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A COMPARATIVE STUDY OF INTRAOPERATIVE APPLICATION OF MITOMYCIN C IN ENDOSCOPIC DACRYOCYSTORHINOSTOMY.

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ABSTRACT Endoscopic dacryocystorhinostomy is done to relieve symptoms of epiphora in patients with obstructed nasolacrimal duct. The surgical outcomes vary with expertise of the surgeon and infections or fibrosis at the stoma. Many methods have been adopted by surgeons to reduce failure rates. Use of stents or application of antiproliferative agents like Mitomycin C has been tried for better outcomes. Aim: In this prospective study surgical outcomes of endoscopic dacryocystorhinostomy were compared with and without intra-operative application of Mitomycin C at stoma. Method: In this study 72 patients were included and they were randomly divided into two groups. In one group Mitomycin C was applied during surgery at stoma and in other group Mitomycin C was not used. Patients were regularly followed up for 6 months to evaluate the relief of epiphora and stomal patency. Results: It was observed that the adjunctive use of Mitomycin C in dacryocystorhinostomy gives a higher success rate compared with surgery performed without its application. Conclusion: Intra-operative application of Mitomycin- C, is simple and cost-effective method with minimal or no complications, for better outcomes in patients with epiphora with nasolacrimal duct obstruction.

KEYWORDS : Dacryocystorhinostomy, Nasolacrimal duct, Mitomycin C, Endoscopic DCR, NLD obstruction

INTRODUCTION

Dacryocystorhinostomy (DCR) is surgical procedure for the treatment of epiphora caused by obstruction of nasolacrimal duct. In dacryocystorhinostomy, fistula is created between the lacrimal sac and the nasal cavity on lateral nasal wall. It can be done either by intranasal approach or extra-nasal approach. With technological advancements in surgical field, use of fiber-optic endoscopes and improved surgical instruments, complications and failure rates have drastically reduced. However, failure and recurrence of epiphora are reported due to blockage of osteotomy site due to granulations, scarring or synechiae formations. Use of antiproliferative agents like Mitomycin-C and 5-Fluorouracil in dacryocystorhinostomy has some promising results in restricting granulations and scarring of ostium, thereby improving surgical outcomes. Though their application has significantly reduced failures of DCR yet there are studies suggesting they create no differences in outcomes.

Dacryocystorhinostomy by intranasal approach was first described by Caldwell[1] in 1893. In 1904 Toti[2] described extranasal approach for DCR. Endoscopic trans-nasal DCR using rigid Hopkins endoscopes was first described by McDonogh and Meiring[3]. Use of stents in nasolacrimal duct gained popularity when in 1967 Gibbs[4] described a technique of inserting silicone rubber tube. Many surgeons preferred using stents to prevent failure of DCR. However, DCR with stent insertion is also associated with failure of the surgery due to infections and granulations. The most common cause of failure of dacryocystorhinostomy is fibrosis of the fistula around site of osteotomy[5]. Adjuctive application of mitomycin C (MMC) to the osteotomy site has improved surgical outcome by preventing scarring of the fistula.

For many years, topical application or injection of Mitomycin C in DCR, at or around the osteotomy-site, has been practised to reduce scarring and granulations. Mitomycin -C is derived from *Streptomyces caespitosus.* It is an antimetabolite antibiotic that inhibits DNA and cellular proliferation[6]. It also reduces collagen production by inhibiting fibroblast proliferation as it is known to inhibit DNA-dependent RNA synthesis[7].

In 1997, *Kao et al*[8] were the first to report the use of Mitomycin C in lacrimal surgery. Histopathological effects of MMC in endoscopic DCR were first studied by *Ugurbas et al*[9]. They found that the loose subepithelial connective tissue of nasal mucosa became hypocellular and epithelium showed attenuation with intracytoplasmic vacuoles resulting in limited fibrosis of the osteotomy site. *Hu et al* demonstrated the efficacy of MMC in preventing the proliferation of cultured nasal mucosa fibroblasts, in doses ranging from 0.1 to 0.4 mg/ml for 1 to 5 minutes[10].

