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ENT

EFFECT OF MITOMYCIN C ON ENDOSCOPIC NASAL DACRYOCYSTORHINOSTOMY

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ABSTRACT Application of a wound healing inhibitor is a new treatment modality in endoscopic lacrimal surgery, intraoperative use of Mitomycin C in endonasal DCR is safe and effective in increasing the success rate as a useful adjunct in DCR surgery. The prospective observational study was carried out in patients, who were admitted in the department of ENT at RNT medical college Udaipur, a tertiary care teaching hospital of Rajasthan during timeline January 2014 to December 2014 (approximately for one year). In the study, sixty patients were suffering from chronic dacryocystitis included and all of them were subjected to Endonasal Endoscopic Dacryocystorhinostomy. All patients were divided into two groups, the control and mitomycin C group, each comprising of 30 cases. The Mitomycin C drug was applied topically intraoperatively after completion of surgery to one group and control group was withheld. The results of both groups were evaluated during follow up, scheduled at one week, one month,3 months and 6 months after day of surgery. The operation was considered as successful if patients had no symptoms and patent nasolacrimal drainage system confirmed by endoscopy and irrigation at completion of follow up period. In all 22 primary DCR surgeries were done in Control group out of which 20 were successful and 2 failed, whereas in Mitomycin C group 23 primary DCR surgeries were done in which 22 were successful and 1 failed. There were 15 cases of revision DCR surgeries were done in our institute in which 8 surgeries were done in control group, out of these 8 cases, 3(37.5%) cases were successful and 5 (62.5%) cases failed; and 7 revision surgeries were performed in Mitomycin C group, out of which 6(85.7%) cases were successful and 1(14.3%) case was failed. The use of Mitomycin C in revision cases significantly improved the success rate although no much difference is seen in primary cases.

KEYWORDS : Endonasal Endoscopic Dacryocystorhinostomy, Mitomycin C

INTRODUCTION:

Epiphora is the term commonly used to describe a "watery eye". More specifically, lacrimation describes persistent welling of tears in the eye and epiphora is the technical term used when these tears spill over. It is caused either by overproduction of tears or obstruction of the lacrimal pathway.

Dacryocystorhinostomy (DCR) is a surgical technique for treating symptomatic obstructions of the lacrimal sac or the nasolacrimal duct, or dacryocystitis in cases with no response to conservative treatment like stents and antibiotics. The purpose of DCR is to create a bypass, a rhinostoma, between the lacrimal sac and the nasal cavity.

The procedure was first described by Caldwell in 1893 (Caldwell 1893). He reported an endonasal approach for the treatment of nasolacrimal duct obstruction (NLDO). However, the technique did not gain popularity due to difficulties in visualization of the rhinostomy site and poor instrumentation. In 1904, Toti reported an external approach for the treatment of Nasolacrimal duct obstruction (Toti 1904). This technique, which has a high success rate, has been. the gold standard of Dacryocytorhinostomy for many decades. Nevertheless, this external approach has some disadvantages and it leaves an external scar.

Therefore, during the last two decades, less invasive techniques such as endonasal endoscopic dacryocystorhinostomy (Endonasal dacryocystorhinostomy) have gained popularity. They became possible with the development of rigid endoscopes and otherwise improved instrumentation. An Endonasal endoscopic dacryocystorhinostomy will avoid a facial scar, will not interfere with the lacrimal pump mechanism, preserves the medial canthal ligament and carries a shorter operating Dacryocystorhinostomy time as compared to External approach.

