Heliyon 10 (2024) e36245

Contents lists available at ScienceDirect

Heliyon

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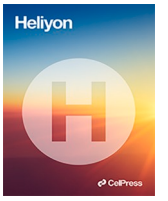

Research article

Probing and nasolacrimal intubation outcomes in children over 18 Months of age with congenital nasolacrimal duct obstruction

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ARTICLE INFO

Keywords:
Nasolacrimal duct obstruction
Epiphora
Probing
Nasolacrimal intubation
Lacrimal drainage
Monoka
Masterka

ABSTRACT

Purpose: To evaluate how risk factors impact success rates of initial probing and nasolacrimal duct (NLD) tube intubation in children over 18 months of age with congenital nasolacrimal duct obstruction (CNLDO).

Methods: This cohort study included 98 CNLDO patients aged 18 months to 10 years who underwent NLD probing with stent insertion. We employed the multivariate frailty model as our final model to conceptually elaborate on our correlated eye data, with the primary outcome measure evaluating the success rates of probing and tube intubation. Factors such as age, probing complexity, tube type, prior surgeries, and passive smoking were considered in the evaluation.

Results: The study involved 98 patients (54 males, 44 females) with a mean age of 41.46 months and an average follow-up of 98.37 days (95 % CI 87.65–109.1). Out of the 110 eyes that underwent surgery, 13 (11.8 %) experienced failure while 97 (88.2 %) were censored. Kaplan-Meier analysis indicated significant differences in age category and probing (P-value = 0.03 and 0.006 respectively), but not tube type (P-value = 0.8). Multivariable analysis confirmed that older age and complex probing were associated with higher failure rates in CNLDO cases, with each monthly increase correlating to a two percent higher likelihood of intubation failure.

Conclusions: Patient age and probing complexity influence CNLDO treatment, impacting surgical techniques and outcomes. Tube type, prior surgery, and passive smoking have no significant impact on treatment success.

1. Introduction

Congenital nasolacrimal duct obstruction (CNLDO), defined as a congenital blockage of NLD drainage system [1], is a prevalent disorder in infants, affecting 5–20 % of children due to the persistence of Hasner's membrane [2], with a higher prevalence among premature infants [3]. Periorbital redness due to rubbing of the eyes and ocular mucopurulent discharge are common symptoms of CNLDO [4]. Diagnostic modalities like clinical symptom evaluation and dye disappearance tests can confirm the disease [5]. Treatment follows an age-based stepwise approach, initially monitoring visual development and performing lacrimal sac massage along

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https://doi.org/10.1016/j.heliyon.2024.e36245
Received 10 November 2023; Received in revised form 9 August 2024; Accepted 13 August 2024
Available online 13 August 2024

with topical antibiotics followed by probing as the initial procedure [6]. Many patients aged 6–10 months often resolve without surgery, while optimal probing timing remains uncertain for those older than 12 months [7]. However, due to low spontaneous resolution likelihood, probing becomes the preferred initial treatment option for individuals above 24 months [8]. Nonsurgical treatments have shown higher rates of spontaneous resolution and lower chances of requiring surgery later on [9]; however, when probing is required, success rates decrease with patient age during probing surgery due to anatomical variations and scar tissue challenges in treating CNLDO [10,11].

Alternative interventions for primary probing failure in CNLDO include repeated probing, lacrimal duct intubation, balloon dacryoplasty, and dacryocystorhinostomy [12]. Two approaches are available for children over 18 months old who have not received prior treatment. The first involves late initial probing with re-probing if needed. The second proposes NLD stenting after the initial probing to mitigate inflammation and fibrosis risks associated with this age group [13]. Nasolacrimal silicone tube intubation is preferred when conservative treatment fails and has shown higher success rates than repeat probing [14]. The monocanalicular intubation (MCI), which is one of the prevalent methods, comprises the Monoka method (pulling a tube through the NLD) and the Masterka method (pushing a tube from the distal part of the NLD). Recent research indicates that the Masterka method yields more effective outcomes in children over 12 months old with CNLDO [15].

