## **Original Research Article**

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# Use of mitomycin c versus gentamicin and dexamethasone in endonasal endoscopic dacrocystorhinostomy

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#### **ABSTRACT**

Background: Dacrocystorhinostomy (DCR) is the procedure done to drain the lacrimal sac in cases of nasolacrimal duct obstruction or in chronic dacrocystitis. New advancements in nasal endoscopic surgeries have given results comparable to external DCR. This is a prospective, case control, randomized, double blinded study to compare efficacy of mitomycin c local application versus gentamicin + dexamethasone local application intraoperatively.

Methods: Fifty two patients who underwent endonasal endoscopic DCR at our Tertiary care centre between October 2015 and February 2017. All patients were operated by a single surgeon with double blind method of assigning case. In 26 patients pledgets soaked with 0.4 mg/ml mitomycin C were kept over operative site for 10 min and in other 26 patients pledgets soaked with gentamicin and dexamethasone. Post operatively patients were assessed after 1<sup>st</sup> and 2<sup>nd</sup> week and 1<sup>st</sup> and 3<sup>rd</sup> month after surgery; post-operative complaints of epiphora were graded.

Results: Maximum patients belonged to the age group of 31-60 yrs (78%), females constituted the majority with n=36 (69%). At the end of the study Group A had 92% success and Group B had 85% relief in complaints.

Conclusions: We have found statistically insignificant difference between the outcome of local application of Mitomycin C and Gentamicin and dexamethasone. Thus it can be used as substitute or adjuvant with mitomycin C in the intraoperative procedure.

Keywords: DCR, Mitomycin C, Gentamicin, Dexamethasone

## INTRODUCTION

Dacrocystorhinostomy (DCR) is the procedure done to drain the lacrimal sac in cases of nasolacrimal duct obstruction or in chronic dacrocystitis. First endonasal approach was described by Caldwell, Rice performed the first modified endoscopic endonasal DCR in 1988, although due to poor naked eye visualization popularity was limited throughout 20th century. New advancements in nasal endoscopic surgeries have given results comparable to external DCR.

Endoscopic DCR has significant advantages over external DCR, like no facial scarring, no division of medial canthal ligament and physiological preservation of pump action of orbicularis oculi muscle.2

Various modifications have been added to the collection of various techniques such as application of mitomycin C to nasolacrimal fistula to reduce stenosis, use of silicon stents, and laser assisted endoscopic DCR.

Mitomycin C is an antibiotic alkylating agent which inhibits fibroblast proliferation and alters wound healing

response leading to less fibrosis and scarring around the common canaliculus and osteotomy site.<sup>3</sup>

Gentamicin antibiotic nasal irrigations have been frequently in patients with chronic rhino sinusitis, with decreased inflammatory symptoms. Dexamethasone is well proven glucocorticoid agent which exerts inhibitory effect on inflammatory pathways of Chronic rhinosinusitis.

This is a prospective, case control, randomized, double blinded study to compare efficacy of mitomycin c local application versus gentamicin+dexamethasone application.

#### **METHODS**

Fifty two patients who underwent endonasal endoscopic DCR at our tertiary care centre at Shri Vasant Rao Government Medical College and Hospital, Yavatmal between October 2015 and February 2017 were included in our study. All patients complained of epiphora.

## Inclusion criteria

All patients complaining of epiphora, with regurgitation on lacrimal sac syringing.

#### Exclusion criteria

Acute inflammation of lacrimal apparatus, malignancy of lacrimal apparatus, concomitant nasal pathologies, failed or revision DCR patients.

All patients were operated by a single surgeon with double blind method of assigning case, whereby the patient and the surgeon did not know which group they were in or being operated upon. Patients underwent the procedure under general anesthesia with throat pack, Nasal cavity was packed with pledgets soaked in 4% lignocaine and 1:10000 adrenaline for 10 min and then removed for mucosal decongestion. Nasal cavity was examined for any co existent disease or pathology; if present the DCR was combined with septoplasty or FESS. Under guidance of 0° or 45° rigid nasal endoscope. A posterior based semi lunar incision was taken on lateral wall of nose along anterior to uncinate process, axilla of attachment of middle turbinate and attachment of inferior turbinate. Mucosal flap was taken with help of sickle and freer's periosteum elevator. Underlying lacrimal bone and frontal process of maxlla bone was removed with help of Kerrison's bone punch. Thick part of the fronto nasal process of the maxilla was saucerised with 3 mm diamond burr, so as to get good exposure of the medial part of the sac.

Medial wall was given a vertical incison and medial end excised with Blakesley forceps or through cut forcep. Patency was checked with normal saline irrigation via the inferior canaliculus, which was seen in the nasal cavity. Mucosal flap was excised partially near the superior end and placed over the raw bone, care was taken not to overlap mucosa over the newly created nasolacrimal fistula region.

In 26 patients pledget soaked with mitomycin C 0.4 mg/ml pledget was kept for 10 min and rest of the 26 patients pledget soaked in solution of Gentamicin and dexamethasone was kept of 10 min. Light packing of operated nostril was done and pack was removed post operatively on day 2.