The success of primary Endonasal endoscopic Dacryocystorhinostomy has been reported to vary between 74% and 94% and a systematic review of outcomes after Dacryocystorhinostomy in adults indicated that the outcomes after Endonasal endoscopic- Dacryocystorhinostomy and Dacryocystorhinostomy were comparable. However, external revision procedures tend to have a lower success rate, indicating that in patients with unsuccessful surgery, there may be some factors predisposing towards failure. The most common reason for the failure is the formation of a scar over the rhinostomy site. In an attempt to prevent potential excessive scar formation, intraoperative topical application with Mitomycin C has been used because it exerts antiproliferative properties.Mitomycin C is derived from *Streptomyces caespitosus* and is an alkylating antibiotic. It reduces fibroblast collagen synthesis by inhibiting DNA dependent RNA synthesis and can suppress cellular proliferation in any period of cell cycle. Although its action is not cell cycle specific, rapidly dividing cells are preferentially sensitive to these effects. In order to prevent excessive scar formation in glaucoma surgery MITOMYCIN C has been used as adjunctive therapy. It is also used in pterygium excision and trabeculectomy by ophthalmologist. In this study we are going to use Mitomycin C in Endonasal Endoscopic Dacryocystorhinostomy at rhinostomy site to prevent excessive scar formation so that success of Endonasal Endoscopic Dacryocystorhinostomy could be improved. It is a comparison study between Mitomycin C applied and control cases to know whether the use of Mitomycin C really improves the success rate of Endonasal Endoscopic Dacryocystorhinostomy.

AIMS AND OBJECTIVE

1. To study comparative success between Mitomycin C applied & without application of Mitomycin C in Endonasal Endoscopic Dacryocystorhinostomy.
2. To assess the postoperative complication of the procedure.
3. To review the results of the surgery for both short term and long-term time period.

MATERIAL AND METHODS

This is a randomized, prospective study involving patients who were admitted and surgically treated for chronic dacryocystitis. The study had been conducted for the patient admitted between January 2014 and December 2014, with follow up done for extended six- month period. In all sixty patients were included and all of them were subjected to Endonasal Endoscopic Dacryocystorhinostomy.

All cases were admitted either from ENT department or referred from ophthalmology department of R.N.T. medical college. The technique of Endonasal DCR procedure was similar in both groups, except that, in Mitomycin C group at the end of procedure a piece of cottonoid soaked in mitomycin C (concentration 0.5mg/ml) was placed into the

rhinostoma for 5 minutes. The mitomycin C used (LYCOMIT 10, 10mg vial, UNITED BIOTECH(P) LIMITED, Solan, HP) in the study was delivered by the hospital pharmacy. The allocation done by sealed opaque envelop method was used to ensure blinding until randomization.

Preoperative Assessment

The general particulars of patients like name, age, sex, religion etc. were noted. The Clinical history pertaining to the mode of onset, duration with progression of symptoms were noted. The patients were clinically assessed by complete E.N.T. check-up with special reference to ophthalmological examination. Routine investigation like CBC, Blood sugar, Blood urea, Serum Creatinine, BT, CT, PT, INR, Urine examination HIV & Hepatitis B were done and written informed consent was taken.

Inclusion Criteria

1. All cases presenting with epiphora with established nasolacrimal duct obstruction.
2. Patient agreeing for 6-8 months follow-up.
3. Patient who was giving consent for study and use of Mitomycin C.
4. Patient who was fit for surgery.

Exclusion Criteria

1. Canalicular or common canalicular blockade ascertained by syringing and probing.
2. Patient not agreeing for follow-up.
3. Noticeable lid laxity of lower lid.
4. Previous lacrimal trauma.
5. Suspicion of malignancy.
6. Patient not giving consent.
7. Patient not fit for surgery.

Surgery:

All the operations were conducted Endo-nasally with endoscopic technique. The endotracheal general anaesthesia technique was used. For topical decongestion and hemostasis, all the patients were packed with lignocaine 4% (30ml vial) with adrenaline (3ml) soaked nasal packing before the surgery.