Various factors can influence silicone intubation success rates in the treatment of CNLDO. These include the child's age at surgery, with older children potentially experiencing lower success rates. Additionally, outcomes may be affected by the duration, severity, associated ocular or systemic abnormalities of symptoms, as well as the location and extent of obstruction within the NLD system. Surgeon experience level, technique proficiency during the procedure, stent type, and postoperative stenting duration also impact results [4]. Despite advancements in CNLDO treatment, understanding of its management and how age affects success rates remains limited. This study aims to examine treatment success rates related explicitly to NLD probing and stenting in patients over 18 months old. The findings will provide valuable insights to improve surgical techniques and postoperative care protocols and inform clinical decision-making.

2. Method

In our retrospective cohort study conducted at Nikookari Hospital, Tabriz, Iran, from September 2017 to September 2022, according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline [16]. We analyzed medical records of 103 patients, aged 18–120 months, who manifested epiphora below 3 months of age and then underwent probing and monocanalicular stenting for CNLDO. Defective medical records, presence of punctum and canalicular atresia, patients with canalicular rupture, and patients who manifested epiphora after 3 months of age, with a potential indication of acquired etiology, were excluded from the study. Additionally, NLD probing for patients under 18 months of age has demonstrated high success rates in previous research [17]. However, due to the elevated failure rates associated with probing performed on patients over 18 months of age [10], in practice, our department experts recommend only opting for NLD stent placement in such cases, without performing any probing prior to stenting. Therefore, patients below 18 months were also excluded from the study.

All patients underwent comprehensive assessments, including detailed history and comprehensive ocular examinations. The diagnosis of CNLDO was made based upon patient's medical history and examinations such as unilateral epiphora, positive dye disappearance test, and regurgitation test. Other potential differential diagnoses were also ruled out in the diagnostic process [4].

The following diagnosis, all patients were operated on by a single pediatric ophthalmologist surgeon under general anesthesia. During the probing procedure, after dilating the punctum, the Bowmen probe (manufactured by Surtex Instruments, Sialkot, Pakistan), available in sizes 000–1, was inserted into the NLD. Following this step, the patency of the duct was assessed using normal saline or fluorescein dye. Monocanalicular methods were employed for placing stents in NLD, utilizing either the Monoka (FCI Monoka, manufactured by FCI Ophthalmics company, Issy-les-Moulineaux, France) or Masterka (FCI Masterka, manufactured by FCI Ophthalmics company, Issy-les-Moulineaux, France) technique. The Monoka method involved passing a stent through the inferior punctum and canaliculi, securing it onto the nasal wall by an anchor, with the other end generally secured within the nasal cavity. In contrast, the Masterka technique directed a stent accompanied by a guide toward the nasal cavity floor, securing it adjacent to the lower punctum, without the need for a knot.

Subsequently, patients underwent a follow-up examination during six months after the surgery. If symptoms were fully resolved, the stent was removed; however, if symptoms persisted, the stent remained for an additional three months. If symptoms persisted at this point, the treatment was considered unsuccessful, and the stent was removed.

Finally, the success of nasolacrimal intubation was assessed, considering factors such as age at surgery, gender, treatment type, methods used (Monoka or Masterka), the complexity of probing, presence of allergic rhinitis, nasal anomalies, and passive smoking. In contrast to simple probing, which was characterized by the surgeon experiencing a distinct "pop" sensation when breaching the distal membrane, complex probing- or probing with complexity-referred to cases where the obstruction blockage was more challenging due to its location, extent, or the presence of additional anatomical abnormalities such as multiple strictures or hard fibrotic tissue [18]. Postoperative stenting duration in each patient's eye and other punctum and canalicular problems were also assessed. The criteria for successful surgical outcomes were defined as resolution of symptoms within the follow-up period. The failure of surgery was defined as the absence of symptom resolution for 3 months after the last visit, or the development of granulation tissue in the punctum area or deformation of the punctum during the 6-month follow-up period.

