Pushed Monocanalicular Intubation Versus Probing for Management of Congenital Nasolacrimal Duct Obstruction

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Abstract


Methods: Randomized interventional case controlled study included 60 eyes (of 53 patients), 30 eyes underwent probing and 30 eyes intubation using Masterka tube as a primary treatment for congenital nasolacrimal duct obstruction.

Children were aged 6 to <36 months at the time of surgery, with no prior nasolacrimal surgical procedure, and had at least one of the following clinical signs of NLDO: Epiphora, mucous discharge and/or increased tear lake.

Results: Treatment success was defined as absence of epiphora, mucous discharge and increased tear lake at the outcome visit two month after tube removal. The overall success rate in the probing group was 80% while in the intubation group was 83.3%.

Conclusion: Pushed monocanalicular intubation (Masterka) is an effective and simple method for treatment of CNLDO and it requires only mask inhalation anesthesia, however there was no statistical difference between it and primary probing.

Key Words: Nasolacrimal duct obstruction – Epiphora – Probing – Pushed monocanalicular intubation.

Introduction

70% of neonates present with CNDO at delivery. However, only 6-20% of all neonates have symptoms, because the obstruction usually resolves spontaneously before lacrimal secretion begins [1]. The characteristic presentation of congenital lacrimal obstruction is watering (epiphora) and mucopurulent discharge observed from the first month of life. This usually affects only one eye, although both eyes may be affected in up to 20% of cases [2].

There is considerable controversy surrounding the management-both conservative and surgical-of childhood epiphora. The treatment of congenital nasolacrimal duct obstruction (CNLDO) includes observation, topical antibiotics with tear duct massage, and surgical interventions ranging from simple probing to more invasive procedures, such as stent intubation and dacryocystorhinostomy [3].

Silicone intubation of the lacrimal system has become very popular in the treatment of CNLDO resistant to conservative therapy and/or probing [4-6]. Increasing experience with the technique and the introduction of monocanalicular intubation has led to the use of intubation as a primary procedure for NLDO in younger children [4,6].

We conducted a prospective randomized study to assess the use of pushed monocanalicular intubation in comparison to simple probing for primary management of CNLDO.

Patients and Methods

Randomized interventional case-controlled study included 60 eyes; patients were selected from the outpatient Ophthalmology Clinic of Abo El-Reesh Teaching Hospital, Cairo University. The protocol was revised and approved by Cairo University Ophthalmology Ethical Committee; informed written consent was obtained from all parents/guardians before the initiation of any procedure.

The study was carried out from September 2012 to December 2013, and a total of 60 eyes were included.

Patient selection:

Inclusion criteria: Children aged between 6 and 36 months with primary CNLDO symptoms.
resistant to conservative therapy were included in the study. The diagnosis of CNLDO was based on a history of tearing, repeated infections, the fluorescein dye disappearance test (FDT).

Exclusion criteria: Children younger than 6 months of age were excluded because of known self-resolution during maturation of the nasolacrimal duct. Patients with previous eyelid and/or lacrimal surgery, punctal and/or canaliculic obstructions, eyelid mal-positioning were excluded.

Treatment groups:
Patients were randomly assigned to one of 2 groups.

Group A: 30 eyes underwent probing of the nasolacrimal duct.

Group B: 30 eyes underwent pushed monocanalicular intubation (Masterka).

Preoperative evaluation:
Complete ophthalmological evaluation was done with detailed history taking.

The drainage function of the lacrimal system was assessed by:
- History of onset of symptoms, severity of lacrimation, symptoms of repeated infections as discharge and itching, history of previous medical therapy or nasolacrimal massage.

- Clinical examinations: Tear retention and conjunctival sac evaluation, medial canthus observation and/or palpation.

- Modified fluorescein dye disappearance time: A drop of fluorescein is instilled in the conjunctival sac and the amount of dye remaining after 5 minutes is recorded.

The history and the modified fluorescein dye disappearance time were considered to be the major endpoints.

Grading of the patients:
Grade 0: No lacrimation or tear lake, complete fluorescein clearance.

