Original Research Article

Endoscopic DCR with and without prolene stent in rural area: a prospective randomized study

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ABSTRACT

Background: The objective of the study was to compare the results of endoscopic DCR with and without prolene stenting and to assess subjective and anatomical success in patients undergoing prolene stenting.

Methods: The surgical outcomes of endoscopic endonasal DCR was compared in 100 patients of chronic dacryocystitis with nasolacrimal duct obstruction from June 2013 to May 2018. The successful outcome of surgery was defined by subjective improvement of symptoms and anatomical patency of the neo-ostium on syringing by nasal endoscopy.

Results: In our study females were predominant in both groups with around 60% being females in group with stenting and 64% in group without stenting. Male to female ratio was 1:1.5 and 1:1.77 in group with stenting and without stenting. The symptomatic success rate of the surgery at the end of 3 months was 92% in group without stenting and 88% in group with stenting. There was no statistical difference in the results of two groups.

Conclusions: We recommend that stenting is not routinely required for endoscopic DCR surgeries. A selective stenting approach may be advocated using prolene 3-0, using stenting for specific indications. With proper surgical technique and good follow up, endoscopic DCR without stenting is treatment of choice for chronic nasolacrimal duct obstruction.

Keywords: Endonasal DCR, Chronic dacryocystitis, Prolene stent, Nasolacrimal duct obstruction

INTRODUCTION

Chronic dacryocystitis is a permanent state of nasolacrimal duct obstruction, with causes constant tearing because of the closed natural route of tears. It is caused by stenosis of the nasolacrimal drainage system due to acute or chronic inflammation, trauma and congenital malformations, and presents with recurrent conjunctivitis, lacrimal sac inflammation and chronic epiphora.

Toti in 1904 described classic treatment of this chronic obstruction as external dacryocystorhinostomy, traditionally performed by the Ophthalmologist.¹ The endoscopic method of endoscopic dacryocystorhinostomy (DCR) has been gaining popularity due to advances in endoscopes and was first described by McDonough and Meiring.²,³

The success rate of endoscopic DCR is reported to be in the range from 70% to 98%. Many factors influence the outcome of endoscopic DCR, and one of the most important prognostic factor is the obstruction level in the lacrimal drainage system. Most authors advocate the use of a bicanalicular silicone stent (sometimes referred as “intubation”). It is passed from inferior and superior canaliculi, through the common canaliculus and lacrimal sac; the ends of which are tied together in the middle meatus.⁴,⁵
There is much controversy regarding the use of stenting for DCR. Some advocate its use since it takes less time, less bleeding, increased patency rate, absence of scar and possibility to correct associated intranasal pathology during the same procedure.³⁻⁶ While Allen and Berlin reported a higher failure rate when using silicone tubing. A suggested reason for this was the presence of granulomatous inflammation in association with silicone intubation.⁷ Okuyucu et al suggest that efficacy, defined as anatomic and functional success, is equally high for both silicone and prolene stents (Prolene; Ethicon, Inc.).⁸

As no such studies were undertaken before in our institution and adjoining rural area, a need for prospective randomized study is required to determine the outcome in success rate of lacrimal sac surgery, which enables us to formulate better treatment guidelines for chronic nasolacrimal duct obstruction cases in our hospital. Purpose of the current study was to evaluate the functional and anatomic success of primary endonasal DCR with and without prolene stent.

METHODS

Ours is prospective randomized comparative study with 100 patients from department of ENT and referred cases from ophthalmology department, with complaint of chronic epiphora were included after evaluating inclusion and exclusion criteria, informed consent and obtaining clearance from ethical committee of U.P. Rural Institute of Medical Sciences and Research, Saifai, Etawah, Uttar Pradesh, India from June 2013 to May 2018.

Inclusion criteria were age more than 15 years, nasolacrimal duct obstruction with patent upper and lower canaliculi, symptoms like epiphora, discharge from the eye, swelling in the lacrimal region, hard stop on lacrimal syringing and previous failed endoscopic endonasal DCR. While Cases of congenital dacryocystitis, gross systemic diseases, common canalicular obstruction and chronic granulomatous diseases of the nose, polyps and patients not willing to consent were excluded from the study.

