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| ARIPET | ROLI FOR DAC | E OF MITOMYCIN C IN SILICONE INTUBATION FAILED EXTERNAL RYOCYSTORHINOSTOMY: A PILOT STUDY. | KEY WORDS: Silicone Intubation, Mitomycin C. | |
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| Background: To evaluate the role mitomycin C with silicone intubation along in cases of failed external dacryocystorhinostomy. | | | | |

Background: To evaluate the role mitomycin C with silicone intubation along in cases of failed external dacryocystorhinostomy. **Methods:** Prospective, longitudinal, comparative case series. Consecutive patients of failed external dacryocystorhinostomy were randomized into two groups. In group A patients underwent external dacryocystorhinostomy followed by mitomycin C application and silicone intubation of the lacrimal system. In group B patients underwent external dacryocystorhinostomy followed by silicone intubation alone. Patients were followed up for minimum six months. Parameters evaluated included reduction in watering, discharge and patency of lacrimal pathway on syringing.

Results: N = 40. 20 patients in each group. Six months postoperative anatomic success was 100% in both groups. Functional success was 90% in both the groups

Conclusion: Use of mitomycin C as an adjunct did not show any clinical or statistical difference to surgical outcomes.

Introduction

External Dacryocystorhinostomy (DCR) is a gold standard surgery for nasolacrimal duct obstruction but failure still occurs in 0-23% of cases.[1,2,3]The two commonest causes of DCR failure are obstruction of the common canaliculus and closure of the osteotomy site by granulation tissue [4,5,6].

Studies have shown to increase the success rate of primary DCR using silicone intubation and mitomycin C. [3, 7, 8, 9, and 10] Silicone tube ensures patency of the fistula and canalicular system in the early postoperative period thus increasing the success rate of DCR surgery. MitomycinC (MMC) inhibits synthesis of DNA, cellular RNA, and proteins, thus inhibiting the synthesis of collagen by fibroblasts. This prevents the development of cicatrisation and granulation tissue. This anti proliferative action increases success rates of DCR surgery. Failed DCR is a commonly encountered scenario and multiple modalities have been advocated. There is scant literature on usefulness of silicone intubation and mitomycin C in these cases. A comparative clinical trial for these cases requires an extremely large sample size to assume significance. Hence we envisaged a pilot study to compare the effectiveness of this technique in management of failed DCR. The cumulative evidence of such case series will pave way for future multicentric trials to establish efficacy of this intervention.

Material and method

Study Design: Prospective, longitudinal, comparative case series. **Study Population:** Consecutive patients of failed DCR presenting to a tertiary eye care hospital were included.

Inclusion criteria:

- 1. Age more than fifteen years
- 2. Documented history of undergoing external DCR
- 3. Symptoms of watering and discharge following failed external DCR

Exclusion criteria

- 1.Punctal or canalicular block
- 2. Acute inflammation of sac or perisac area
- 3. Deviated nasal septum, nasal polyps intranasal tumors or other
- intranasal causes of failed DCR
- 4.Bleeding diathesis

After Institutional Ethics Committee clearance patients were randomized into two groups using a computer-generated logarithm. In group A patients underwent external dacryocystorhinostomy followed by mitomycin C application and silicone intubation of the lacrimal system. In group B patients

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underwent external dacryocystorhinostomy followed by silicone intubation alone Demographic data was obtained and tabulated. Pre and postoperative symptoms of watering and discharge were documented for each patient. Repeat syringing of lacrimal sac, probing by nettleship's punctum dilator and probing set was done.Dacryocystography was conducted for all patients. Each patient underwent external and internal nasal examination including nasal endoscopic examination. After confirmation of anatomical failure of previous DCR surgery, patients were explained about the cause of surgical failure and option of resurgery using silicone intubation and mitomycin C application. After obtaining informed consent, patients underwent external DCR with simultaneous silicone intubation and mitomycin C application. Patients were followed up daily for one week, weekly for four weeks and monthly up to six months of surgery. Symptoms of watering and discharge were documented on each visit as a measure of functional success. Repeat syringing and dacryocystography confirmed anatomical success at end of 3 and 6 months (silicone tube was removed at end of 3 months). Patient data was tabulated and subjected to statistical analysis.

Surgical Technique: Surgery was performed by a standard technique by one surgeon under local anesthesia. Preoperative oral and topical antibiotics, nasal decongestants and nasal packing were done. Osteotomy size was noticed and extended with Citelli bone punch to a size of 15mm x 15 mm approximately with the boundaries extending anteriorly to approximately 5 mm anterior toe anterior lacrimal crest, posteriorly to posterior lacrimal crest, superiorly under the reflected position of the MCT, and inferiorly to the inferior orbital rim. Any granulation tissue present at the osteotomy site was removed. In group A patients mitomycin C (0.3 mg/ml) was applied for 5 minutes using soaked sponges at osteotomy site and then washed off thoroughly with saline. One end of the silicone intubation tube (PRICON) was inserted in the upper canaliculus through the newly created osteotomy into the middle meatus and then withdrawn from the external nose with help of a curved artery. The procedure was then repeated through the lower canaliculus so that both ends of the tubing were delivered out the nose. The tubing was tied tightly with four to five knots in the external nares and reinforced with a 6.0 silk suture; the tube was cut close to the knots and placed in the middle meatus area. Standard surgical closure of DCR and post operative regimen was administered.