Grade 1: Occasional lacrimation <5 times/day, 25% dye present after 5 minutes.

Grade 2: Lacrimation 5-10 times/day, 25-50% dye after 5 minutes.

Grade 3: Lacrimation 10 times daily, 50-75% dye after 5 minutes.

Grade 4: Excessive lacrimation >10 times daily, 75-100% of the dye after 5 minutes.

Procedure technique:
Probing:
Under a mask anesthesia, probing of the canaliculi and nasolacrimal duct was used to assess the anatomy and functional status of the lacrimal drainage system, and to exclude cases other than those with membranous obstruction at the level of Hasner’s valve.

The both puncti were dilated with a punctal dilator, a small lacrimal probe was then used initially to probe the lacrimal passage followed by progressively larger probes if possible.

After the probe enters the lacrimal sac (as signaled by the presence of a "hard stop"), it was rotated superiorly, with the body of the probe against the brow. Once the probe was rotated to the level of the supraorbital notch at the superior orbital rim, it was guided down the nasolacrimal duct, directed slightly posteriorly and laterally as it is advanced. Any significant resistance at this point was not overcome with force; instead, the probe was withdrawn, in probing cases and the procedure repeated.

Masterka intubation:
The Masterka is a preloaded device made up of silicone tubing and a metallic guide. It consists of a pushed lacrimal intubation stent with a self-retaining meatic fixation; the Masterka is a "pushed" type of lacrimal intubation stent. It consists of a fixation device in the shape of a punctal plug connected to a length of silicone tubing with a metallic guide that assists insertion by pushing the tubing into the canaliculus and nasolacrimal duct. It is actually possible to remove the guide completely and to reinsert it without altering the stability and shape of the Masterka tubing Fig. (1).

Fig. (1): Masterka tube.

- Done under face mask anesthesia. Preliminary lacrimal exploration by probing of upper canaliculus as described above, we chose to insert it in the upper canaliculus to keep the lower one virgin to allow for subsequent intervention if required.
Initial probing allowing to:
- Identify the location and severity of the obstruction only simple mucosal obstruction cases were included.
- Avoid potential sub mucosal and false passages.
- Choose the appropriate Masterka length: Done by measuring the distance between the punctum and the nasal floor by inserting the probe and marking the distal end with an artery, and the distance is measured on the probe by a ruler. The proper stent is chosen and it should be always longer the distance measured.

Insertion of masterka tube:
- The upper lacrimal punctum is carefully dilated. The Masterka is pushed through the upper canaliculus all the way to the “hard stop” or bony contact.
- While maintaining bony contact, the Masterka is rotated inferiorly to catheterize the lacrimal sac and the nasolacrimal duct, just as done in routine probing, until the nasal floor is reached. At this moment, the plug may be against the punctum, or may be a little bit close to the punctum. Metal to metal contact is searched at the nasal fossa floor using a larger, blunt probe, Positive metal-to-metal contact confirms proper placement (no submucosal and/or false passage).

Removal of the metal guide is done very carefully, the anchoring plug is held secure against the punctual opening while the guide/introducer is carefully removed. The guide/introducer is removed by gently pulling it from the external section of the tube, while rotating it to help slide it out of the tube. Throughout this phase the anchoring plug is held in firm contact with the lacrimal punctum with a non-toothed forceps. Once the introducer is completely removed, the anchoring plug is inserted into the canaliculus taking care that the collarette of the plug/fixation head is flush against the lid margin.

Post-operative care:

Patients of both groups were given combined antibiotic steroid eye drops for 5 days. Follow-up at 1, 2, 4 weeks and 2, 3 months. Group B tubes were removed at 4 weeks in most patients as the original designers of Masterka tube advised. The stent is removed an office procedure with a forceps instrument by pulling on the collaret. The removal is painless and does not require ant anesthetic.

Complete therapeutic success was defined as FDT grade 0, and this result had to correspond with a complete resolution of previous symptoms. Partial success was defined as FDT 1 with substantial improvement and some residual symptoms. Failure was defined as the absence of improvement or the worsening of the symptoms.