The pre-operative evaluation consisted of a standard ophthalmic and otolaryngologic examination, lacrimal probing followed by irrigation and Nasal Endoscopy. The nasal cavity was examined and the need for additional nasal surgery (i.e., septoplasty, middle turbinate reduction) also was determined pre-operatively. Randomization of patients into two groups was done on the basis of simple randomization technique by computer generated token system after their Pre-anesthetic checkup. 50 patients underwent endoscopic DCR with Prolene stenting and 50 without stenting.

Operative procedure

The procedure was done under local anaesthesia with sedation. Xylocaine 4% with adrenaline (1: 20,000) in form of neurosurgical patties was kept in the nose/middle meatus area for 10 min using 0° and 30° 4 mm Hopkin rod lens endoscopes. It was followed by injecting local anesthesia (2% xylocaine in 1:200,000 adrenaline) in the nasal mucosa around the area of the lacrimal sac. A -shaped incision was made with sickle knife 1cms anterior to the middle turbinate and C shaped mucosal flap, based posteriorly, was elevated. Kerrison’s punch forceps was used to break the frontal process of maxilla in thin lacrimal bone when it could be engaged or by diamond drill burr for complete bone removal, if needed, in remaining cases leading to exposure of the medial sac wall. After lacrimal probing to tent the medial wall of sac, posterior vertical incision of the sac wall was performed with sickle knife followed by the removal of the medial wall of sac. The free flow and patency was confirmed by syringing under endoscopic guidance. At this point attending sister will provide us the computer-generated token, for stent placement to reduce bias (discussed earlier). A 3-0 polypropylene (Prolene; Ethicon, Inc.) suture was passed from the inferior canaliculus (monocanalicular) into the nasal cavity using a disposable Viscoelastic cannula, (23G, angled at 45°) and tied outside the nose loosely to prevent laceration. A small gel foam patch was placed in the exposed sac and nasal packing was given for 24 hours (Figure 1-6).

Figure 1: Incision anterior to the middle turbinate.

Figure 2: Flap elevation.
Postoperative care and follow up

Broad-spectrum oral antibiotics were given for 5 days together with Ofloxacin eyedrops for 7 days. Nasal saline drops were also prescribed after pack removal for 4 weeks. All patients were followed weekly for 1 month then at 6th week, 3, 6 and 12 months post-operatively. Prolene stent was removed at 6 weeks.

At every visit residents assessed subjective symptom of epiphora as No epiphora (0), Minimal epiphora (1), Moderate epiphora (2) and Severe epiphora (3), Grade 0, 1 and 2 were classified as success and 3 as a complete failure. While anatomical patency was assessed by lacrimal syringing under endoscopic guidance as patent and not patent.

RESULTS

Data were analysed by using Microsoft excel 2016 and IBM SPSS Statistics 23 software.

Out of 100 recruited patients, only 89 patients completed 12 months of follow-up. Six patients were lost to follow-up. A total of 50 patients received prolene stent, and 50 patients did not. Ratio of female to male in group with stent is 1.5:1 and ratio of female to male in group without stent is 1.77:1. Range of age is 16 to 70 years in group with stenting and 24 to 79 years in group without stenting. The mean age of patients in a group with stenting (47.1±15.3) is less than mean age for the group without stenting (51.2±14.5). The demographic data are shown in Figure 7.

Symptomatic success and anatomic patency

Improvement of symptoms of grade 0 i.e. no epiphora post operatively seen more in group with stenting (88%) than in group without stenting (64%). Grade 1 level of improvement of symptoms is seen more in group without (24%) stenting than with stenting (4%). As grades 0, 1, and 2 were regarded as successful outcome of surgery, the success rate of the surgery at the end of 3 months was 92% in the group without stenting and 88% in the group
with stenting. There was no statistical difference between the two groups (p>0.05) (Table 1).

Table 1: Subjective assessment at 3 months.

| Subjective assessment of the symptoms at 3 months | With stent (N=50) | Without stent (N=50) | P value* |
|--------------------------------------------------|-------------------|----------------------|---------|
| No epiphora (0)                                  | 44 (88.0%)        | 32 (64.0%)           | 0.094   |
| Minimal epiphora (1)                             | 2 (4.0%)          | 12 (24.0%)           |         |
| Moderate epiphora (2)                            | 0 (0.0%)          | 0 (0.0%)             |         |
| Severe epiphora (3)                              | 4 (8.0%)          | 6 (12.0%)            |         |

*On Pearson chi-square test there is no significant association found.