MATERIALS AND METHOD

The present prospective study was conducted to compare the surgical outcomes of endoscopic dacryocystorhinostomy performed with and without the intraoperative application of Mitomycin C.

This study was conducted from August 2019 to August 2024 and included 72 patients diagnosed with chronic dacryocystitis secondary to distal nasolacrimal duct obstruction. These patients were followed up for a period of 6 months after surgery.

Patients having acute dacryocystitis, malignant tumours, maxillofacial deformities, atrophic rhinitis, epiphora due to common canaliculi obstruction or obstruction proximal to lacrimal sac and pregnant women were excluded from the study.

Preoperative evaluation

- A proper history was taken from all the patients presenting in OPD with complaints of epiphora. Complete general, ophthalmic and clinical ENT examination was carried out including ROPLAS (regurgitation on pressure over lacrimal sac) test.
- Lacrimal syringing was carried out using Bowman lacrimal dilator and lacrimal canula through both lower and upper puncta for ensuring blockage of lacrimal system.
- Diagnostic nasal endoscopy was done for pre-surgical evaluation.
- Distal nasolacrimal duct blockage was confirmed with dacryo-cystogram.
- Patient was prepared for the endoscopic dacryocystorhinostomy.
- Pre operative antibiotic therapy was given to patients with acute infections.
- All the 72 participants in the study were randomly separated into 2 equal groups

- Group A - dacryocystorhinostomy with intraoperative application of Mitomycin C.
- Group B - dacryocystorhinostomy without application of mitomycin C .
- Endoscopic Dacryocystorhinostomy with posterior based flap was performed under general anesthesia and in patients under group A, Mitomycin C was applied at the site of osteotomy and stoma of the marsupialized sac.

Fig. I. Sac syringing

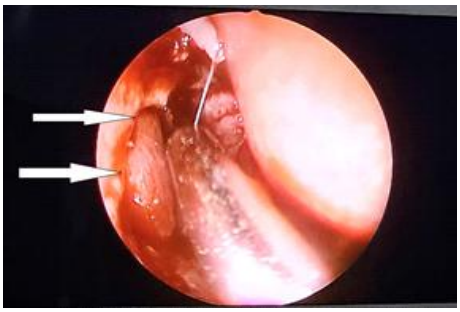

Fig. II. Exposed lacrimal sac

- Cotton pledgets soaked in 0.2mg/ml solution of Mitomycin c were applied to the osteotomy site and marsupialized lacrimal sac for 5 minutes. Copious irrigation with normal saline was done to remove excess Mitomycin C.

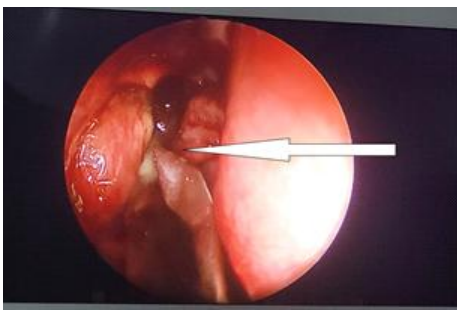

Fig. III. Incision over lacrimal sac

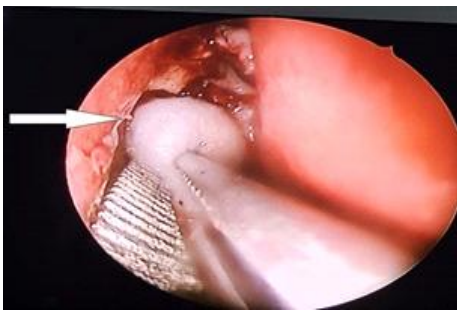

Fig. IV. Mitomycin C pledget over stoma

- Nasal packing was done with Merocel soaked in normal saline. Pack was removed after 48 hours.
- Lacrimal syringing was done on the same day after pack removal to ensure patency of lacrimal system.
- Post operatively broad spectrum antibiotics, analgesics and antibiotic eye drops were given to the patient for 5 days.