During the procedure, for local anaesthesia, the patient had an injection of lignocaine 2% with adrenaline into the nasal mucosa over the proposed rhinostomy site after endotracheal intubation. Each operation was performed by experienced otorhinolaryngologist. All operations were done by the same surgeon. The surgeon used 0° and 30° 4mm rigid endoscopes (Karl Strorz, Germany) with a video display monitor. Incision was made horizontally 8 to10mm above the axilla of middle turbinate, starting 3mm posterior to the axilla and coming forward about 10mm onto frontal process of maxilla then blade was turned vertically and vertical incision was made to about two third of vertical height of middle turbinate, stopping just above the insertion of inferior turbinate into lateral wall of nose. The blade was then turned horizontally and inferior incision was started at the insertion of the uncinate process and brought forward to meet vertical incision. Freer elevator was used to raise mucosal flap. After that frontonasal process of maxilla and lacrimal bone was removed by kerrison punch. Rhinostome created in medial wall of lacrimal sac mucosa. Rhinostome size was measured by tailor's measuring tape. In Mitomycin C group, mitomycin C soaked cottonoid was applied at rhinostomy site at concentration 0.5mg/ml for 5 minutes and in control group normal saline soaked cottonoid applied for 5 minutes. Anterior nasal packing was done with ribbon gauze soaked with ointment neomycin, polymixin B, zinc bacitracin and liquid paraffin. Additional surgery, such as septoplasy, endoscopic sinus surgery, conchoplasty, were performed when necessary.

Postoperative Care And Follow Up

Nasal packing was removed on second postoperative day. The patient was taught lacrimal massage. The patients were treated with topical dexamethasone- ciprofloxacin eye drops for two weeks in tapering doses and intranasal saline spray for one month. Alkaline nasal douching was also done for one month. There were at least four post operative visits, scheduled at one week, one month, 3 and 6 months after surgery. The objective assessment was done, using a rigid endoscope and by lacrimal sac irrigation. During the first postoperative visit, one week after surgery, before irrigation of lacrimal sac, debridement with nasal suctioning was performed. The extent of mucosal edema, polyposis, crusting, secretions and scarring was assessed. The subjective assessment was done by asking the patient about relief of symptoms (epiphora).

Definition Of Successful Case

For a Dacrocystorhinostomy to be called successful both criteria symptoms and anatomical patency need to be fulfilled it means, the patient should be completely asymptomatic and there should be endoscopically confirmed patent nasolacrimal system. (Peter-John Wormald- Endoscopic Sinus Surgery Third edition).According to above definition in this study we labelled a case as successful, when the patient was symptoms free (no epiphora) and there was patent nasolacrimal system which was confirmed endoscopically, during and at completion of 6month follow up.

RESULTS

- **Distribution of Age-**In our study youngest patient was 21-year-old and eldest was 70- year-old. The Mean age for Control group was 45.7 years and for Mitomycin C group it was 44.5 years.
- **Distribution of Gender**- Out of total 60 patients there were 40 female and only 20 were males which shows female predominance. In GROUP A (CONTROL GROUP) there were 12 (40%) males and 18 (60%) females and in GROUP B (MITOMYCIN C GROUP) there were 8(26.66%) males and 22(73.33%) females, shows female predominance in both groups.
- **Sign and symptoms** - Out of 60 patients, all were suffering from epiphora, there were 45 patients which were suffering from discharge from eye and 23 patients had a swelling at the corner of eye.
- **Side of Presentation-** Control Group had 20 (66.7%) patients with left sided disease and 10 (33.3%) with right sided disease. Mitomycin C Group had 14 (46.7%) patients right sided disease, 16(53.3%) left sided disease. Total 36 patients had left eye affected and only 24 patients had diseased right eye.
- **Status of previous surgery**- According to previous performed surgery patients were divided into two groups primary cases and revision cases (in which there were history of previously performed endonasal DCR and now came with failure). In Control Group there were 22 primary cases and 8 came fo a revision surgery. In Mitomycin C Group there were 23 primary case and 7 were revision surgeries.

Outcome:

Comparison of Results between Control group & Mitomycin C Group for all cases- Out of 60 cases, 30 cases were included in Mitomycin C Group, success rate of 93.33% (28/30) was achieved. In Control Group, success rate of 76.66% (23/30) was achieved.