3. Statistical analysis

We used R and R Studio 2022.02.0 + 443 for data analysis. Quantitative data were reported as mean (standard deviation), and Qualitative data were shown as numbers (percentages). The survival time (days from surgery to the failure of intervention) was illustrated using the Kaplan-Meier method and stratified by age category, type of probing, and tube type of intubation. The difference in the aforementioned strata was assessed using the log-rank test. Univariate and multivariate Cox proportional hazard model was used to assess the influence of the following variables on the outcome of surgery: age, sex, probing, tube type, prior surgical intervention (none, probing, or intubation), and passive smoking. We then used a two-level survival analysis for the correlated eye data. For this purpose, the Cox proportional hazard model with random intercept (frailty model) was used. A two-sided p-value <0.05 is considered statistically significant.

4. Result

Among a total of 103 patients which undergone surgery for CNLDO at our referral center, 98 patients, involving 110 eyes, were included in the final analysis, and three patients were excluded due to self-extubation, one patient for duplication, and the other one for being probing as the primary surgical intervention. Fig. 1 shows the STROBE flow diagram. Twelve patients (12.2 %) had bilateral eye involvement, and both of them were selected for data analysis, and correlation was addressed using frailty modeling. The mean age of the study group was 41.46 (95 % CI 37.79–45.13); 54 (55.1 %) were males, and 44 (44.9 %) patients were females. Rhinosinusitis was reported in five patients' past medical history (5.1 %), asthma in one patient (1.0 %), acute dacryocystitis in one patient (1.0 %), nasal cavity abnormality including mass and septal deviation in two patients (2.0 %), and punctum stenosis and canalicular stenosis in six (6.1 %) and twelve patients (12.2 %), respectively. The baseline demographic and clinical characteristics of patients are presented in Table 1. Twenty-eight eyes (28.6 %) were undergone prior surgical intervention for their CNLDOs; of these, their mean duration from the present surgery was 21.46 months (95 % CI 14.79–28.14).

The mean follow-up time for the outcome of surgery was 98.37 days (95 % CI 87.65–109.1). Among 110 eyes that had undergone surgery, 13 (11.8 %) eyes had failed surgery, and 97 (88.2 %) eyes were still under observation at the time of data analysis. The Kaplan-Meier plots are presented in Fig. 2(a–d) and are stratified by age category, probing, and tube type. We performed the log-rank test to compare the aforementioned strata, which were statistically significant for the age category and probing (P-value = 0.03 and 0.006, respectively), but non-significant for tube type (P-value = 0.8) (Table 2).