Results

The patients were selected from the outpatient Ophthalmology Clinic of Abo El-Reesh Teaching Hospital, Cairo University. The surgeries were performed in Abo El-Reesh Teaching Hospital from September 2011 to December 2012 in both groups. A total of 26 patients (43.3%) were males (12 in group A: 14 in group B) and 34 patients (56.7%) were females (18 in group A: 16 in group B.

Group A, age of the patients ranged between 7 and 34 month with a mean of 15.63 months. Group B, age ranged between 7 and 34 months with a mean of 18.13 months.

Preoperative data:

The table below shows the distribution of patients in both groups according to the grade of nasolacrimal duct obstruction using modified dye disappearance test, only cases of simple obstruction at the level of hasner valve were included, the diagnosis made intraoperative.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Probing Group A</th>
<th>Intubation Group B</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0 (3.3%)</td>
<td>1 (3.3%)</td>
<td>1 (1.7%)</td>
</tr>
<tr>
<td>2</td>
<td>10 (33.3%)</td>
<td>5 (16.6%)</td>
<td>15 (25%)</td>
</tr>
<tr>
<td>3</td>
<td>13 (43.3%)</td>
<td>14 (46.7%)</td>
<td>27 (28.3%)</td>
</tr>
<tr>
<td>4</td>
<td>7 (23.3%)</td>
<td>10 (33.3%)</td>
<td>17 (28.3%)</td>
</tr>
</tbody>
</table>

Post-operative data:

Follow-up of the patients was done at 1 week, 1 month, 2 and 3 months post operative.
First week post operative:

First week post-operative examination of patients showed 7 patients (23.3%) of group A complained of postoperative epistaxis that continued till second day compared to 3 patients (10%) of group B, one patient in group B showed a central corneal ulcer.

**Group A**: Successful cases were 26 cases (86.6%).

**Group B**: Successful cases were 25 cases (83.4%).

p-value 0.029.

One month post procedure:

**Group A**: 23 eyes (76.6%) were successful i.e. ranging between grade 0 and 1.

**Group B**: 24 eyes (80%) were successful the tube was removed from 24 eyes, 7 eyes (23.3%) removal of tube was delayed for 2 weeks and one case (3.3%) the tube was lost. p-value: 0.754.

Three months post procedure:

**Group A**: 24 cases were successful (80%), 6 cases (20%) required further intervention.

**Group B**: 25 cases were successful (83.3%), no recurrence was noted after removal of the tube at 2 and 3 months postoperative.

p-Value: 1.00.

Table (2): Three months post operative grading.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Probing Group A</th>
<th>Intubation Group B</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>19 (63.3%)</td>
<td>22 (73.3%)</td>
<td>41 (68.3%)</td>
</tr>
<tr>
<td>1</td>
<td>5 (16.7%)</td>
<td>3 (10%)</td>
<td>8 (13.3%)</td>
</tr>
<tr>
<td>2</td>
<td>3 (10%)</td>
<td>5 (16.7%)</td>
<td>8 (13.3%)</td>
</tr>
<tr>
<td>3</td>
<td>2 (6.7%)</td>
<td>0 (0%)</td>
<td>2 (3.3%)</td>
</tr>
<tr>
<td>4</td>
<td>1 (3.3%)</td>
<td>0 (0%)</td>
<td>1 (1.7%)</td>
</tr>
</tbody>
</table>

Outcome of the procedure:

Cases were considered successful if reached grade 0 or 1.

**Group A**: 24 eyes (80%) were successful and 6 cases (20%) required further intervention; with 63.3% of cases showing complete resolution of symptoms (Grade 0).

**Group B**: 25 eyes (83.3%) were successful and 5 cases (16.7%) required further intervention; with 73.3% of cases showing complete resolution of symptoms (Grade 0).

Progress of the cases during follow-up:

**Group A**:

Follow-up of cases who went probing showed a higher success rate 26 cases in the first week 86% compared to 24 cases (80%) at 2 months follow-up.