Surgical outcomes were assessed on the basis of

- Relief of epiphora and nasolacrimal duct irrigation
- Patency of the stoma evaluated with Diagnostic nasal endoscopy on weekly and monthly follow up (for 6 months).

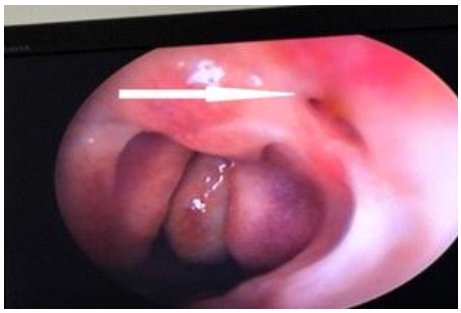

Fig. V. Post operative sac stoma

- To calculate P value and statistical analysis Chi- Square test was applied. A *p*-value of < 0.05 was considered statistically significant.

RESULTS

Out of the total 72 patients included in the study 32 (45%) were males and 40 (55%) were females. The mean age with standard deviation of study population was 46.40±16.5. Mean age in Group A was 48±15.6 and in Group B was 44±17.13. Most of the patients were in the age group of 20 to 60 years. Youngest patient operated was of 9 years of age and oldest patient was of 87 years of age.

Table I. GENDER DISTRIBUTION

	TOTAL	GRP A	GRP B
MALE	32(45%)	15 (42%)	17 (47%)
FEMALE	40 (55%)	21 (58%)	19 (53%)

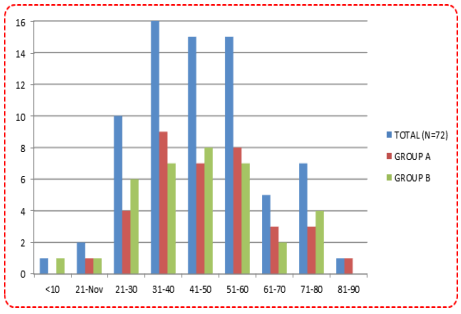

Fig. VI. AGE DISTRIBUTION

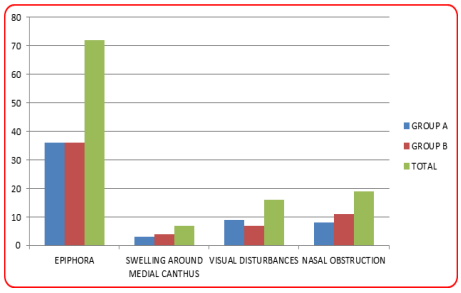

Fig. VII. CHIEF COMPLAINTS

The chief complaints of the patients were epiphora (100%) followed by nasal obstruction (52.7%) due to deviated nasal septum and visual disturbances (44.4%) because of diagnosed cataract in the same eye. Other common complaint observed was swelling around medial canthus of the affected eye (9.7%) due to acute infection of the sac with chronic epiphora.

Table II. CHIEF COMPLAINTS

S.NO	COMPLAINTS	GRPA(%)	GRP B(%)	TOTAL(%)
1.	EPIPHORA	36(100)	36(100)	72
2.	SWELLING AROUND MEDIAL CANTHUS	3(8.33)	4(11.1)	7(9.77)

3.	VISUAL DISTURBANCES	9 (25)	7(19.44)	16(44.44)
4.	NASAL OBSTRUCTION	8(22.22)	11(30.55)	19(52.77)

Major complications of the surgery were granulations and fibrosis around the ostium. One patient (2.7%) in Group A and 2 patients in Group B (5.5%) had intra-operative orbital fat prolapse, which were managed conservatively. It had no effect on surgical outcome after 6 months follow up.

