A COMPARATIVE STUDY OF ENDOSCOPIC DACRYOCYSTORHINOSTOMY WITH AND WITHOUT THE ADJUVANT MITOMYCIN C.

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ABSTRACT
Objective: The aim of this study is to evaluate and compare the changes in Quality of Life (QoL) before and after Endoscopic Dacryocystorhinostomy with & without Mitomycin C.

Introduction: With the advent of Endoscopic Dacryocystorhinostomy over the last few decades there arises need for reducing failure and tackling the complications of this surgery. Studies done still show a better success rate for External Dacryocystorhinostomy over the endoscopic approach. Mitomycin-C can be used to reduce fibrous proliferation to maintain patency of stoma and improve the success rate.

Objective and Study Design: A Prospective Randomized study to compare the patency of stoma and relief of epiphora after Endoscopic Dacryocystorhinostomy with Mitomycin C and without in cases of Chronic Dacryocystitis.

Materials and Method: 22 patients with Chronic Dacryocystitis were included in the study after considering inclusion and exclusion criteria. 11 cases underwent Endoscopic Dacryocystorhinostomy with adjuvant application of Mitomycin-C 0.4mg/ml at the rhinostomy site and 11 without. They were followed up for 2 weeks, 4 weeks and 6 months after surgery and evaluated both subjectively and objectively.

Results: The success rate at 6 months after surgery was found to be 100% for Endoscopic Dacryocystorhinostomy irrespective of the use of Mitomycin C. Presence of synechae in the post-operative period was found to be less with the drug but not statistically significant.

Conclusion: Mitomycin C has no significant bearing on the success of Endoscopic Dacryocystorhinostomy. It does appear to induce a good healing profile in terms of mucosal recovery and wound healing. An atraumatic and meticulous surgical technique ensures good results irrespective of the adjuvant usage of Mitomycin C.

Key words: Endoscopic Dacryocystorhinostomy, Mitomycin C, Chronic Dacryocystitis.

INTRODUCTION
Integrity of the Lacrimal Apparatus in its secretory function and drainage mechanism is most vital for normal functioning of the eye. All factors which upset the drainage mechanism distal to the sac or at Nasolacrimal duct level can lead to the clinical condition of Dacryocystitis. The traditional treatment for Chronic Dacryocystitis has been External Dacryocystorhinostomy (EXT-DCR) performed by an ophthalmologist 1. Success rates of 87% to 97% for EXT-DCR have been reported 1,2.

The endonasal approach was introduced in 1893 by Caldwell and was later modified by West and Halle.

With the advent of rigid endonasal endoscopes, otorhinolaryngologists have popularized Endoscopic Dacryocystorhinostomy (EN-DCR) over the last three decades. It is now a well established alternative to the external approach with various studies showing a success rate of 80 to 95% 3,6. Major advantages of EN-DCR

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include the avoidance of a cutaneous wound and the limitations of tissue injury to the discrete fistula site without disruption of the medial canthal anatomy and function. Failures encountered in EN-DCR is due to closure of the stoma created in the lateral nasal wall due to scar formation during the healing process which will decrease or compromise the created surface area of the osteotomy site. Some of the common reasons for the surgery to fail are improper position and size of the ostium, common canalicular obstructions, development of synechae and lacrimal fossa pathology.

Thus if we can reduce fibrous proliferation at the osteotomy site and anastomosis of flaps, the success rate of EN-DCR could improve. Many methods have been devised to prevent closure of the stoma such as creation of mucosal flaps, intubation of canaliculi, lacrimal sac and stoma using silicone tubes and use of alkylating agent such as Mitomycin C.

The aim of EN-DCR is not only to establish a free passage between lacrimal sac and the nasal cavity, but also to keep this passage patent. Some studies have tried application of 0.2 mg/ml or 0.5mg/ml of Mitomycin-C to the rhinostomy opening for ensuring a permanent rhinostomy. Mitomycin-C, an antibiotic isolated from Streptococcus caespitosus is used as a chemotherapeutic agent in neoplastic diseases. It acts as a bifunctional or trifunctional alkylating agent. It inhibits DNA synthesis and cross links DNA at the N6 position of adenine and at the O6 and N7 positions of guanine.