**Group B**:

Follow-up showed progressive improvement of symptoms in patients who underwent intubation patients the success rate during the first week was 83.3% and the 3rd month 83.3%. Cases which showed complete resolution of symptoms (grade 0) were in the first week 26.7% which increased to 73.3% at the end of follow-up.
Discussion

There is an extensive literature advocating treatments for CNLDO, opinions have diverged for more than 2 centuries as to the appropriate treatment regarding nature and timing. Probing has traditionally been advocated as a first-line management of CNLDO; after conservative treatment has failed. Most specialists perform probing as the subsequent interventional therapy [7-11].

Recently, however, some authors prefer to stent all patients at initial probing, regardless of complexity as it is thought to be associated with a high success and a low complication rate [6]. Silicon intubation has been recommended by some authors as the primary procedure in patients who are older than 18-24 months, because of the presumed reduced success rate of probing with age [12]. Also a small proportion of newborns with CNLDO have anatomical variations that are unlikely to resolve spontaneously or be relieved by simple probing [13].

In the present study we attempted to assess the role of the newly designed pushed monocanalicular intubation (Masterka) as a primary treatment for congenital nasolacrimal obstruction; versus simple primary probing.

Our study included 60 eyes of 50 patients with CNLDO between the ages of 6-36 months, 30 eyes did primary monocanalicular intubation with Masterka and 30 eyes did primary probing. The overall success rate in the intubation group was 83.3% while in the probing group was 80%. However the difference in the success rates between the 2 groups was not statistically significant (p-value of 1).

We found the success in the probing group in 80% of cases (24 cases). Studies of primary surgical management have found probing to be also successful in 70% to 97% of cases, with many reports around 90% [13].

Our results are higher than those of Pediatric eye disease investigator group in 2009 in a prospective non randomized multicenter study that included 955 eyes of 718 children aged 6 to <48 months at the time of surgery, with no prior nasolacrimal surgical procedure; underwent probing. The proportion of eyes treated successfully was 78% overall and was 78% for the 421 eyes in children aged 6 to <12 months, 79% for the 421 eyes in children aged 12 to <24 months, 79% for the 37 eyes in children aged 24 to <36 months, and 56% for the 11 eyes in children aged 36 to <48 months [14].

Results are higher than Casady and coworkers in 2006 in a retrospective interventional case series study that included 127 patients, ranging in age from 1 month to 81 months, with 173 lacrimal systems diagnosed with CNLDO were treated with initial probing showed a success rate of 76.9% [15].

Multiple studies have been done to assess the role of intubation as a primary treatment for congenital nasolacrimal duct obstruction, to our knowledge none of which was a case controlled study.

Success in the intubation group was achieved in 83.3% of cases (25 cases) this success is comparable with the original designer of Masterka tube Fayet and co workers (2012) in a study that assessed the role of pushed monocanalicular intubation using Masterka tube as a primary management of CNLDO, the trial included 110 eyes, success was achieved in 94 eyes (85%) [16].

Comparing our results to other trials that assessed the role of silicon intubation in primary
management of CNLDO but with a different type of tube showed that our success rate is less than that reported by pediatric eye disease investigator group in 2008 in a non randomized non comparative trial that included 182 eyes of children between 6-48 months, they found that intubation is successful as a primary management in 90% of cases, they used MCI in 70% of cases [17].

Engel and colleagues, they reported in a retrospective case series of 635 patients (6 to 104 months) in whom they found an overall success rate of 96%. The success rate for treatment performed in infants younger than 24 months of age (684 eyes) was 97%, declining to 90% when surgery was performed in infants older than 24 months of age. This difference in success rate could be attributed to the larger number of cases or different type of tube used [6].

Kaufman and Co Workers showed in a retrospective study on 50 eyes treated with monocanalicular intubation with Monoka tube (36 as primary treatment) with an overall success rate of 79% [4].

On following the results of our patients over time, it was noted in cases of probing a higher success rate 26 cases during the first week 86% compared to 24 cases (80%) at 3 months follow-up. However in the intubation group follow-up showed sustained improvement of symptoms showing a success rate during the first week of 83.3% and the 3rd month 83.3%. There was no recurrence after removal of the tube. Cases which showed complete resolution of symptoms (grade 0) were in the first week 26.7% which increased to 73.3% at the end of follow-up. These findings didn't show considerable statistical significance ($p$-value of 0.40).

