | 469 patients (no control) | absence of symptoms and/or signs of CNLDO | Follow-up intervals not indicated | 90.62% resolved; younger age associated with higher success |
| Nanda and Sarkar[17] (2022, India) | Prospective | Lacrimal sac massage by parents, 10 strokes/time, 4×/day, ±topical antibiotics | 853 patients (no control) | Improvement of epiphora and FDDT | Monthly observation until the age of 12mo | 86.75% resolved by the age of 12mo |
| Srivastava *et al*[18] (2023, India) | Prospective | Lacrimal sac massage by the parents, 2-3×/day, ±topical antibiotics | 335 eyes (no control) | No clear definition provided | Assessment at 4 and 7mo after intervention initiation | 83% resolved after 7mo from intervention initiation |
| Asano *et al*[19] (2024, Japan) | Randomized controlled | Crigler massage by parents, 10 strokes/time, 2×/day each day until resolution or 1mo, with topical antibiotics to all patients | 102 patients with unilateral CNLDO (51 intervention, 51 control) | Disappearance of epiphora, discharge, high tear meniscus and negative FDDT | Follow-up at 1mo from intervention initiation | 31.4% resolved in the massage group; 33.3% resolved in the control group. No significant difference between the groups |

HPA: Hydrostatic pressure application; FDDT: Fluorescein dye disappearance test; CNLDO: Congenital nasolacrimal duct obstruction.

reassurance that the massage technique is executed correctly. Parents' understanding of the lacrimal drainage system anatomy is limited, and as they are naturally reluctant to cause discomfort to the infant, they are less likely to perform the massage appropriately with the required amount of force. Hence, we do not recommend additional home treatment with lacrimal massage between medical appointments. When HPA is administered with the right technique and adequate force, a single application can be sufficient to induce resolution of CNLDO. Furthermore, based on the current understanding, performing lacrimal massage multiple times a day, as recommended by many physicians to the parents, may not be logically coherent. Since CNLDO is mostly due to a distal mechanical obstruction caused by a membrane at the valve of Hasner, if the pressure application is not executed adequately with the required force to distribute the pressure exerted by the accumulated fluid, the distal membrane will not rupture, regardless of the number of massage attempts performed. Also, adherence to frequent lacrimal massage for several months can be challenging and may cause pain and discomfort to the infant as well.

The studies that showed favorable results with lacrimal massage applied by the parents, may reflect, in part, the known natural history of high spontaneous resolution rate, as the follow-up intervals spanned several months or the total resolution rate by the age of one year was presented[14-16,18]. By comparison, resolution of symptoms within 48h of HPA, as defined in our study, cannot be attributed to the natural history course alone. Given that the rate of spontaneous resolution in CNLDO is high, some of the eyes that resolved after HPA might have eventually resolved spontaneously. However, this process may extend over several months, during which the infant and caregivers experience ongoing discomfort and symptoms. In contrast, a successful HPA can resolve symptoms promptly, reducing distress for both the infant and parents. Moreover, early resolution of CNLDO might contribute to reducing the risk of developing refractive errors. While some studies have demonstrated a higher incidence of anisometropia in patients with CNLDO[21-22], others have found no significant difference in amblyopia risk factors compared with controls[23] or between early and delayed intervention groups[24]. Further prospective studies are required to clarify the impact of earlier resolution on anisometropia and amblyopia risk factors.

A one-time HPA can be sufficient in many patients. If the first HPA fails, a second attempt may be reasonable. According to our outcomes, the second HPA had a lower success rate of 26.1%, with no significant difference among age groups. It is not clear why a second HPA, which was administered by the same physician using the same technique, succeeded in resolving CNLDO, while the first HPA failed. It is also unclear why in some infants and young children HPA works and in others not. Some of the failures might be attributed to the presence of complex CNLDO, associated with bony obstruction or nondevelopment of the nasolacrimal duct. However, such anomalies are usually identified after failure of conservative treatment or during surgical intervention and were not documented in our cohort.

The lack of a control group is the main limitation of our study. As HPA is administered to all patients with CNLDO in our practice as a standard of care, there are no patients who did not undergo HPA. In addition, the relatively small size of the second pressure application sample group may have influenced the outcomes. Further research including a larger patient cohort can be conducted to evaluate the efficiency of repeated HPA maneuvers.

We recommend an active conservative approach with hydrostatic pressure applied by a physician in patients with CNLDO, especially in infants younger than 6mo of age. While many physicians choose to observe only in these cases, an early HPA as described by Crigler can resolve the obstruction and eliminate the typical epiphora and discharge. This approach not only shortens the duration of symptoms but can also prevent the need for future surgery.

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