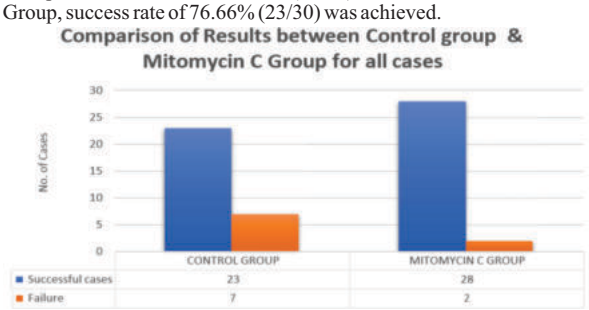

Figure-1: Comparison of Results between Control group & Mitomycin C Group for all cases

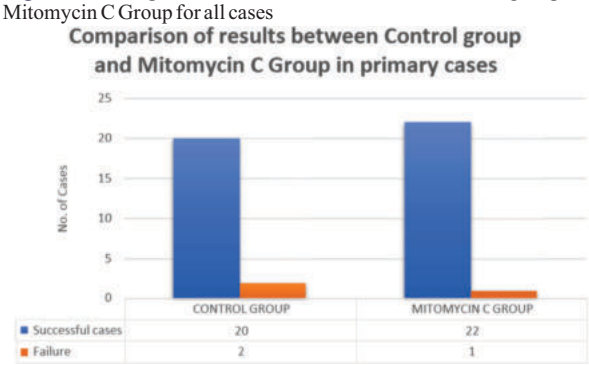

Figure-2: Comparison of results between Control group and Mitomycin C Group in primary cases

Comparison of results between Control group and Mitomycin C Group

in primary cases- This comparison of results of primary endonasal DCR between Control group and Mitomycin C GROUP shows that there was success rate of 90.9% (20/22) in control group and it increase up to 95.6% (22/23) when Mitomycin C was used at the rhinostomy site.

Comparison of results between Control group & Mitomycin C group in revision cases- Out of 8 cases in Control group there was 3(37.5%) successful cases and 5(62.5%) cases came with failure. In Mitomycin C group there was 6(85.7%) successful cases and 1(14.3%) case failed.

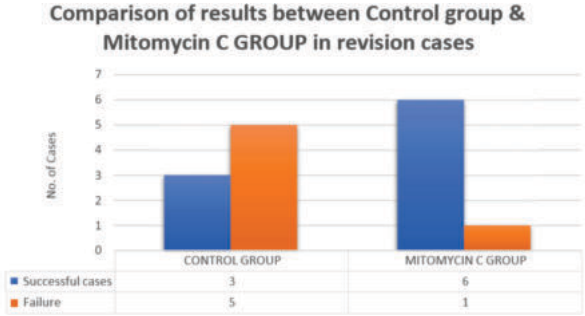

Figure-3: Comparison of results between Control group & Mitomycin C GROUP in revision cases

DISCUSSION

Chronic dacryocystitis is a common health problem with which patients are visiting to ophthalmologist and otorhinolaryngologist, even it is more common in rural areas because poor hygiene practices. Our institution is established in a area where most patient come from rural background. So, we get 60 patients to operate in a period of almost one year and follow up of all patients completed in one and half year.

In our study we also get most of the patient of 40s and 50s age group and mean age group was 45.7 year for control group and 44.5year for Mitomycin C group.

As this problem of chronic dacryocystitis is more common with female, we were also having more female patient to operate. There were 40 female patients came with this problem and only 20 male patients suffered with the same. There are many reasons written in literature that why women more prone to chronic dacryocystitis than men, some of these are, because females having narrow nasolacrimal duct due to this obstruction of this lacrimal system is more common (Nishi Gupta Endoscopic Dacryocystorhinostomy- second edition) another reason is given that is, due to long duration of exposure to smoke in kitchen, use of kajal and othercosmetics increases chances of transmission of infections as well as these fine particles get lodged in puncta than into the nasolacrimal duct causing obstruction of the duct (Shrinivas et al 2010).

