ABSTRACT
Background: Congenital nasolacrimal duct obstruction (CNLDO) is usually caused by a membranous block at the valve of Hasner. Symptoms of CNLDO include epiphora, mucous discharge, or mucopurulent discharge. Many CNLDOs can resolve spontaneously by the first year of life. Children who ultimately have unsuccessful responses to canalization will undergo invasive procedures for CNLDO, including probing, silicone intubation, balloon dacryocystoplasty and dacryocystorhinostomy. There are two types of lacrimal intubation, monocanalicular and bicanalicular. Pushed monocanalicular stent is characterized by the probe guide actually placed inside the silicone tube, rather than attached at the end as in conventional “pulled” intubations stents.

Aim of the work: was to compare the success rate of pulled monocanalicular (MCI) versus pushed monocanalicular silicone intubation (PMCI) of the nasolacrimal duct for congenital nasolacrimal duct obstruction.

Patients and methods: In a prospective randomized clinical trial 67 eyes of 67 patients with CNLDO underwent either pulled monocanalicular silicone intubation (MCI) (=32 eyes) or PMCI (=35 eyes). Cases were considered successful if reached grade 0 or 1 in fluorescein dye disappearance test -complete or partial resolution of symptoms - after two months after tube removal.

Results: This study included only patients with simple obstruction at the level of the Hasner valve and diagnosed intraoperative during the initial probing thus, the surgical outcome was assessed in 30 eyes of 30 patients in the MCI groups. 15 eyes received MCI in the upper punctum and 15 eyes received MCI in the lower punctum. The other 30 eyes 30 patients did PMCI with Masterka tube. 15 eyes received PMCI in the upper punctum and 15 eyes received PMCI in the lower punctum. 33 females (55%) & 27 males (45%) with age ranged from 12 to 46 months with mean of 26 ± 11 months. Follow-up of the patients was done at 1 week, 1 month, 2 and 3 months post-operative. Tube removal was done 3 months post operatively in both types of tube. The overall success rate in the MCI intubation groups was 86.7%, whereas in the PMCI intubation groups was 80%. However, the difference in the success rates between the two groups was statistically insignificant (P= 0.4884) using Chi-square test.

Conclusion: Results indicate that MCI has higher success rate in CNLDO treatment compared with PMCI in this small series of patients.

Keywords: lacrimal drainage system; congenital nasolacrimal duct obstruction; silicone intubation.

INTRODUCTION
The etiology of congenital nasolacrimal duct obstruction (CNLDO) is most commonly a membranous obstruction at the valve of Hasner at the distal end of nasolacrimal duct. General stenosis of the duct is the second most common cause of duct obstruction (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).

CNLDO is a common condition in early childhood, which is reported to occur in 3-5% of mature children (3).

Most cases resolve spontaneously or after lacrimal sac massage (4). For those children whose obstruction does not spontaneously resolve, probing is an initial procedure (5).

There is considerable controversy surrounding the management-both conservative and surgical- of childhood epiphora. The treatment of CNLDO includes conservation , topical antibiotics with tear duct massage till age of 10 months , and surgical intervention ranging from simple probing to more invasive procedures, such as stent intubation around one year and dacryocystorhinostomy at age of 4 years (6).

Nasolacrimal silicone intubation is a treatment for CNLDO after failed probing and irrigation (7). Intubation was more successful than probing in patients with Down syndrome (8).

Many studies have indicated excellent results with monocanalicular silicone intubation for the initial correction of congenital nasolacrimal duct obstruction (9).

Most intubation stents are composed of a silicone tube attached at each end by stainless steel probe guide or flexible Polyethylene-ether-ketone (PEEK) thread. Because the probe guide must reach to the inferior turbinate and then drawn out...
A Comparison Between Pulled and Pushed Monocanalicular Silicone Intubation

...the nostril, they can be termed "pulled" intubations. The recovery of the guide in the nasal cavity, however, can be difficult and can potentially cause significant bleeding. For this reason, "pulled" nasolacrimal silicone intubation requires general anesthesia with mechanical ventilation and laryngeal protection (10). In pulled monocanalicular silicone intubation (MCI), the stent is retrieved in the nasal cavity with a special hook (11).