Tubes were removed at 4 weeks postoperative as advised by the original designers of Masterka tube [16].

On comparing the effect of age of our patients to success in both groups there was no statistical significance. The numbers of treatment failures in our study were too small for a meaningful statistical assessment of an age effect.

Probing is thought to be less successful with advancing age [12,17-19]. Katowitz & Welsh recommended probing before 13 months of age because they found that probing before 13 months of age was associated with a cure rate of 97%, which dropped to 54.7% after 13 months of age [18]. That's why some authors recommend intubation as a primary interventional treatment in the older patient subgroup because of the decrease in success rates for late probing [6,20].

However some studies have suggested that probing maintains a high success rate without any age related decline [3].

Advocates of primary intubations see that probing can, at times, induce minor injuries to the lacrimal duct epithelium which may cause a cicatricial stricture and prevent the resolution of CNDO [1]. When probing fails, iatrogenic canalicular obstructions occur in 44% of cases [21]. The silicone tube prevents the formation of granulation-related obstruction around the newly patent tract [22,23].

Complications that occurred in the intubation group included a case of one corneal ulcer and one lost tube. In our study in which monocanalicular tubes were inserted into the superior canaliculus, corneal abrasion was observed in only one child (2.8%) a few days after the surgery. The abrasion was central and healed within 3 days without premature removal of the tube.

Fayet and Co Workers observed only three (1.5%) corneal ulcers in 223 eyes with MCI, whereas no corneal ulcers were observed in 1,620 BCI placements. They assumed that the placement of the MCI in the superior canaliculus is a predisposing factor for corneal irritation, especially if the size and length of the collaret is larger. On the other hand, Engel and Co Workers recommend performing MCI through the superior canaliculus, and found only a 2% risk of conjunctival or corneal abrasions in their series of 635 eyes. If MCI is used, corneal abrasions or ulcers can be caused by the ocular end of the MCI. The abrasions usually occur in the inferior nasal quadrant (if the tube is fixed in the inferior canaliculus), and usually heal in a few days after local treatment [24].

We had one case of lost tube before the intended time of removal, premature removal of tube may result in the recurrence of obstruction [17,25].

Advantages of the pushed monocanalicular intubation includes the type of anesthesia used; a “pulled” self-threading monocanalicular stent requires placing the patient under general anesthesia for adequate intranasal stent retrieval, and laryngeal protection usually is recommended as well. The pushed stent is inserted by using a metallic guide that is retracted from the stent lumen upon intubation. Because there is no intranasal retrieval of the stent required with this procedure, insertion of the stent can be accomplished with masked airway anesthesia alone.
In our study we were able to insert the tube in selected cases (3 cases) under sedation only using chloral hydrate as an outpatient procedure without the need for admission to the surgical facility.

Another advantage is the simplicity of insertion in comparison to other monocanalicular and bicanalicular tubes. Many intubation stents are composed of a silicone rod attached to a malleable stainless steel probe or to a nylon suture that can be pushed through the lacrimal ducts into the nose. The probe or suture must be identified beneath the inferior turbinate and then drawn out the nostril. The recovery of the probe or suture in the nasal cavity can be difficult and can potentially cause significant bleeding. In the Masterka, the probe guide or introducer is placed inside the silicone stent rather than attached at the end as in conventional pulled intubations stents. The silicone is thus pushed into the lacrimal ducts with catheterization. The removal of the introducer is accomplished via an “upper” route, thus avoiding the nasal recovery step of pulled intubations. Thus the use of a pushed intubation method resembles a simple probing technique more than does pulled intubation.

The manipulation in only one canaliculus is also advantageous because the risk of possible iatrogenic traumatisation of the lacrimal system is lower [26] and the tube is fixated in the punctum without the need of anchoring sutures, there is no risk of cheese wiring of the puncta due to excessive tension as in cases of bicanalicular intubation [18,26]. Although we intubated the upper canaliculus with no manipulations in the lower one there was a high success rate. We chose to insert the tube in the upper canaliculus to keep the lower one virgin for further intervention if required.