Table 2: Objective assessment of patency of ostium.

| Objective assessment by Nasal Endoscopy on syringing at 3 months | With stent (N=50) | Without Stent (N=50) | P value* |
|------------------------------------------------------------------|-------------------|----------------------|---------|
| Patent Ostium                                                     | 46 (92.0%)        | 44 (88.0%)           | > 0.5   |
| Blocked Ostium                                                   | 4 (8.0%)          | 6 (12.0%)            |         |

*On Pearson chi-square test there is no significant association found.

Table 3: Results of the study.

| Result of the study | With stent (n=50) | Without stent (n=25) | P value* |
|---------------------|-------------------|----------------------|---------|
| Success             | 46 (92.0%)        | 44 (88.0%)           | 0.64    |
| Failure             | 4 (8.0%)          | 6 (12.0%)            |         |

*On Pearson chi-square test there is no significant association found.

Blocked neo ostium on nasal endoscopy after syringing seen in more number of patients (6 out of 50) in a group without stenting than with stenting (4 out of 50). The failure rate of surgery was found to be 8% in group with stenting and 12% in group without stenting at the end of 3 months. There was no statistical difference between the two groups (p>0.05) (Table 2).

Complications

There were no major complications, nasal bleeding, granulation, synechiae, punctal trauma and lid edema were most common complications. There was no documented orbital and subcutaneous emphysema, conjunctival fistula formation, retrobulbar hemorrhage, medical check ligament injury, medial rectus paresis or orbital fat herniation.

Overall success

The success rate of the surgery in group with stenting is 92% and 88% in group without stenting. There was no statistical difference between the two groups (p>0.05) (Table 3).

DISCUSSION

The current prospective study included 100 patients presenting with epiphora due to NLD obstruction, who were operated for endonasal DCR in a medical college which caters mostly to the rural population, during the study period of 5 year from June 2013 to May 2018.

In our study females were predominant in both groups with around 60% being females in group with stenting and 64% in group without stenting. Male to female ratio was 1:1.5 and 1:1.77 in group with stenting and without stenting Table 4.

The successful outcome of surgery is defined by subjective improvement of symptoms and patency of the neo-ostium on syringing by nasal endoscopy. The symptomatic success rate of the surgery at the end of 3 months was 92% in group without stenting and 88% in group with stenting. Unlu et al further had similar results (84.2 % with stenting and 94.7 % without stenting).11

The surgery is reported to be a failure if there is no improvement of symptoms and blocked ostium indicated by regurgitation of saline on lacrimal syringing. Failure rate of surgery was found to be 8% in group with stenting and 12% in group without stenting.7 There were no major complications, nasal bleeding, granulation, synechiae, punctal trauma and lid edema were most common complications.

Some authors recommend the application of Mitomycin at the rhinostomy site to reduce post-operative fibrosis and discourage stomal closure.12 Silicone stent has also been used successfully to keep the neo-ostium patent, however, various researchers have reported no statistically significant benefit on using a silicone stent in a primary DCR.10,13
Prolene is cheap, effective, and readily available in almost all operating theaters. It might be used successfully in endoscopic dacryocystorhinostomy and is promising as an alternative to silicone stent intubations, especially in settings with limited resources.14

Our strengths
Prolene suture and Viscoelastic cannula are freely available low-cost non-toxic ancillaries that can be easily procured even in rural areas, where silicone intubation set are not conveniently available. Although many studies have been done on this topic, results from a rural area are lacking. Our sample size is big enough, complete randomization and long study period are our strengths.

Our limitations
The stent is visible externally which was not preferred by many patients. Dacryocystography (DCG) and fluorescein disappearance test (FDT) was not available to us.

CONCLUSION
To conclude, we recommend that stenting is not routinely required for endoscopic DCR surgeries. A selective stenting approach may be advocated using prolene 3-0, using stenting for specific indications. With proper surgical technique and good follow up, endoscopic DCR without stenting is treatment of choice for chronic nasolacrimal duct obstruction.

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| Present study | Unlu et al11 | Mortimore et al10 | Naik SM et al7 |
|--------------|--------------|------------------|----------------|
| stent        | With         | Without          | With           | Without         | With           | Without         |
| Male to female ratio | 1:1.5 | 1:1.77 | 1:3.7 | 1:7 | 1:3.33 | 1:1.7 | 1:1.86 |

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