An alternative type of intubation stent, a "pushed" form, has been devised in an effort to reduce the complications of "pulled" intubations. This type of stent is characterized by the probe guide or introducer actually placed inside the silicone tube, rather than attached at the end as in conventional "pulled" intubations stents. The silicone is thus pushed into the lacrimal ducts by catheterization. The removal of the introducer is then accomplished via an "upper" route thus avoiding the nasal recovery step of "pulled" intubations. Use of a "pushed" intubation method is more similar to a simple probing technique than "pulled" intubation (10). The Aim of the current work was to compare the success rate of pulled monocanalicular (MCI) versus pushed monocanalicular silicone intubation (PMCI) of the nasolacrimal duct for congenital nasolacrimal duct obstruction.

PATIENTS AND METHODS

This prospective randomized study included a total of 67 patients suffering from congenital nasolacrimal duct obstruction attending at outpatient Ophthalmology Clinic of Al-Azhar University Hospitals. Approval of the ethical committee and a written informed consent from all the subjects were obtained. This study was conducted between March 2016 until March 2018.

The 67 eyes of 67 patients with CNLDO were grouped, in MCI groups (group 1 and group 2) (=32 eyes) and in PMCI groups (group 3 and group 4) (=35 eyes).

Children with simple congenital nasolacrimal duct obstruction and a history of failed probing (secondary treatment) or Age of 12-48 months (primary treatment) were included in this study. Patients with previous eyelid surgery, punctal or canalicular anomaly, previous dacryocystorhinostomy, history of trauma to the nasolacrimal system and other causes of epiphora were excluded.

Preoperative evaluation:

History: Detailed history taken about time of the start, course, duration and intermittency of epiphora. History of any previous intervention including probing, number of probing, age at which probing was done and if any improvement of epiphora happened after probing.

Lacrimal system examination: Lacrimal sac was inspected for any swelling by using of magnification loupe with overhead light. Regurge test was done for mucoccele diagnosis.

Ear, Nose and Throat (ENT) consultation: for detection of any cause of obstruction.

Special examination procedure for detection of CNLDO

Fluorescein dye disappearance test (FDT):

A drop of fluorescein or fluorescein strip 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 daily, 0-25% of the dye 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.

All nasolacrimal intubations were performed under general anesthesia. General anesthesia was achieved by inhalation of a halothane gas using a facial mask and mechanically assisted ventilation (using orotracheal intubation). The punctum was dilated using punctal dilator, then injection of viscoelastic material through the punctum to facilitate introduction of the tube, then probing was done. Patency was confirmed by touching the probe under the inferior meatus in the nasal cavity with a Crawford hook (metal on metal).
In the monocanalicular technique, we placed a medium collaret Monoka Fayet tube (Guide of Crawford, FCI, Paris, France) through the punctum; the tube was retrieved in the nasal cavity with Crawford hook. The head was then fixed in the punctal ampulla with a plug inserter.

In the pushed monocanalicular technique, The appropriate Masterka stent 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 appropriate stent is chosen by adding 5 mm to the distance between the punctum and the nasal floor. Masterka stents available in 3 lengths (30 mm, 35 mm, 40 mm). Once the proper stent length was selected, the Masterka (FCI, Paris, France) was inserted into the canaliculus. Once the Masterka was advanced completely into nasolacrimal duct and the plug came in contact with punctum, the metal guide was removed by holding the plug firmly in contact the punctum. The head was then fixed in the punctal ampulla with a plug inserter. Following the surgery, the child was given topical combined Tobramycin and Dexamethasone 4 times daily for a week after intubation. Broad-spectrum systemic antibiotic, amoxicillin preparation was given every 8 hours for 3-4 days postoperatively.