Sign And Symptoms

In our study only those patients were included who came with chronic dacryocystitis primary acquired nasolacrimal duct blockade with history of epiphora more than one year. Patients with absence or obstruction of both upper and lower canaliculi or common canaliculi blockade were excluded from study. Patients suffering from acute dacryocystitis, recurrent abscesses and tumours of lacrimal apparatus were also excluded from the study.

In our study all sixty patients were suffering from chronic dacryocystitis with chief complaint of epiphora of more than one year. In these sixty patients, 23 patients were having symptoms of epiphora, eye discharge and swelling at medial canthus of eye, 22 patients were afflicted with epiphora and discharge from eye and 15 patients suffered from epiphora only.

Guler et al (1998) included patients with epiphora, chronic dacryocystitis and included revision surgery (patients with history of previous lacrimal sac surgery). They also included patients with aetiology of trauma. In our study we did not include any patient with aetiology of trauma.

These sign and symptoms are comparable to study done by Soumitra et al (2006) where they included 30 patients with recurrent epiphora not responding to medical therapy.

Our study is also comparable to study of Thomas Prasannaraj et al (2012) where they included patients with primary acquired posit saccal obstruction of lacrimal apparatus causing chronic dacryocystitis. We also have included patients with primary acquired post saccal obstruction of lacrimal apparatus. In our study as well as their study no case of congenital nasolacrimal duct blockade and nasolacrimal duct blockade secondary to trauma were included.

Our study is also comparable to study done by Rekha R Mudhol et al (2013) where they included 45% patients with epiphora, 25% patient with epiphora with discharge and 30% patient presented with mucocele Sign and symptoms of our study is comparable to study of Yi-an You et al (2001) because in their study they also included patients only with primary acquired nasolacrimal duct blockade and duration of epiphora symptoms of longer than 1 year.Most common symptom of nasolacrimal duct blockade is epiphora. Due to inability of drainage of tears in nose, tear remain stagnant in the lacrimal sac this stagnation with repeated bacterial infection causes discharge from eye and later on formation of swelling mucocele). (Nishi Gupta- Endoscopic Dacryocystorhinostomy-second edition)

Nasal Endoscopy

In our study we found 8 cases of gross septal deviation towards the affected eye in which septoplasty was done followed by DCR In one case, we noted polyp also, which was arising from maxillary antrum endoscopic sinus surgery was performed before DCR surgery. In 5 cases we found enlarged middle turbinate towards affected eye, in 3 cases middle turbinoplasty was done.

Our study is comparable with study done by Rekha R. Mudhol et al (2013) in their study they found 4 cases with gross septal deviation in whom they did septoplasty before DCR and 5 cases with middle turbinate hypertrophy, in one of these cases they did middle turbinoplasty.

Side Of Presentation

In our study there were 36(60%) patients with diseased left eye and 24(40%) patients with right affected eye. Our study is comparable with study done by Shrinivas et al (2010).

In their study they observed that 28 (70%) patients were having left eye involvement and 7 patients (17.5%) were having involvement of right eye and 5(12.5%) were having bilateral involvement.

Other studies in which right eye was predominant, are described below. Angela et al (2010) stated in their study that there was 48% (108 out of 224 eye) were right sided and 52% (116 out of 224 eyes) were left sided. Mahmut Ozkiris et al (2012) observed that there was 25(69.44%) eyes with right sided nasolacrimal duct and 11 eyes of left side were with nasolacrimal duct blockade. Thomas Prasannaraj et al (2012) observed 28 out of 38 eyes were right sided and in 10 out of 38 cases there was left affected eye.

Rekha R. Mudhol et al (2013) found both side equal involvement.It has been observed that nasolacrimal duct and lacrimal sac form a greater angle on right side than left side, it increases chances of stasis and obstruction of nasolacrimal duct on left side. It was therefore attributed as cause of preponderance of chronic dacryocystitis on left side. (Shrinivas et al 2010)

Success In Primary Endonasal Dcr Procedure

In our study there were 22 primary DCR surgeries in Control group and 23 primary DCR surgeries in mitomycin C group. Success is defined as absence of symptoms (epiphora) and patent nasolacrimal duct system at completion of 6 months.