Table III. Complications

S.NO	COMPLICATIONS	GRP A(%)	GRP B(%)	TOTAL(%)
1.	Infection	1 (2.7)	0	1 (1.3)
2.	Fibrosis	2(5.5)	3(8.3)	5(6.9)
3.	Synechiae	0	3(8.3)	3(4.1)
4.	Granulations	0	6(16.7)	6(8.3)
5.	Orbital complications	1(2.7)	2(5.5)	3(4.1)

At first follow-up, after 1week, 2 patients (5.5%) in Group A showed mild fibrosis around the ostium. But ostium was patent on subsequent follow ups, till 6 months. One patient (2.7%) in this group had developed infection post operatively which was successfully managed with antibiotics.

Table IV. Follow up after 1week

S.NO	EVALUATION	GRP A(%)	GRP B(%)	TOTAL(%)
1.	Subjective relief	36 (100)	32 (94.4)	68(94.4)
2.	Epiphora	1 (2.7)	3 (8.33)	4(5.5)
3.	ROPLAS	1(2.7)	1(2.7)	2(2.7)
4.	DNE(stomal patency)	36(100)	33(91.6)	69(95.8)
5.	Sac syringing (regurgitation)	0	3(8.33)	3(4.1)

Table V. Follow up after 1month

S.NO	EVALUATION	GRP A(%)	GRP B(%)	TOTAL(%)
1.	Subjective relief	34 (94.4)	27(75)	61(84.7)
2.	Epiphora	2(5.5)	9(25)	11(15.2)
3.	ROPLAS	2(5.5)	9(25)	11(15.2)
4.	DNE(Stomal patency)	34(94.4)	28(77.7)	62(86.1)
5.	Sac syringing (regurgitation)	2(5.5)	8(22.2)	10(13.8)

Table VI. Follow up after 6 month

S.NO	EVALUATION	GRPA(%)	GRP B(%)	TOTAL(%)
1.	Subjective relief	34(94.4)	27(75)	61(84.7)
2.	Epiphora	2(5.5)	9(25)	11 (15.2)
3.	ROPLAS	2(5.5)	9(25)	11(15.2)
4.	DNE(stomal patency)	34(94.4)	27(75)	61(84.7)
5.	Sac syringing (regurgitation)	2(5.5)	9(25)	11(15.2)

In group B, 5 out of 6 patients who developed granulations around the stoma, subsequently developed epiphora again and were labeled failure. All 3 patients who had fibrosis around stoma and 1 patient out of 3 who had developed post operative nasal synechiae had complete blockage of stoma.

Table VII. Surgical outcome

S. NO	OUTCOME	GROUP A(%)	GROUP B(%)	P value
1.	SUCCESS	34 (94.4)	29 (75)	0.021848
2.	FAILURE	2(5.55)	9(25)	

Successful outcome of surgery was defined by relief of epiphora and patent nasolacrimal system on sac syringing post operatively, after 6 months follow-up. Cases were labeled as failures if there was persistent epiphora and inability to irrigate nasolacrimal system on sac syringing. Success rate in group A, where mitomycin-c was applied intra-operatively, was 94.4% whereas in Group B success rate was 75 %. There were 2 failure cases in group A and 9 failure cases in group B. The success rate was more in group A (94.4%), where Mitomycin c was used intra-operatively as compared to group B (75%). The Chi-Square test showed result is statistically significant with $p < 0.05$.

DISCUSSION

The success of any surgical procedure is marked by achieving the desired outcome, and in case of dacryocystorhinostomy it is complete relief from epiphora. Both external and endoscopic approaches are equally efficient but endoscopic approach has added advantage of avoiding external scars and facility of creating adequate stoma for marsupialization of lacrimal sac. Fibrosis, granulations around stoma or synechiae between stoma & turbinates often lead to failure and persistent epiphora. To avoid this complication approaches like adequate stomal widening, use of silicone stents or application of mitomycin C has been widely advocated.

