

Comparative Study of Effect of Mitomycin-C and Merocel Packing on Ostial Patency in Primary Endoscopic Dacryocystorhinostomy

Aftab Ahmed¹, Abu Sayeed², Syed Abrar Hasan³

¹Senior Resident, Department of Otorhinolaryngology, J. N. Medical College, Aligarh Muslim University, Aligarh, India.

²Junior Resident, Department of Otorhinolaryngology, J. N. Medical College, Aligarh Muslim University, Aligarh, India.

³Professor, Department of Otorhinolaryngology, J. N. Medical College, Aligarh Muslim University, Aligarh, India.

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ABSTRACT

Background: To compare the post operative ostial patency at the rhinostomy site in the patients undergoing the primary endoscopic dacryocystorhinostomy, using Mitomycin-C application and Merocel packing. **Methods:** The patients visiting the Otorhinolaryngology out patients department at the tertiary referral hospital were included in this study. The study was prospective in nature and comprised of 50 patients suffering from primary dacryocystitis. Endonasal endoscopic dacryocystorhinostomy was done in the patients suffering from the chronic dacryocystitis with postsaccular obstruction of lacrimal system. The patients were divided in two equal groups containing 25 patients in each group. In first group (Group-A) Mitomycin-C (0.5 mg/ml for 15 min) was locally applied at the rhinostomy site and nasal cavity was packed with bactigras after the surgery, whereas in the second group, nasal cavity was packed with Merocel after reposition of the flap without application of any drug. Follow up was done every week in the first month, then monthly till the six months after the surgery. The post operative results were compared in terms of ostial patency at the rhinostomy site at one month, three months and six months of follow up. The surgical technique used remained same throughout the period of study. **Results:** The post operative ostial patency of rhinostomy stoma was better in the group of the patients undergoing application of Mitomycin-C at the rhinostomy site as compared to the packing of the nasal cavity with Merocel. The difference between both the groups was statistically significant. The rhinostomy created was free from synachiae and granulation tissue formation on follow up examination in the group of the patients having application of Mitomycin-C at the time of surgery. Ultimately the ostial patency was better in the patients having application of Mitomycin-C. **Conclusion:** Mitomycin-C has statistically significant beneficial effect in the maintenance of ostial patency after primary endonasal endoscopic dacryocystorhinostomy as compared to the merocel packing alone after the surgery.

Keywords: Chronic dacryocystitis, Endoscopic dacryocystorhinostomy, Mitomycin-C, Merocel.

INTRODUCTION

In the past few decades endoscopic dacryocystorhinostomy (DCR) has gained popularity due to the growing interest in the endoscopic endonasal surgeries. This is because of the better visualisation through the endoscopes and availability of wide range of new instruments. They have enabled us to use these procedures routinely. Dacryocystorhinostomy was first described by Killian in 1889.

Name & Address of Corresponding Author

Dr. Aftab Ahmed
Senior Resident, Department of Otorhinolaryngology,
J. N. Medical College,
Aligarh Muslim University, Aligarh, India.

The endonasal approach to the lacrimal sac was first described by Caldwell, an Otorhinolaryngology surgeon in 1893.^[1] He, after performing the

rhinostomy removed the part of the inferior turbinate following the nasolacrimal duct to the lacrimal sac. Caldwell's surgery did not become popular due to the requirement of considerable skill development. Moreover advancement in the instrumentation was also required.

Toti in 1904 first described the external approach to the lacrimal sac and this was later modified by Dupuy-Duetemps and Bourget. As most of the external approaches were performed by the ophthalmologic surgeons, this led to a temporary shift of this surgery under the purview of the ophthalmologists.^[2] West modified Caldwell's technique, he performed a window resection over the lacrimal sac. The early results of the endoscopic approach of dacryocystorhinostomy was published by Steadman, Mc Donagh and Meiring after almost 100 years after the first description of this procedure. The technical advancements in the instrumentation

and optics have once more brought this surgery into mainstream otorhinolaryngology practice.