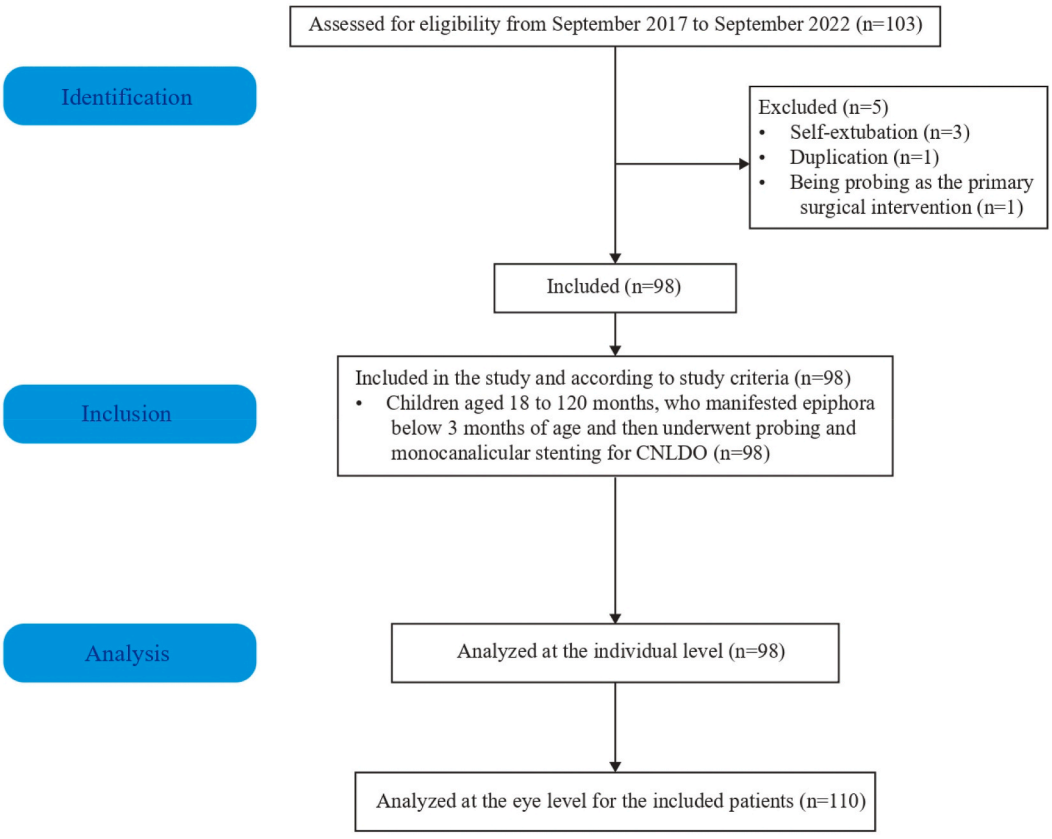

Fig. 1. STROBE flow diagram illustrating the selection process of participants in the study.

Table 1
Baseline patient demographic and clinical characteristics.

Characteristic	Total (N = 98 patients)
Age at surgery (months)	41.46 (18.31)
Gender	
Male	54 (55.1)
Female	44 (44.9)
Involved eye	
Right	43 (43.9)
Left	43 (43.9)
Both	12 (12.2)
Probing (by eye)	
Simple	84 (76.4)
Complex	26 (23.6)
Prior surgical intervention (by eye)	
No	82 (74.5)
Probing	20 (18.2)
Intubation	8 (7.3)
Intubation type at present surgery (by eye)	
Monoka	98 (89.1)
Masterka	12 (10.9)
Punctum stenosis (by eye)	6 (5.5)
Canalicular stenosis (by eye)	12 (10.9)
Passive smoking	12 (12.2)
Past medical history	
Rhinosinusitis	5 (5.1)
Asthma	1 (1.0)
Acute dacryocystitis	1 (1.0)
Nasal cavity abnormality (mass and septal deviation in two patients)	2 (2.0)

Quantitative data were shown as mean (standard deviation). Frequencies were shown as number (percentages).

Our finalized multivariate frailty model, selected for its ability to comprehensively account for correlated eye data, revealed significant associations between the complexity of probing and a higher hazard rate. Additionally, it exhibited a lower Akaike information criterion (AIC) value (64.31 versus 73.14) and higher concordance (97 % versus 82 %) compared to the multivariable-only significant model, indicating better predictive accuracy and improved model fit. CNLDO with complex probing was significantly associated with a higher hazard rate (HR 6.2, P-value = 0.04), indicating that surgeries accompanied by complex probing failure are 6.2-fold higher than simple probing at any given time.

Multivariable analysis with only significant variables revealed that every month getting older increases the rate of failure by 2 % (HR 1.02, P-value = 0.04). However, this was not statistically significant in the frailty model considering correlated eye data (HR 1.03, P-value = 0.18). Sex was only significant in multivariable analysis (HR 11.52, P-value = 0.016) but not in univariable analysis (HR 2.22, P-value = 0.19). Other variables encompassing stenting type (Monoka or Masterka), prior surgical intervention (none, probing, or intubation), and passive smoking were insignificant in univariable or multivariable analysis (Table 3).

5. Discussion

Age category and probing were significant predictors of intubation failure rates after surgery; CNLDO with complex probing had a higher hazard rate compared to simple probing surgeries at any given time, while sex, tube type, prior surgical intervention, or passive smoking were not found to be significant predictors in either univariable or multivariable analysis.