The children were examined for improvement of symptoms (disappearance of epiphora and discharge), complications within 1 week and then again after the first, second and third months of surgery. Tube removal was done 3 months postoperatively in both types of tube and was performed in the office with a forceps by pulling on the collaret.

Statistical Analysis

- Statistical package of Graph pad prism 7 was used for analysis of data.
- Data was summarized as mean ± SD. Comparison between and in groups was carried out using two-tailed t test.
- Chi-square test was used to compare the outcome parameters between groups.
- Pearson's correlation was also done to examine the correlation between parameters.
- P-value was considered significant if ≤ 0.05 at confidence interval 95%.

RESULTS

A total of 67 eyes of 67 patients with CNLDO were included, in MCI groups (group 1 and group 2) (=32 eyes) and in PMCI groups (group 3 and group 4) (=35 eyes). In the MCI groups, two patients were unavailable for follow-up after tube removal. In the PMCI groups, three patients were unavailable for follow-up after tube removal and one patient diagnosed as canalicular obstruction and one patient diagnosed as severe ductal stenosis.

Our study included only patients with simple obstruction at the level of the Hasner valve and diagnosed intraoperative during the initial probing thus, the clinical results of 30 eyes of 30 patients in the MCI groups and 30 eyes of 30 patients in the PMCI groups were evaluated.

Group 1: included 15 eyes received MCI in the upper punctum. Group 2: included 15 eyes received MCI in the lower punctum. Group 3: included 15 eyes received PMCI in the upper punctum. Group 4: included 15 eyes received PMCI in the lower punctum.

33 females (55%) & 27 males (45%) with age ranged from 12 to 46 months with mean of 26 ± 11 months. : 26 patients (43.3 %) ≥ 12 months, 19 patients (31.7 %) ≥ 24 months, 15 patients (25 %) ≥ 36 months.

Pre-operative grading: The table below shows the distribution of patients according to the grade of nasolacrimal duct obstruction using fluorescein dye disappearance test, only patients with simple obstruction at the level of the Hasner valve were included whom were diagnosed intraoperatively during the initial probing.

Table (1): Distribution of patients in fluorescein dye disappearance test grading among the study pre-operatively:

<table>
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<th>Grade</th>
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<td>0</td>
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<tr>
<td>1</td>
<td>0</td>
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<tr>
<td>2</td>
<td>18 (30%)</td>
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<tr>
<td>3</td>
<td>27 (45%)</td>
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<td>4</td>
<td>15 (25%)</td>
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Operatively:

Follow-up of the patients was done at 1 week, 1 month, 2 and 3 months post-operative.
First week post procedure: Examination of patients to assess the presence of the tube in its site, any complication, conjunctival sac evaluation, medial canthus observation and/or palpation.

One-month post procedure: 43 eyes (71.6 %) were successful, 17 eyes (28.3%) shows no improvement in symptoms.

Two-months post procedure: 48 (80 %) cases were successful, 2 eyes (3.3%) shows partial improvement and 10 eyes (16.7%) failed.

Three-months post procedure: 50 eyes (83.3%) were successful.

Figure (1): Progression of success rates through the follow-up period in the two groups.

However, the difference between the success rates in the two groups was statistically insignificant (P= 0.4884) using Chi-square test.

Post-operative data:
Table (2): Distribution of improvement in fluorescein dye disappearance test grading among the study post-operatively.

<table>
<thead>
<tr>
<th>Grade</th>
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<tbody>
<tr>
<td>0</td>
<td>43 (71.6%)</td>
</tr>
<tr>
<td>1</td>
<td>7 (11.7%)</td>
</tr>
<tr>
<td>2</td>
<td>7 (11.7%)</td>
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<tr>
<td>3</td>
<td>3 (5%)</td>
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Outcome of the procedure:
Cases were considered successful if reached grade 0 or 1 in fluorescein dye disappearance test -complete or partial resolution of symptoms - after two months after tube removal.

Complications: 4 patients (6.7%) with slit punctum, 3 patients (5%) with corneal abrasion, 4 patients (6.7%) with nasal bleeding and 4 patients (6.7%) had lost tube.