The endoscopic dacryocystorhinostomy (DCR) is a surgical procedure of choice for nasolacrimal duct obstruction. The success rates for endoscopic DCR are 82% to 95%^[3,4] as compared to the external DCR with a success rate of >90%,^[5] with minimal morbidity and possibility to treat sinonasal diseases simultaneously. In order to enhance the success rate of the endoscopic DCR the causes of the failure must be studied thoroughly. Most frequent cause for the failure of dacryocystorhinostomy is due to reclosure of the rhinostomy stoma.^[6] The pathological events leading to the reclosure of the rhinostomy stoma are fibrosis and formation of adhesions and granulation tissue. Topical application of Mitomycin-C an antineoplastic drug is found to suppress the fibrosis and vascular in growth at the rhinostomy site and thus enhancing the success rates. Mitomycin-C in concentrations of 0.2 mg per ml applied topically to the rhinostomy site decreases the fibrosis and formation of the postoperative adhesions. This leads to the maintenance of the stomal patency, decreasing the failure rate of endoscopic dacryocystorhinostomy.^[6]

Various surgical modifications have been proposed by the different authors to maintain the patency of the dacryocystorhinostomy stoma. These modifications includes the different methods of producing the nasal mucosal or lacrimal sac flaps^[7,8], to vary the size of the bony ostium^[9], the placement of lacrimal sac incision^[10], and silicone tube stenting^[11]. Despite all these measures the ostial reclosure or obstruction at the rhinostomy site still commonly occurs mostly due to excessive adhesions, scars and granulation formation at the rhinostomy site.^[12] Merozel is a polyvinyl alcohol (PVA), highly advanced biocompatible synthetic material used for packing the nasal cavity after endoscopic surgeries. It has sponge like unique reticulated form which makes it both absorbent and hydrophilic. The Merozel material is exceptionally strong and durable, yet soft and comfortable when hydrated. Merozel packing after endoscopic DCR helps in reposition of the mucosal and/or lacrimal sac flap and thus minimising the synechia formation and improving the outcome.

In the present study we have compared the effect of the Mitomycin-C application and the Merozel packing at the rhinostomy site on the maintenance of the ostial patency after primary endoscopic dacryocystorhinostomy.

MATERIALS AND METHODS

The study was prospective in nature and was carried out from June 2015 to September 2016. The patients attending the Otorhinolaryngology outpatient department at the Jawaharlal Nehru Medical

College, Aligarh Muslim University, Aligarh, India, were considered for this study.

The patients were subjected to detailed history, general examination, systemic examination and local examination which included clinical examination of the ear, nose, paranasal sinuses, larynx and pharynx. The diagnosis of the chronic dacryocystitis was made on the basis of a history of epiphora with purulent discharge from lacrimal puncta. Syringing of the lacrimal system was done and regurgitation of fluid mixed with mucoid or purulent secretion from the opposite punctum was confirmatory of nasolacrimal duct obstruction. Patients with the acute dacryocystitis, previous lacrimal surgery, previous physical scars, previous facial fractures, eyelid malposition such as ectropion or entropion and patients having nasal diseases, in the form of polyps and chronic rhinosinusitis were excluded from the study. Patients having isolated deviation of nasal septum were not excluded from the study. Endonasal endoscopic DCR was performed in all the patients by a single surgeon. Before surgery, all patients were randomly divided in two groups. The first group received Mitomycin-C application at the rhinostomy site and the nasal cavity was packed with the bactigras after surgery, the second group received the Merozel packing at rhinostomy site, which covered the wound 1–2mm around the ostium.

Pre-Operative Evaluation

Endoscopic Examination: Diagnostic nasal endoscopy was done in all the patients using 0° and 30° Hopkins rigid endoscopes to assess the anatomical accessibility of the lacrimal sac area. On endoscopic examination our objective was to notice the presence of significant nasal septum deviations at the level of the middle meatus or at the anterior end of the inferior turbinate as they would compromise the access to the lacrimal sac area during the surgery. The presence of such findings guided us to plan for the appropriate septal surgery at the time of endoscopic DCR. The detection of coexistent sinus pathology in otherwise asymptomatic patients can also be done at the time of the nasal endoscopy. This allowed for pre-operative exclusion of cases with nasal polyposis or inflammatory conditions of the para nasal sinuses.