Finally removal of the tube is simple and done under light sedation as an office procedure. And the relative early removal (4 weeks) in comparison to other tubes didn’t show an increase in the recurrence rate at 1 and 2 months post tube removal.

One of the main drawbacks of the use of Masterka for treatment is that it’s only effective for simple mucosal obstructions of the nasolacrimal duct, unlike other types of silicon intubations. Complex cases with a stenotic nasolacrimal duct is determined by absence of metallic contact, difficulty during insertion of the tube and the silicon bunches up around the introducer without passing the stenosis, if this is found then the Masterka is not indicated.

Another problem is that during pulled intubation, most cases of false passage can be corrected to a certain extent, during recovery of the stent by the lower nasal approach; a variable length of nasal mucosa will be damaged. In contrast, with pushed intubation, removal of the metallic guide by the upper approach will not correct the false passage. This may be reduced by detecting the metallic contact within the nasal fossa to confirm the presence of a ductal opening below the inferior turbinate.

The major obstacle for recommended routine use for primary treatment is the cost of the Masterka, both intubation and probing is performed in a surgical facility under mask ventilation anesthesia. The tubes currently cost the facility around $70, whereas the probing doesn’t require this extra cost. Also intubation requires a visit to remove the tubes but this is done in the office and doesn’t need a surgical facility.

**Conclusion:**

Pushed Monocanalicular intubation proved to be a simple method for intubation with a fast learning curve, minimal complication and it requires mask ventilation anesthesia and could be even done under light sedation with chloral hydrate in the outpatient facility.

It is effective in primary management of congenital nasolacrimal duct obstruction. However, our results raise the question of whether this ease and effectiveness of the tube could be weighed against the extra higher cost compared to simple probing as there was no statistical difference between the two procedures.

**References**


الملخص العربي

في هذا البحث درسنا الفرق بين استخدام الأنبوب الأحادي بطريقة الدفع وتسلك القناوات الدمعية كعلاج أولي للأطفال بإنسداد خلق في القناوات الدموع.

إنسداد القناوات الدموع الخلقية مشع شائع في الأطفال حديثي الولادة، يصيب 5% من المواليد. هناك طرق كثيرة لعلاج الإنسداد في القناوات الدمعية، بدء بالمتابعة وإنترنت القنوات التلقائي خصوصاً في أول 6 أشهر ثم بتسلك القناوات الدمعية أو تركيب الأنبوب في القناوات الدمعية، أو توسيع القناوات بالباولون أو عمل جراحة.

لقد أجرينا الأنبوب المدفع في 50 عم وترسل في 10 عم، عمر الأطفال كان يراوح بين 8 و32 شهر ولم يجرؤ أي تدخل من قبل. متابعة المرضى كانت بعد أسبوع، شهر، شهرين، 6 أشهر، وإزالت الأنبوب بعد شهر وكابغنا المرضى لمدة شهرين بعد إزالة الأنبوب وقد وجدنا نسبة النجاح في مجموعة التسلك 80% ولنسبة النجاح في مجموعة الأنبوب 82.5% ولا يوجد فارق إحصائي من الطرق الشائعة في علاج الإنسداد. استخدم التسلك كعلاج أولي ولكن هناك من يوصي بوضع أنبوب أولي لتحسين نسب النجاح وتقليل الحاجة لعمليات أخرى.

استخدام الأنبوب المدفع إجادة القناة هو وسيلة جديدة لعلاج الإنسداد الخلقية في القناوات الدموع ومن مميزاته أنه سهل التركيب ولا يحتاج سوى تخدير خفيف للمريض وهو فعال في علاج حالات الاستضداد.

ومع ذلك الدراسة أثبتت أنه لا فرق بين التسليك والأنبوب المدفع الإجادة حيث لم يكن هناك فرق إحصائي بينهم لذلك نوصي بعمل دراسات أخرى للتحقيق من فاعلية الأنبوب في تقليل نسبة الحاجة لعمليات أخرى.