It has been used as an adjunct to surgery to inhibit wound healing and reduce scarring. Its property of suppressing fibrosis and vascular in growth may help in maintaining the patency of stoma in EN-DCR and improve surgical outcome.

**THE AIM OF THE STUDY:**

The present study is to compare the patency of stoma and relief of epiphora after EN-DCR surgery with Mitomycin C and without in cases of Chronic Dacryocystitis.

**MATERIALS AND METHODS:**

Ethical clearance was obtained from the institutional ethics committee, JJM Medical College, Davangere. A single blind randomized clinical trial was conducted on 22 patients (11 cases with Mitomycin C and 11 cases without) who were diagnosed to have chronic dacryocystitis between November 2013 and March 2015 in Bapuji Hospital attached to JJM Medical College, Davangere. The 22 cases were randomized for either EN-DCR with Mitomycin C or without.

Patients referred to our Otorhinolaryngology Out-patient department for nasolacrimal obstruction were investigated using lacrimal irrigation and probing of the canaliculi with a blunt tipped Bowman’s probe. The lids were inspected, focussing on the positions of the lacrimal puncta and the function of the orbicularis muscle. Anterior rhinoscopy was done for every patient. The cases with presaccal block, suspicion of malignancy, pregnant or lactating women and age less than 12 years were excluded from the study. Patients who required other nasal procedures like septoplasty, release of adhesions, and clearance of agar nasi or functional endoscopic sinus surgery were included in the study.

The diagnosis was made by patient’s history of recurrent infections of the lacrimal sac and intermittent or permanent epiphora were the most frequent symptoms. Diagnostic procedures included irrigation of the lacrimal duct.

All the cases were operated under General Anaesthesia. A topical decongestant was applied to the nasal cavity and the mucosa of the lateral nasal wall was infiltrated with 2% lignocaine with adrenaline (1: 200,000). Under Rigid 4-mm 0 degree endoscopic guidance, a scalpel is used to cut a mucosal flap starting approximately 1cm above the insertion of the middle turbinate on the lateral nasal wall (axilla of the middle turbinate). This incision is brought anterior to the axilla for approximately 1cm.

A vertical incision is then made to the midpoint of the middle turbinate with a sickle knife. The incision is extended posteriorly to the insertion of the uncinate process. Mucosa was lifted up using a Freer’s elevator keeping the dissection under the mucoperiosteum (Figure 1). The mucosal flap is tucked around the anterior end of the middle turbinate. The junction of the lacrimal sac and nasolacrimal duct was visualized. A knife and suction elevator are used to elevate the thin lacrimal bone off the posterior half of the lower
lacrimal sac. The hard bone of the frontal process of the maxilla is removed with a Kerrison’s forward biting punch and the anterior half of the lower third of the lacrimal sac is uncovered (Figure 2).

A coarse diamond burr attached to a microdebrider is used to remove the thick bone overlying the upper two thirds of the lacrimal sac (Figure 3). Probing was done to confirm entry into the sac and tenting of the medial wall of the sac was done in its posterior aspect (Figure 4). A sickle knife is used to open the sac (Figure 5) as far posterior as possible thereby creating a large anterior flap. Superior and inferior releasing cuts are given with a sickle knife after which releasing cuts are applied in the posterior flap. A sharp through biting straight Blakesley forceps is then used to cut the middle third out of the original mucosal flap. This creates a U shaped flap that, when replaced, meets the flaps from the lacrimal sac end to end, thus creating a close apposition of the edges that should result in primary intention healing without granulation. Syringing was done to clear discharge and other debris. After creation of adequate rhinostomy, using single blinded randomised trial the rhinostomy site was applied with Mitomycin C 0.4 mg/ml by means of gelfoam for 5 minutes in half the cases. Following this the nasal cavity and the stoma site is washed with saline. Nose was packed with Merocel nasal packs soaked with saline for 24 hours. The average time for surgery was 45 minutes. In 2 cases which had recurrence after a previously done external Dacrocystorhinostomy stenting with silicone tube was done.

Nasal douching was performed during the follow up period along with the application of topical antibiotic eye drops for 1 week. Short term complications of the procedure like pain, bleeding and infection were also evaluated. Endoscopic examination was done during the follow up period to clear secretions, crusting, granulation and adhesions. The cases were followed up at the end of 1 week, 1 month and then at the end of 6 months.