Radiological Examination: The patients included in this study underwent radiological assessment performed by CT scan. The scan was done in both the coronal and axial cuts. These cuts allowed complete assessment of the paranasal sinuses and detection of anatomical abnormalities such as concha bullosa, or agger nasi air cells that could impede access to the surgical site. The combination of pre-operative evaluation by the nasal endoscopy and CT scanning helped in the detection of the anatomical variations causing difficulty in access to the operative site and there correction before

approaching the lacrimal area. It also helped in the exclusion of the cases having concomitant paranasal sinus disease and neoplastic lesions causing obstruction of the lacrimal sac system. The additional information provided by the CT scan was the thickness of bone of the frontal process of maxilla which has to be removed at the time of surgery by the Kerrison punch or the drill.

Operative Technique

Nasal preparation is performed with both pledget-applied vasoconstrictor and lateral nasal wall injection of 2% lidocaine with 1 : 80,000 adrenaline. The injection is performed in two places: superior to the axilla and well anterior to the uncinat process. If a septoplasty is to be performed, the septum is likewise injected. Endoscopic septoplasty is performed because any narrowing of the anterior nasal cavity increases the complexity of the procedure dramatically.

A 0-degree scope was used during the entire procedure for visualization around the frontal process of the maxilla. The posteriorly based DCR flap is created with the underlying lacrimal sac in mind. Because approximately half of the sac extends above and posterior to the insertion of the middle turbinate, the superior incision for the flap is created 5 mm posterior and 10 mm superior to the axilla. The flap is brought 10 mm anterior to the middle turbinate, because a shorter flap would limit the ability to marsupialize the lacrimal sac fully. The inferior incision is created at the insertion of the inferior turbinate about two thirds of the way down the middle turbinate.

A suction Freer elevator is used to establish a subperiosteal plane along the incisions onto the frontal process of the maxilla. The flap should be developed over the broadest possible area and mobilized over the frontal process of the maxilla until the lacrimal bone is identified. When completed, the posteriorly based DCR flap is pedicled inferiorly off the superior aspect of the inferior turbinate and insertion of the uncinat. In the midportion of the flap, the pedicle is rather weakly attached to the uncinat bone, and tears in this portion of the flap may occur.

A round knife (from the ear instrument set) is used to identify the frontal process–lacrimal bone junction and to flake off the lacrimal bone. This region is difficult to see if a 0-degree scope is used; this manoeuvre exposes the posteroinferior aspect of the lacrimal sac and adjacent nasolacrimal duct. Next Kerrison punch is used to remove the frontal process of the maxilla overlying the anteroinferior aspect of the lacrimal sac. As this bone removal continues superiorly, the bone thickens and it becomes increasingly difficult for the Kerrison punch to grip the bone. The completion of this task requires drilling, for example with a 25-degree angled DCR diamond bur. The bur is used to thin the remaining

visible bone within the limits of the DCR flap, avoiding the bone-sac junction.

As the bone removal continues to the edges of the mucosal flap incisions, the lacrimal sac begins to “stand proud” of the lateral nasal wall, so that when it is opened it will lie flat on the lateral nasal wall. Effectively the sac is marsupialized into the lateral nasal wall. When bony work is completed, the lacrimal puncta are inspected and are dilated if too small to accommodate a lacrimal probe. The sinus endoscope provides adequate lighting and magnification to assist with this part of the procedure. An assistant holds the endoscope while the primary surgeon passes a Bowman's lacrimal probe along the inferior canaliculus and into the lacrimal sac. Passing the lacrimal probe to the assistant, the surgeon then identifies the metal of the lacrimal probe visible within the translucent sac wall. If the probe is not creating a sharp-pointed projection, but instead is causing a more generalized movement of the sac, the probe has not yet emerged from the common canaliculus and requires further manipulation until its point is clearly seen within the sac. An angled keratome is then used to cut down on the lacrimal probe and open the sac superiorly and inferiorly with a rotating cutting movement. This angled keratome is used to make the superior and inferior flap cuts in the anterior lacrimal sac. These cuts allow the anterior lacrimal sac to be rolled out over the frontal process of the maxilla, approaching the anterior vertical mucosal incision. The posterior cuts are made with a microscissors in the most superior and inferior aspects of the sac again, allowing the posterior sac to be rolled posteriorly, resulting in a complete marsupialization. The common canaliculus should be visible in the lateral sac wall in every case and is easily located by placement of a lacrimal probe back through the inferior canaliculus.