According to above criteria in our study there was 90.9% (20 out of 22) success rate in Control Group and 95.6% (22 out of 23) success rate was found in Mitomycin C group. Our success rate in Mitomycin C Group is comparable to success rate of study done by Rekha R. Mudhol et al (2013). The success rate in Mitomycin C group after 6 months of follow up

Table-1: Success rate in Mitomycin C group after 6 months of follow up

	Success Rate	Successful Cases
Present Study	95.6%	22/23
Rekha (2013) R. Mudhol et al	97%	36/37

Results in Mitomycin C group in primary DCR surgeries are equivalent to results of Rekha R. Mudhol et al (2013).

In our study we found that difference of success rate between Mitomycin C and Control group in primary endonasal DCR surgery is statically insignificant which is comparable to study done by Guler et al (1998), Soumitra Ghosh et al (2006), Thomas Prasannaraj et al(2010).

Table-2: Comparison of Success Rate in Primary Cases With Previous Studies

Study	Mitomycin C group	Control group	P value
Present study	95.6% (22/23)	90.9% (20/22)	0.52
Guler et al (1998)	78.5% (11/14)	77.8% (7/9)	0.96
Soumitra Ghosh et al (2006)	80% (12/15)	86.67% (13/15)	0.62
Thomas Prasannaraj et al(2010)	82.3% (13/17)	85.7% (18/21)	0.46

Our study and study done by Guler et al (1998), Soumitra Ghosh et al (2006) and Thomas Prasnnaraj) et al (2010) shows no statistically significant difference between success rates of Mitomycin C gup and Control group in primary endonasal DCR surgeries which shows that there is no distinct advantage of adjuvant Mitomycin C in primary endonasal DCR surgeries.

Success Rate In Revision DCR Surgeries

In our study there were 8 cases of revision DCR surgeries, included in Control group and 7 cases were included in Mitomycin C group.

Table-3: Comparison of Success Rate in Revision DCR Surgeries

	Mitomycin C group	Control group	P value
Successful Cases	6 (85.7%)	3(37.5%)	0.05
Failure Cases	1(14.3%)	5(62.5%)	

In control group out of 8 cases, only 3 cases were considered as successful after completion of 6 months follow up and in Mitomycin C group, there were 6 patients with successful outcome at completion of 6 month follow up.

This difference in success rate between mitomycin c group and control group in revision DCR surgeries statically is significant and our study is comparable to study done by Mohmut Ozkiris et al (2012).

Table-4: Comparison of Success Rate in Revision Endonasal DCR Surgeries with Previous Studies

	Mitomycin C group	Control group	P value
Present study	6/7(85.7%)	3/8(37.5%)	0.05
Mahmut Ozkiris et al (2012)	16/18(87.5%)	10/18(53.3%)	0.02

In our study we found that difference between the success rate of Mitomycin C group and Control group in revision DCR surgeries is statistically significant and is equivalent to study done by Mahmut Ozkiris (2012), which shows that use of Mitomycin C increases the success rate and its use is beneficial in revision DCR surgeries.The rhinostomy site is compromised by fibrous tissue growth, scarring and granulation tissue formation during the healing process and thereby leading to surgical failure. As is expected in revision cases there is lot of fibrous tissue formation so use of adjunctive mitomycin C in preventing excessive scar formation is helpful.

Dose Of Mitomycin C

In different studies different doses were used at rhinostomy site for different periods of time. A comparison between doses and exposure time various studies given below.