The impact of age on surgical intervention and silicone intubation success rates in children with CNLDO has been extensively studied. Sathiamoorthi et al. confirmed that increasing age after 15 months has a negative impact on initial surgical intervention success, which can be attributed to complicated obstructions caused by chronic infections and scarring [19]. Contrarily, the research conducted by Lim et al. illustrated notable success rates among children aged four years or younger [20]. Age influences not only the success rates of silicone tube intubation but also the outcomes of initial probing procedures in children with CNLDO. various studies suggest diverse optimal timing for probing in CNLDO [21,22]. Early intervention, specifically at 12 months, is suggested for complex cases [17]. However, opinions vary on the age limit, with some studies supporting probing up to 36 months for patients less than three years old [22,23]. Delaying intervention can increase inflammation and is generally associated with lower success and increased complexity, as probing failure risk is shown to double every six months with age [3,24,25]. However, some studies contradict the negative impact of older age on success rates, maintaining the efficacy of probing for a broad age range [26]. Our study elucidated the relationship between age and treatment success in CNLDO patients, finding a 2 % increase in intubation failure likelihood with each age increase. We hypothesized that, this reduction in success rate, could be due to age-related changes in duct anatomy, such as narrowing and occlusion, formation of fibrosis and scarring from chronic inflammation or infections, decreasing patency, and increased rigidity of the NLD with age. This finding highlights the significant impact of age on the outcome of interventions, emphasizing the need for personalized strategies to optimize outcomes across a range of age groups.

Discrepancies exist among studies regarding the influence of age on treatment outcomes related to nasolacrimal intubation in