The surgical outcome was evaluated both subjectively and objectively in the follow up period. Subjective evaluation was based on the relief of symptoms.

Statistical Analysis: Except the age, other parameters in the study are of qualitative nature. Hence student’s unpaired T test was used to compare the ages of 2 groups and constructing suitable contingency table. Chi square test was used to compare the other results in the study.

RESULTS:

In this study 22 EN-DCR operations were done under a single blinded clinical trial (11 cases with Mitomycin C and 11 cases without). The age group ranged from 13 years to 58 years. The mean age was 34.9 years (range 13 to 55 years) in patients where Mitomycin-C was used and in the other group of patients where it was not used the mean age was 41.18 years (range 27 to 58 years). The difference was statistically insignificant (P-value was 0.4232). The group where Mitomycin C was used comprised of 6 male individuals (54.5%) and 5 female individuals (45.5%). The non Mitomycin C group comprised of 4 male individuals (36.4%) and 7 female individuals (63.6%). This difference of gender in the groups was found to be insignificant. 63.6% cases (14/22) had left sided disease whereas 36.4% cases had right sided disease. The coexistent nasal pathologies treated or corrected during the procedure comprised of 3 cases of deviated nasal septum, 3 cases of a concha bullosa, 1 case of an enlarged agar nasi cell and a case of Maxillary sinus polyp on the contralateral side. Procedures such as septoplasty were done for 3 patients, one in the Mitomycin C group and two in the other group. Conchoplasty was done for 3 cases, two in the mitomycin C group and one in the other group. One patient in the mitomycin C group underwent clearance of agar nasi cells. One patient in the non mitomycin C group underwent endoscopic sinus surgery on the contralateral side of the pathology for maxillary polyposis. Three cases out of the 22 were revision cases having undergone External Dacrocystorhinostomy prior, 2 in the mitomycin C group and 1 in the non mitomycin C group.

Figure 1: Endoscopic Picture showing mucosal flap being lifted over the ascending process of maxilla.
Synechae formation was one of the main complications seen in the post-operative period between the lateral nasal wall and anterior end of middle turbinate or nasal septum. 2 of the 11 cases (18.2%) in the Mitomycin C group had synechae. 4 out of the 11 cases (36.4%) in the non Mitomycin C group had synechae. There was no statistical difference between the two groups however (p=0.33835 and is not significant at p<0.05). One patient in the non mitomycin-C group (9.1%) had granulation tissue formation. Other complications such as bleeding, infection were not seen in our patients. Serious complications such as damage to orbit, orbital contents and damage to anterior cranial fossa resulting in a CSF leak were not seen in our study.

All patients had significant subjective improvement by the third Post-operative visit with disappearance of symptoms seen prior to surgery. Rhinostomy was visible in all the cases in the follow up visits. During follow up endoscopy the surgical stoma was seen (Figure 6) along with the visualisation of tears which were seen to flow with blinking. The surgical stoma was found to be patent at the end of 6 months in all 22 cases.

DISCUSSION:

The use of nasal endoscopes has gained significant popularity over the last few years for all nasal and paranasal sinus surgeries due to its precise technique and sophisticated instrumentation. To prevent the formation of granulation/ fibrous tissue occluding...
rhinostomy site, Mitomycin C placed at the osteotomy site has been used in different concentrations for different durations for example 0.5 mg/ml for 10 minutes, 0.5 mg/ml for 5 minutes, 0.2 mg/ml for 3 minutes.

In our study the female to male ratio is 6:5. The difference of gender in between the 2 groups was statistically insignificant (p=0.3918). Other studies prior have also shown a female preponderance in the cases and it has been explained that it is due to long duration of smoke in the kitchen, dust in external environment and use of cosmetics such as kajal.

Our study also showed an increased incidence of left sided disease (63.6%) when compared to right sided disease (36.4%) as was seen in other studies. According to Arist, the left side was more involved than the right due to the greater angle formed by the nasolacrimal duct and lacrimal fossa on the right side. Other explanation could be more right handed people with preponderance to use their free left hand to clean the left eye or mop tears which in turn can increase the chances of infection. Another possibility could be congenital, anatomic narrowing of Nasolacrima duct on the left side.