The mucosal flap is then positioned to evaluate where it needs to be cut to create flaps to ensure that approximation of the nasal mucosa to the lacrimal mucosal occurs. Usually a superior flap is required to cover the exposed bone above the lacrimal sac, and occasionally an inferior flap is required to cover bone. The middle portion of the flap is removed until the posterior aspect of the flap approximates the posterior edge of the lacrimal sac. The flaps are then positioned with a ball probe. In our study, Mitomycin-C packs were applied at the rhinostomy site (0.5 mg/ml for 15 minutes) in the Group-A patients and after that nasal cavity was packed with bactigras. Whereas in Group-B patients the nasal cavity was packed with Merocel without application of Mitomycin-C at the rhinostomy site.

Post-Operative Care and Follow Up

All patients undergoing endoscopic DCR received antibiotics, analgesics, intranasal steroid spray and antibiotic and steroid eye drops. The nasal packs were removed after 72 hours of surgery. As with

endoscopic sinus surgery, close post-operative management is important to remove secretions, crusting and granulations from the rhinostomy site. The patients were assessed one week post-operatively at which time nasal endoscopy was done and suction clearance was done. Syringing of the lacrimal system was also done at this time and its patency was assessed. Patients were followed up weekly in the first month and then monthly till the 6 months post operatively, nasal endoscopy and syringing was done and patency of rhinostomy stoma was evaluated.

The patent rhinostomy ostium was taken in those cases in whom there was free flow of fluid on nasolacrimal syringing. The well epithelised rhinostomy stoma can also be seen in the patients having patent ostium. The successful outcome of endoscopic DCR was defined subjectively as resolution of all the symptoms of epiphora and purulent discharge and objectively by a patent ostium of the rhinostomy at the follow up.

Data Analysis

Data was analyzed by using SPSS 20 and Chi-square test was used for comparing statistical significance. P value of <0.05 was considered significant while p value <0.01 was considered highly significant.

RESULTS

The study comprised of 50 patients, the age of the patients ranged from 16-59 yr. Out of total 50 patients 11(22%) were male and 39(78%) were female, with male to female ratio of 1:3.5. The highest prevalence was seen in the patients between 51-60 yr of age. Total patient in this age group was 19(38%) out of total 50 patients. In our study out of total 50 patients, 41 patients were from the rural background whereas 9 patients were from the urban population. The demographic variables of the study are summarised in Table 1.

Table 1: Classification of Cases on The Basis of the Demographic Variables.

0	No. of Cases	Percentage
Age Group (Years)		
0-10	-	-
11-20	1	2.0%
21-30	6	12.0%
31-40	10	20.0%
41-50	14	28.0%
51-60	19	38.0%
Sex		
Male	11	22.0%
Female	39	78.0%
Population		
Rural	41	82.0%
Urban	9	18.0%

In our study of 50 patients, there were no major complications reported in any of the patients undergoing endoscopic dacryocystorhinostomy. On

endoscopic examination during the post operative follow up, synachiae formation between the middle turbinate and lateral nasal wall or nasal septum and granulation tissue formation at the rhinostomy was seen. The synachiae formation was less in the group of the patients receiving application of Mitomycin-C at the rhinostomy site. The complications of the endoscopic DCR in our study are mentioned in Table 2.

Table 2: Complications of the Endoscopic DCR.

Complications	Group-A (n=25)	Group-B (n=25)
Synachiae	6	11
Granulations	4	7

The endoscopic DCR was considered successful when there was resolution of the symptoms of epiphora and purulent discharge from the puncta. Moreover the patent rhinostomy stoma can be seen in the lateral wall of the nose on endoscopy. The flow of tear can also be visualized with blinking of the eye during endoscopy.

Surgical failure of the endoscopic DCR was present when there was persistence or recurrence of symptoms of epiphora and purulent discharge during the follow up period and on endoscopic examination the surgically created stoma in the lateral wall of the nose was not visible and it closed following the surgery.

The patients undergoing endoscopic dacryocystorhinostomy were followed up to the 6 months post operatively. Nasal endoscopic examination was done weekly in the first month, then monthly till the six months after the surgery. The result of the endoscopic dacryocystorhinostomy was compared at one month, three months and sixth months post operatively. The patency of the rhinostomy stoma was evaluated by endoscopic examination. Syringing of the lacrimal system was also done and free flow of fluid on syringing was taken as an indicator of osteal patency.