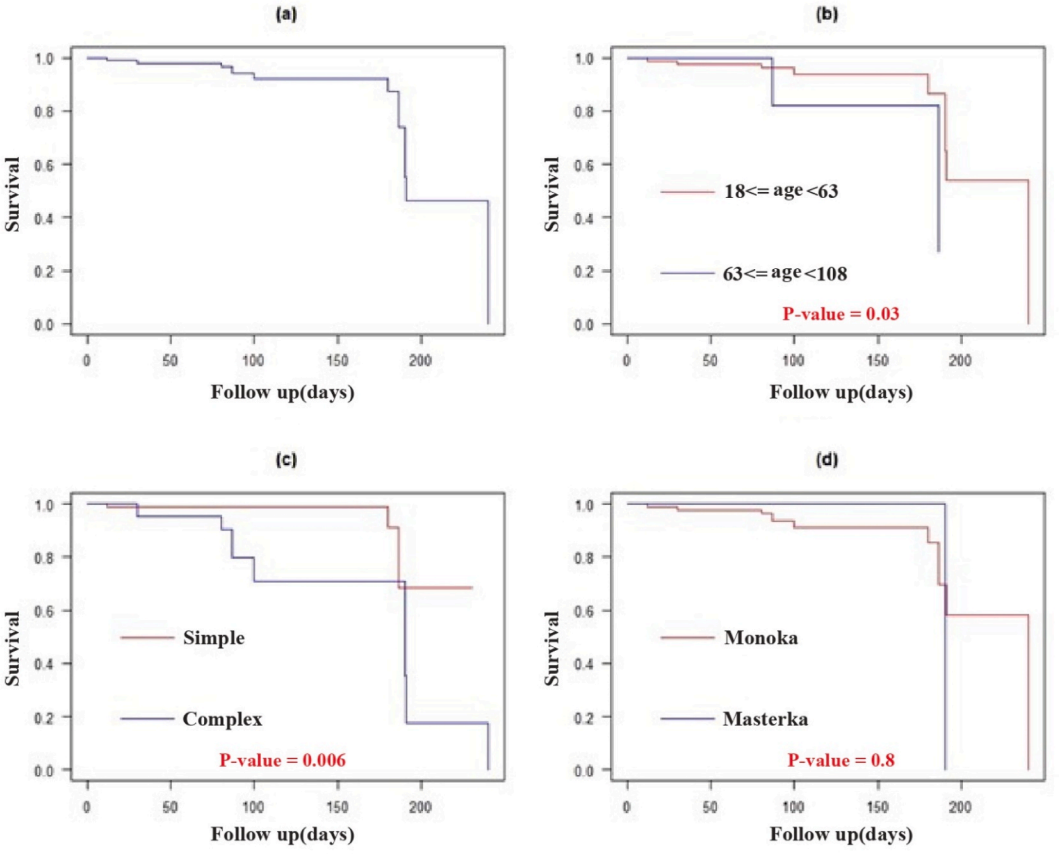

Fig. 2. Survival curve of congenital nasolacrimal duct obstruction (CNLDO) patients using the Kaplan-Meier method. (a) Kaplan-Meier overall survival curve. (b), (c), (d) Kaplan-Meier estimates of the survival curves CNLDO data stratified by age category, type of probing, and tube type of intubation, respectively.

Table 2
Failure frequency based on age group, probing, and tube type.

Variable	Ratio (%) (N = 110 eyes)	P value[a]
Age		
< 63 months	9/94 (9.5 %)	0.03[b]
=> 63 months	4/16 (25 %)	
Probing		
Simple	4/84 (4.7 %)	0.006[b]
Complex	9/26 (34 %)	
Tube type		
Monoka	11/98 (11.2 %)	0.8
Masterka	2/12 (16 %)	

[a] Log-Rank test was used to compare between strata.
[b] p value < 0.05 considered significant.

CNLDO patients. Some findings suggest that untreated NLD stenosis and older age can lead to complications, adversely affecting the success rates of silicone tube intubation [27,28]. in our view, the discrepancies in success rates are due to a lack of standardization in multiple aspects of study and treatment protocols, including patient selection criteria, surgical technique, follow-up period, study design, sample size, and definitions of treatment success. In this study, we tried to get more reliable results by utilizing a larger sample size and enhanced analysis of each eye separately.

The association between complex probing and higher failure rates in NLD interventions for children with CNLDO has been investigated. Previous research consistently indicates lower success rates for CNLDO cases with complex probing compared to simple ones, with some studies noting three times higher success rates in the simple probing group [29,30]. Additionally, another study showed lower success rates in patients with additional complications like bony ductal stenosis and craniofacial syndrome [31]. Our

Table 3
Cox proportional hazard models for the association of potential predictors with the outcome of surgery in congenital nasolacrimal duct obstruction patients.

predictor	Univariable Analysis			Multivariable analysis (full)[d]			Multivariable analysis (sig. only)[e]			Frailty model analysis (sig. only)[e]		
	HR[a]	95 % CI[b]	P value	HR	95 % CI	P value	HR	95 % CI	P value	HR	95 % CI	P value
Age	1.03	1–1.06	0.02[f]	1.046	1.01–1.07	0.003[f]	1.02	1–1.06	0.04[f]	1.03	0.98–1.08	0.18
Sex	2.22	0.66–7.43	0.19	11.52	1.58–83.85	0.016[f]						
Probing	4.75	1.39–16.18	0.01[f]	10.81	1.74–67.07	0.011[f]	4.35	1.27–14.84	0.02[f]	6.2	1.04–36.89	0.04[f]
Tube type	1.34	0.28–6.28	0.71	0.57	0.09–3.46	0.54						
PSI[c]	1.23	0.5–3.23	0.67	0.77	0.20–2.89	0.70						
Passive smoking	1.72	0.44–6.63	0.4	1.68	0.21–13.03	0.61						

[a] Hazard ratio.
[b] Confidence interval.
[c] Prior surgical intervention.
[d] All predictors.
[e] Only the significant predictors from the univariable analysis.
[f] Significant at $\alpha = 0.05$.

study aligns with these findings, demonstrating that complex probing is associated with a 6.2 times higher failure rate compared to simple probing. However, based on our innovative study design, extensive follow-up period, and sufficient sample size in both simple and complex probing groups, our results provide more accurate and comprehensive conclusions. The reason behind the lower success rates in complex probing, potentially due to variations in NLD anatomy, anomalies of NLD, maintaining proper positioning of the probe, and navigational challenges, requires further clarification.