Table-5: Comparison Between Doses and Exposure Time with Previous Studies

Study	Dose	Exposure time	Success rate
Present study	0.5 mg/ml	5 minutes	93.3%
Guler et al (1998)	0.5 mg/ml	2 minutes	77.3%
Soumitra Ghosh et al (2006)	0.2 mg/ml	2 minutes	80%
Angela et al (2010),	0.5 mg/ml	10 minutes	95%
Thomas Prasannaraj et al (2012)	0.2 mg/ml	10 minutes	82.3%
Mahmut Ozkiris et al (2012)	0.5 mg/ml	5 minutes	87.5%
Rekha R. Mudhol (2013)	0.2 mg/ml	5 minutes	97%

The optimal dosage and exposure time of Mitomycin C application is controversial. In study done by You and Fang (2001) they have compared the two Mitomycin C groups, one in which 0.2mg/ml was applied in 16 patients while in the other group of 16 patients, 0.5mg/ml applied topically at rhinostomy site and found that there was no statistically significant difference between the two Mitomycin C group. It is felt that there is a need for further randomized studies involving dosage regimen and long term follow up visit to elucidate the optimum drug regimen.

Complications

In our study we did not find any complication other than septo-rhinostomy adhesion, granulation tissue over rhinostomy site and synechia formation.

Complications like abnormal nasal bleeding, mucosal necrosis, infection, delayed wound healing and atrophic rhinitis were not found.

Synechia were found in 4 cases of Control group and in 2 cases of Mitomycin C group. Septo-rhinostomy adhesion was found in 4 cases of control and none in Mitomycin C group. There was granulation tissue formation at the rhinostomy site in 3 patients of Control group and 2 patients of Mitomycin C group.

Complication in our study is comparable to study done by Angel et al (2010), Soumitra Ghosh et al (2006), Thomas Prasannaraj et al (2012), Mahmut Ozkiris et al (2012) and Rekha R. Mudhol (2013).

Soumitra Ghosh et al (2006) found no significant complication other than stenosis of stoma and Synechiae.

Angela et al (2010) found in their study that there were 2 patients with synechiae between middle turbinate and mucosa of lateral wall of nose. One patient had pyogenic granuloma. No other complication was found.

Thomas Prasannaraj et al (2012) found in Mitomycin C Group that granulations were present at stomal margin in 2 patients and synechiae were observed in 5 patients which in their opinion did not influence the success of the procedure, in Control group 6 patients had granulations and 1 patient had synechiae and septo-rhinostomy adhesion.

Mahmut Ozkiris et al (2012) did not find any complication like mucosal necrosis and abnormal healing in their study.

Rekha R. Mudhol et al (2013) found synechiae in one patient. No complication associated with the use of mitomycin C was seen in their study. Other complication like abnormal nasal bleeding, mucosal necrosis, infection or atrophic rhinitis were not present.

Intraoperative application of Mitomycin C does not cause any systemic problem since it is not absorbed from gastrointestinal tract. No nasal or gastrointestinal irritation has been observed during application.

SUMMARY AND CONCLUSION

Application of a wound healing inhibitor is a new treatment modality in endoscopic lacrimal surgery. Intra-operative use of Mitomycin C in endonasal DCR is safe and effective in increasing the success rate and as a useful adjunct in DCR surgery. The use of Mitomycin C also enables endonasal DCR to have success rates almost comparable to external DCR.

In our study, a success rate of 95.6% was observed when Mitomycin C was used in primary endonasal DCR surgery. When Mitomycin C was replaced by normal saline, the success rate did not vary significantly 90.9% (P value 0.52 statistically insignificant). In our study we achieved the success rate of 85.7% when we used Mitomycin C in revision DCR surgeries and when it replaced by normal saline the success rate remains only 37.5%. It shows that significant (P value-0.05-stastistically significant) improvement in success rate occurs when Mitomycin C was used in revision DCR surgery. This may be due to the fact that there is more fibrous tissue and scarring in revision cases, so use of a wound healing inhibitor is a useful adjunct to increase the success rate.

In light of our experience in the study we suggest the use of Mitomycin C in revision case to improve results but routine use of Mitomycin C in primary cases is not necessary.

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