50 eyes (83.3%) were successful and 10 cases (16.7%) required further intervention; with 43 (71.6%) of cases showing complete resolution of symptoms at the end of study (Grade 0).

The overall success rate in the MCI intubation groups was 86.7%, whereas in the PMCI intubation groups was 80%. However, the difference in the success rates between the two groups was statistically insignificant (P= 0.4884) using Chi-square test.

Success rate in group 1 and 2 MCI : was (86.7 %) and in group 3 PMCI was also (86.7 %) whereas in group 4 PMCI (73.3 %).

Figure (2): Comparison between Monoka stent groups & Masterka stent groups as regards success and failed cases.

DISCUSSION
In present study, the overall success rate in the MCI intubation groups was 86.7%, whereas in the PMCI intubation groups was 80%. However, the difference in the success rates between the two groups was statistically insignificant (P= 0.4884) using Chi-square test.

The Success rate in group 1 (Monoka upper punctum) was 86.7%, also the success rate in group 2 (Monoka lower punctum) was 86.7%, while the success rate in group 3 (Masterka upper punctum) was 86.7 %, but the success rate in group 4 (Masterka lower punctum) was 73.3 %.

Comparing our results with those of other trials, we found a variation in the success rates between those trials.

Present study achieved nearly the same success rate of Kaufman and Guay-Bhatia (12) study which was a retrospective study of 50 eyes treated with monocanalicular intubation with Monoka tube (36 as primary treatment) with an overall success rate of 79%.
Our study is partially agree with Andalib and Mansoori (13) study which was a retrospective randomized clinical trial 53 eyes of 49 patients with CNLDO underwent either monocanalicular silicone intubation (MCI) (=28 eyes) or PMCI (=25 eyes). And the surgical outcome was assessed in 20 eyes with MCI and 20 eyes with PMCI. Treatment success was achieved in 18 of 20 eyes (90.0%) in the MCI group compared with 10 of 20 eyes (50%) in the PMCI group (=0.01).

The higher success rate in PMCI groups of present study (80%) may be attributed to the difference in the inclusion criteria between the two studies where in present study it was conducted on patients with simple obstruction at the level of Hasner valve.

The current results are higher than those of the study by Rajabi et al (14) that included a total number of 90 eyes received monocanalicular intubation in the lower punctum which divided into 2 groups: Monoka MCI (=52 eyes) and Masterka PMCI (=38 eyes). Complete and relative success rate was achieved in 37 of 52 eyes (71.2%) in the Monoka group compared with 18 of 38 eyes (47.3%) in the Masterka group with statistically significant difference.

Actually there is no definite explanation to demonstrate the reason of the lower success rate in Rajabi et al (14) study compared to present study as the success rate in group 2 (Monoka lower punctum) was 86.7% and in group 4 (Masterka lower punctum) was 73.3% ; we suppose that using viscodissection prior to the introduction of the probe in the lacrimal pathway has allowed us to use the probe in a pioneering manner in cases of fibrosis as it dilates the pathway and facilitates such a sensitive passage. If this maneuver were not performed, the guide would perforate the silicone due to the pressure being exerted with possible destruction and rejection of the intubation system, in addition to the potential creation of a false pathway.

However, we achieved a lower success rate with PMCI (80%) in contrast to Alanón et al (16), that reported 97.5% success rate in 40 patients treated for congenital nasolacrimal duct obstruction (CNLDO) with the Masterka.

It seems that the number of tube loss before the intended time of removal in PMCI groups of present study may be the cause of the lower success rate.

CONCLUSION

Our results indicate that MCI has higher success rate in CNLDO treatment compared with PMCI in this small series of patients. However, PMCI has the advantages of the simplicity of insertion in comparison to other monocanalicular and bicanalicular tubes.

The manipulation in only one canaliculus is also advantageous because the risk of possible iatrogenic traumatization of the lacrimal system is lower. Removal of the tube is simple and done under light sedation as an office procedure.

REFERENCES