Mc Pherson and Egelston[11] observed in their study that three out of seven patients who underwent revision surgery had dense scar tissue at osteotomy site. Linberg et al[12] concluded that appropriate size of stoma made during surgery leads to a final size of 2 mm due to tissue growth or scarring. Mitomycin C, previously used to reduce scarring during excision of pterygium, was used by *Kao et al*[8] for comparing outcomes of DCR with and without application of Mitomycin C at stomal site. They observed that Mitomycin C favourably affects the ostium size and prevents adhesions.

In our study of comparing outcomes of endoscopic DCR with and without application of MMC, majority of the patients belong to the age group 20-60 years of age in both the groups. The youngest patient was 9 years old and oldest patient was 87 years old.

A higher female predilection has been noted in dacryocystitis. In our study, female to male ratio was 1.25:1. In a similar study *Ram Kumar et al*[13] noted female to male ratio of 1.8:1. Although no specific reason has been conclusively established but *Patel and coworkers*[14] suggested narrower lumen of nasolacrimal canal in females, while Dogan[15] associated it with the nasal index.

In our study the success rate was 97.4% in the group where Mitomycin C was applied at concentration of 0.2mg/ml for 5 minutes at osteotomy site, whereas it was 75% in group where mitomycin C was not applied. This result is statistically significant at $p<0.05$. It proves that mitomycin c prevents scarring and fibrosis restricting granulations and helps in maintaining stomal patency.

You and *Fang*[16] studied the efficacy of different dosages of mitomycin C and compared them with a control group where no Mitomycin C was used. Outcomes were statistically significant in group with Mitomycin C application and control group but no significant differences were noted among different dosages of mitomycin C. A Meta analysis by Qian et al[17] reported increased patency rate with mitomycin C in both external and endonasl DCR.

In our study we used a cotton pledget soaked in Mitomycin C solution for its application at osteotomy site which was followed by copious irrigation. Rathore et al[18] in their series of endonasal DCR packed the nasal cavity with 0.05% Mitomycin C nasal pack for 48 hours. Nemet et al[19] irrigated newly trephined canaliculus via punctum with 0.03% of MMC solution with stents in place. A new technique was introduced by Kamal et al[20], where intramucosal injection of 0.02% of MMC solution administered around the edges of newly created stoma. Nair and Ali[21] in their meta-analysis of application of mitomycin C in dacryocystorhinostomy concluded that all the variations of applying MMC was associated with improved surgical outcomes.

However certain researchers found no advantage of intra-operative application of MMC in DCR. In the study done by Ghosh S. et al[22], they had more success rate in group where mitomycin C was not used. Their study purported that a properly and adequately performed surgery plays more vital role in success. Similarly, in their limited series, Zilelioglu et al[23] concluded that there is no benefit of using mitomycin c in dacryocystorhinostomy.

In other studies of application of mitomycin C in DCR, done by Rahman A et al[24], Ari Seyhmus et al[25], Selig et al[26], Apuhan et al[27], Camara et al[28] etc success was significantly improved with minimum scarring, fibrosis and granulations in groups where MMC was applied. These studies further confirm the advantages of Mitomycin C application in dacryocystorhinostomy.

CONCLUSION

Endoscopic dacryocystorhinostomy with intra-operative application

of mitomycin C provides better surgical outcomes by reducing complications with minimal or no side effects. Its anti-proliferative properties avoid granulations and results minimal scarring and fibrosis. It is simple and safer to use. Other methods like usage of silicone stents should also be promoted wherever necessary. The use of Mitomycin C is promising in DCR surgeries and with properly and precisely done surgeries results are more optimal.

Declaration by Authors
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Dr. Sanjana V. Nemade and Dr Sandeep Chahande conceptualized the study on application of Mitomycin C in dacryocystorhinostomy, performed the surgical procedures, and drafted the manuscript. Dr. Sanjana V. Nemade analyzed the data and revised the manuscript critically for intellectual content.

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