RESULTS:

A total of forty eyes of forty consecutive patients have been included in this pilot study; 20 patients in Gp A and 20 patients in Gp B...Mean age was 31.65 years (range 15-65 years). Male: Female = 14:26. In 55% patient (n=22) right eye was involved and in 45% patient (n=18) left eye was involved.

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All 40 patients complained of watering and discharge, 35% of patients (n=14) had complaints within two months of their primary surgery 70% of patients (n=28) had recurrent complaint of watering and discharge within 6 months of their previous surgery and 100% (n=40) had recurrence within 2years of their primary surgery. In 90% of patients (n=36) lacrimal sac was not visualized on dacryocystography. (Table 1) They were found to have intact sac preoperatively.

80% of patients (n=32) had osteotomy size <1cm and excessive granulation tissue was present at osteotomy site. (Table1). Excessive bleeding was noted in 25% of patients (n=10) which was controlled by applying packs soaked in saline and adrenaline. Two patients (not included in this trial) had excessive bleeding which was not controlled with packs and wound was closed immediately. 10% of patients (n=4) complained of nasal bleed postoperatively. In these patients nasal pack was removed after 24 hour. In other patient nasal pack was removed after 12 hour.

One patient complained of pain & inflammation at medial canthus after 2 week of surgery. That patient was given systemic antibiotic & infection was resolved in 1 week. None of the patient complained of spontaneous tube extrusion. In all patients tube was removed at end of 3 months. Patients were followed up to 6 months.2 patient from each group were not relieved of their symptoms making functional success rate of 90%. Syringing was patent in all 40 patients (anatomical success rate 100%) at end of 6 months.

Table 1. Demographic and Clinical findings of the Patients

| Age(Mean)(Range) | 31.65(15-65 yrs) |
|--|---|
| Gender | Female 65% (n=26) Male 35%(n=14) |
| Affected Eye | Right 55%(n=22) Left 45%(n=18) |
| Time interval from first surgery and recurrence (months) | Within 2 months 35%(n=14) Within 6 months 70%(n=28) Within 24 months100%(n=40) |
| Dacryocystographyy findings | Lacrimal sac not visualised 90%(n=36) Distended sac 10%(n=4) Osteotomy size <10 mm 80% (n=32) |
| Anatomical success rate at 6 months | Group A 100%(n-20) Group B 100% (n=20) |
| Anatomical and functional success rate at 6 months | Group A 90%(n=18) Group B 90%(n=18) |

Discussion

Nasolacrimal duct obstruction (NLDO) affects approximately 3% of general population. DCR is a gold standard surgery for NLDO in which a communication between the lacrimal sac and nasal mucosa is created. A review of literature reveals an average failure rate of 0-23 % [1, 2, 3]. Failure is frequently related to granulation tissue formation at the osteotomy site or common canaliculus, [4, 5, 6]. The intraoperative surgical causes that may contribute to failures include inability to correctly localize the sac, inappropriate osteotomy, inadequate sac opening, and significant septal deviations.

Revision of failed DCR is a challenging job and various treatment modalities available are revision of dacryocystorhinostomy with adjunct use of silicone intubation tube and/or mitomycin C, transcanaliculardacryocystorhinostomy and endoscopic revision.

A metanalysis concluded that the success rate of DCR with silicone tubing was significantly better than that of DCR without silicone tubing during external DCR.[10] Both Mitomycin C and silicone intubation have been reported to increase the success rate of primary DCR but its use in failed DCR has been scantily reported.

Till date no comparative study has been done between mitomycin C with silicone tube and silicone intubation alone in cases of failed DCR. The punctum, the lower and upper canaliculi, the common

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canaliculus, the lacrimal sac and the nasolacrimal canal were carefully examined with syringing and radiography. The level of obstruction and the status of the healthy canaliculi was demonstrated by dacryocystography .Recurrence may occur early or late after the external DCR operation. Early recurrence mostly represents the inaccurate anastomosis of the lacrimal sac and the nasal mucosa flaps and failure to excise the bone window at appropriate topography and size or Sump syndrome (residual lacrimal sac after DCR).Late recurrence represents development of hypertrophic granulation tissue due to residual lamella in the bone window, periosteal development or nasal mucosa. Mitomycin C targets this late recurrence. Frequent cause of DCR failure has been reported as closure of osteotomy site [4, 5, and 6] which is also apparentin presentstudy.We kept emphasis on creating osteotomy as large as 12-15mm canteredover lacrimal sac to prevent recurrence. Excessive bleeding was present upto 45% patients which were higher to that reported in primary DCR. This is most likely due to granulation tissue formation after previous surgery.

After a follow-up of 6 months, the rate of anatomic success alone was 100% and the rate of anatomic success together with functional success was 90% in both the groups. This study revealed that revision of Dacryocystorhinostomy with silicone intubation is a highly effective procedure in failed DCR patient. No added advantage of mitomycin C use was noted in this study. Though the negative result may question the validity of research question, the outcome is extremely significant. Mitomycin C usage in surgery has its own set of complications and should be avoided if possible. Further research and larger controlled trials are required to clearly define the role of silicone intubation and Mitomycin C usage.

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