Our research concludes that the history of prior probing does not appear to impact the success rate of silicone tube intubation, suggesting that chances of successful intubation are undiminished even for patients with previous probing, which aligns with a study by Jeong et al.'s [32]. However, conflicting reports suggest lower success rates in patients with previous probing [33]. Scar tissue or inflammation from previous procedures or infections theoretically complicate the procedure and decrease success rates. Conversely, silicone tube intubation bypasses the need for navigating through scarred tissue followed by previous probing, in contrast to probing. Additionally, intubation functions by providing a physical duct for tear drainage rather than relying on the clearance of NLD obstructions; therefore, it may be less influenced by anomalies of NLD and scar tissue. However, the mechanism behind the impact of prior intubation on surgery success rate requires further elucidation.

Our analysis reveals no significant differences in the success rates between the Masterka and Monoka intubation methods, indicating that both can be utilized similarly to achieve optimal outcomes. Monoka, recognized for its secure stent placement through nasal manipulation, contrasts with Masterka, which employs a simple technique of self-retaining metallic fixation to introduce a monocanalicular silicone tube [34]. Existing literature indicates potential risks with Masterka in complex cases of NLD stenosis and emphasizes its potential treatment failures due to spontaneous withdrawal or dislodgement, although some are constrained by small sample sizes. In contrast, they underline the safety and reliability of Monoka, especially effective with advancing patient age when other methods prove ineffective [35–38]. We attribute discrepancies in previous studies to either inadequate sample sizes or the increased risks intrinsic to Masterka intubation, such as spontaneous withdrawal or dislodgement caused by rubbing.

Our research reveals no statistical significance between passive smoking and silicone intubation success rates in CNLDO in both univariable and multivariable analyses, implying a non-existent association. Although certain investigations have established the association between ocular disease and tobacco smoke [39], the existing literature lacks conclusive results regarding the correlation between smoking and NLD intubation. Therefore, the inconclusive evidence and the variability in exposure levels to passive smoking make it challenging to establish a definitive link. Comprehensive future studies are essential to evaluate the source and duration of passive smoking exposure to further investigate the potential influences of passive smoking on silicone intubation outcomes.

Our study had some limitations, such as limited population diversity, inadequate data about the source and duration of passive smoking among patients, and the study's retrospective nature, which is the most significant limitation. The retrospective nature of our study posed potential challenges to its quality, including incomplete data and selection bias. Additionally, we did not grade the amounts of tears and epiphora, which limited our ability to report the severity of clinical symptoms accurately. However, we attempted to compensate for these limitations by implementing a long-term follow-up period, rigorous data collection methods, using accurate statistical modeling techniques to adjust for confounding variables, and considering multiple intervening variables in our analysis. A prospective version of this study with considering other variables like the source and duration of passive smoking, could have yielded more accurate and complete results.

6. Conclusion

In conclusion, our findings reveal that NLD stenting success decreases with age and is less likely in complex CNLDO cases. The type of intubation does not significantly impact the treatment outcomes. Accordingly, considering the patient's age and probing type is crucial for predicting treatment efficacy and adjusting intervention strategies. Future studies should validate these findings with larger, diverse cohorts and explore additional impacting factors using prospective designs.

Ethics statement

This study was conducted under the principles outlined in the Declaration of Helsinki and received ethical approval from the Tabriz University Committee on Ethics in Medical Sciences Research, with the ethical code IR.TBZMED.REC.1401.140. Legal guardians were informed about the study's aims, benefits, and risks and then provided written informed consent.

Consent for publication

N/A.

Availability of data and materials

Data will be made available on request.

Funding

None.

CRediT authorship contribution statement

Ali Jafarizadeh: Writing – review & editing, Writing – original draft, Software, Project administration, Methodology. **Vahideh Manouchehri:** Supervision, Resources, Investigation, Data curation, Conceptualization. **Navid Sobhi:** Writing – review & editing, Writing – original draft. **Farideh Mousavi:** Writing – review & editing, Supervision. **Farhad Tondro Anamag:** Visualization, Methodology, Formal analysis, Data curation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

We appreciate the support from ref-n-write and Grammarly for their assistance in editing and paraphrasing.

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