A longer operative time is required for EN-DCR with mitomycin C due to the application of the agent for 5 minutes.

Also, in our study, an attempt was made to expose the lacrimal sac fully after removing the maxillary bone surrounding it. This was followed by adequate marsupialisation of the lacrimal sac and covering the exposed bone with preserved nasal mucosal flaps. Studies prior have shown that if the entire lacrimal sac is exposed during an endoscopic procedure the results can be as good as EXT-DCR. A small opening at the medial wall of the lacrimal sac, the sacrificing of nasal and lacrimal sac mucosa during the procedure, inadequate exposure of the lacrimal sac have all been said to hamper the success of the Endoscopic procedure.

The presence of intranasal abnormalities and its correction also has a significant effect on the outcome of the surgery. In our study 8 cases underwent other nasal procedures simultaneously with 6 of the procedures having a direct bearing on the results of the surgery. According to the present study, the overall success rate for endonasal endoscopic DCR was 100% with or without the adjuvant usage of the anti fibrotic agent mitomycin C.

The reported success rates for EN DCR ranges between 80-95%. While there are some studies which have said that intraoperative mitomycin C does not alter the long term outcome, there are others which recommend its use in preventing nasal adhesion, prevention of shrinkage of osteotomy site, better healing profile and less need for debridement. Studies have shown various success rates of EN DCR with mitomycin C ranging from 84-97%.

The importance of post-operative care for a period of at least 6 months cannot be understated and has been shown to have a significant effect on the results of the surgery.

The incidence of post-operative complications such as synechae was more when mitomycin C was not used (36.4%) than when it was used (18.2%), however the difference in the results were not statistically significant (p=0.33835). The synechae were released under local anaesthesia with endoscopic guidance. The number of debridement sessions following the surgery during the postoperative period also appeared to be less in that group of patients where mitomycin C was used. One patient in the non mitomycin C group developed granulation tissue around the stoma site which was removed by endoscopic visualization.

Three cases (two in the mitomycin C group and one in the other group) had undergone EXT-DCR and were revision cases. Two of which (one in each group) underwent silicone tube stenting after the procedure. The stents were removed after 6 weeks. The case where mitomycin C was not applied developed synechae which was treated in the follow up period. Follow up of all three cases for six months showed good results with resolution of symptoms and visualization of patent stoma. While some studies insist on stenting in every case of EN-DCR, others indicate a more selective use such as in revision cases. However one must be aware that sometimes silicone tubing itself may cause tissue granulation, predisposing the site to post-operative infection and adhesions along with canalicul lacerations resulting in surgical failure.

For revision DCR, the endoscopic approach with mitomycin C has been shown to be better than without...
the drug but not always. Functional and aesthetic results have been found to be better with EN-DCR than EXT-DCR in revision cases, as it prevents a second skin incision and also allows one to analyse the intranasal anatomy at the time of surgery.

No adverse effects with the use of mitomycin C was encountered in our study. There have been reports of complications such as corneal ulcers, corneal perforations, and scleral calcification in eye surgeries. However, its use has been generally found to be safe in EN-DCR.

**CONCLUSION:**

EN-DCR is a safe and effective procedure with the success rate appearing to be better than or at least nearly equal to EXT-DCR. An adequate bony window, marsupialisation of the lacrimal sac along with preservation of nasal and lacrimal sac mucosa helps in ensuring a good surgical outcome. Simultaneous correction of other nasal pathologies such as a concha bullosa or a deviated nasal septum which may have an effect on the results of the surgery, reduces the chances of failure.

Our study shows no improvement in the success rate of EN-DCR with the application of Mitomycin C. However, Mitomycin C when used shows a beneficial effect in preventing synechiae post-operatively, induces a good healing profile and reduces the number of debridement sessions.

An atraumatic and meticulous surgical technique along with a good follow up care post-operatively establishes EN-DCR as a better alternative to EXT-DCR.

**DISCLOSURES**

(a) Competing interests/Interests of Conflict- None
(b) Sponsorships - None
(c) Funding - None
(d) No financial disclosures

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