Follow-up examinations were scheduled for 1 week, 2 week, 1 month, 3 months after surgery. At each visit we asked the patients to grade their complaints according to the following scale.<sup>5</sup> Grade 0- no epiphora and complete resolution of tearing; Grade 1- minimal epiphora but not troublesome to the patient; Grade 2- moderate epiphora but still troublesome to the patient; and Grade 3- severe epiphora and no improvement. Size of the ostium was assessed by endoscopic visualization. The procedure was considered successful if the patient had grade 0 or grade 1 epiphora and complete patency of the lacrimal drainage system confirmed by irrigation at the final visit.

Data was compiled and analyzed in Microsoft Excel 2010 and IBM SPSS 10.0.

### **RESULTS**

In our study there were 52 patients who underwent endoscopic endonasal dacrocystorhinostomy surgeries, 26 patient were in Group A with Mitomycin C local application and remaining 26 were in gentamicin+dexamethasone application group. Maximum patients belonged to the age group of 31-60 yrs (78%). There was no significant difference in age between the two groups. We found more females n=36 (69%) than males n=16 (31%) with the similar complaints. However sex distribution was comparable in both groups. 30 patients (58%) presented with right sided nasolacrimal duct obstruction. On presentation 43 patients (82%) had watering with discharge as chief complaints. On ENT examination out of 52 cases, 15 (28%) cases had mild deviated nasal septum.

Table 1: Results at the end of study.

N=52	Relief in symptoms at end of study	Symptoms did not get relieved at end of study period
Group A (n=26)	24 (92%)	2 (8%)
Group B (n=26)	22 (85%)	4 (15%)

Intraoperative complication occurred in 2 cases with immediate postoperative epistaxis, which was promptly and successfully controlled.

Symptomatically 24 (92%) patients in group A and 22 (85%) patients in group B were symptom free. In group A 2 patients and 4 patients in Group B didn't have their symptoms relieved at the end of 3 month study period.

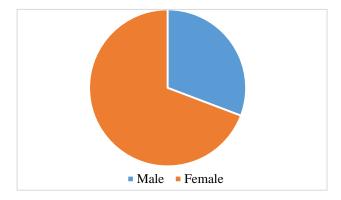


Figure 1: Sex distribution.

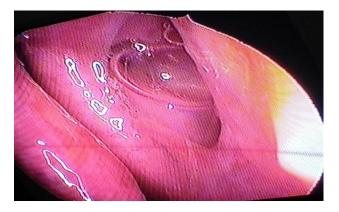


Figure 2: Patent sac post operatively at 1 month.



Figure 3: Intra operative application of mitomycin C solution.

## **DISCUSSION**

There is a discrepancy in the success rates in methods involving the external DCR (EDCR) and endoscopic endonasal DCR (EEDCR), with external DCR enjoying higher success rates than endoscopic endo nasal procedure although not statistically significant. <sup>6</sup> The lower success rate can be attributed to inability of a direct

suturing between nasal mucosa and mucosa of lacrimal sac. Patency of surgical fistula requires an epithelial anastomosis within fistula and continuous pressure or flow of fluid.

EEDCR there is a decrease in the size of the healed intra nasal ostium after surgery as a result of normal wound healing response. Scar tissue which occurred as a result of physiological healing process of sub conjunctival tissue causes failure of this fistula. Antimetabolites like Mitomycin C and 5- flourouracil inhibit DNA or RNA replication, cell division, protein synthesis and fibroblast proliferation have been used as adjunctive therapy to prevent excessive scar formation in glaucoma surgery.<sup>7</sup>

Mitomycin C when given systematically has a very high toxicity, however there are no cases of systemic toxicity after intra operative application. Also the application time for the drug was very short (10 min) with very low concentrations of 0.4 mg/ml.<sup>8</sup>

Gentamicin has been traditionally used in cases of chronic rhinosinusitis and has been found to be very effective antibiotic.<sup>4</sup> Whereas dexamethasone is a glucocorticoid which has been used in conjunction with topical antibiotics for treatment of refractory chronic rhinosinusitis.<sup>9</sup>

In our study the results were comparable with results of other studies. Mak et al reported in a series of noncomparative 83 patients a success rate of 94% with application of Mitomycin C 0.2 mg/ml for 3-10 min although there was a use of post op silicone tubing. Dolmetsch et al and Selig et al reported in similar non comparative studies a success rate 95% and 88% respectively with similar concentrations and application times of average 5-10 min. 10-12

Other case control studies like those of Ghosh involving 30 patients of primary DCR with no silicon tube insertion and MMC application success rate of 80% and in case of irrigation with normal saline success rate of 86%. <sup>13</sup>

## **CONCLUSION**

The core surgical principles of DCR remain constant; newer techniques likes laser ablation and use of radiofrequency to maintain the patency of the flap have been used as lesser invasive and safer procedure with long lasting success. MMC has played a major role in improving success rate of DCR. In centers where there is no availability of advanced instrumentation it can act as a boon. However short term action of MMC is still a point of debate as there are no generalized guidelines regarding ideal dosage, most efficacious mode of drug delivery and minimum effective duration of application of drug.

We have found statistically insignificant difference between the outcome of local application of MMC and Gentamicin and dexamethasone. Thus it can be used as substitute or adjuvant with MMC in the intraoperative procedure. Therefore there is need for larger, multicentric, uniform protocol guided, double masked randomized control trials.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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