In our study the result of the endoscopic dacryocystorhinostomy between both the groups was compared after month of surgery. The group of the patients receiving application of the Mitomycin-C at the rhinostomy site had patent rhinostomy stoma in 24 cases out of 25 cases whereas the group of the patients receiving the Merocel packing had osteal patency in 19 out of 25 cases at the one month of post operative follow up. The difference between both the groups after one month of the surgery was statistically significant with p value of P=0.04. The post operative result at one month is given in Table 3.

In our study at the three months post operatively, the rhinostomy stoma was patent in 23 out of 25 patients in the group of the patients receiving the Mitomycin-C application. Whereas the group of patients receiving the Merocel packing had patent rhinostomy stoma in 17 out of 25 patients. The difference between both the groups being

statistically significant ($P=0.03$) after three months of surgery. The post operative result at three months is given in Table 4.

Table 3: Post-Operative Results After One Month of the Surgery.

Variables	No. of Cases	Patent Ostia	Success Rate	P Value
Mitomycin-C Group(Group-A)	25	24	96%	P= 0.04
Merocele Group(Group-B)	25	19	88%	

At six months post operatively only 45 patients attended the follow up examination, others were lost to the follow up. On examination the rhinostomy stoma was patent in 20 out of 22 patients in the group receiving the Mitomycin-C application. In the group receiving the Merocele packing the rhinostomy stoma was patent in 14 out of total 23 patients available. The difference in the ostial patency between both the groups was statistically significant with a p-value of ($P=0.01$). The post operative result at six months is given in Table 5.

Table 4: Post-Operative Results After Three Months of the Surgery.

Variables	No. of Cases	Patent Ostia	Success Rate	P Value
Mitomycin-C Group (Group-A)	25	23	92%	P= 0.03
Merocele Group (Group-B)	25	17	80%	

Table 5: Post-Operative Results After Six Months of the Surgery.

Variables	No. of Cases	Patent Ostia	Success Rate	P Value
Mitomycin-C Group(Group-A)	22	20	91%	P= 0.01
Merocele Group(Group-B)	23	14	61%	

DISCUSSION

The endoscopic dacryocystorhinostomy is the surgical procedure of choice for the nasolacrimal system obstruction. With the evolution of the endoscopes and wide range of new instruments, the endoscopic dacryocystorhinostomy has become the mainstream surgery for otorhinolaryngology practice. The results of the endoscopic dacryocystorhinostomy are similar to that of external dacryocystorhinostomy^[3,4] but the endoscopic dacryocystorhinostomy has certain distinct advantages such as avoidance of a facial scar, non interference with the lacrimal pump mechanism, preservation of the medial canthal ligament and

simultaneous correction of any intranasal pathology contributing to nasolacrimal duct obstruction.

The post operative failures in the endoscopic DCR are because of the reclosure of rhinostomy stoma. For preventing the post operative closure of the rhinostomy stoma various surgical modifications have been proposed by the different surgeons but none of them have been effective in maintaining the ostial patency. Mitomycin-C in the form of eye drops has been used as adjunctive treatment for primary and recurrent pterygia after surgical excision; it is both safe and effective therapy.^[13] This led the surgeons to use the Mitomycin-C in the endoscopic DCR as an adjunctive treatment to prevent reclosure of the rhinostomy stoma. There is scarcity of the clinical studies evaluating the effect of the Mitomycin-C in preventing the reclosure of the rhinostomy stoma. The present study has been done with the objective of comparing the effect of the Mitomycin-C application and the Merocele packing at the rhinostomy site on the maintenance of the ostial patency after endoscopic DCR.

In our study, out of total 50 patients, 66.0% were above the age of the 40 years with maximum number ($n=19$) in the age group of 51-60 years. The reason for increased incidence in this age group has been suggested due to menstrual and hormonal fluctuations and heightened immune status at this age contributing to the disease process as suggested by Roussos J and Bouzas A.^[14] The age distribution of the patients in our study was in concurrence to the study of Duggal P et al^[15], who also found increased incidence of dacryocystitis in fourth and fifth decade of life.

The incidence of the dacryocystitis was more in the females than the males in our study, the male to female sex ratio being 1:3.5. The result of our study for sex distribution was in concurrence with the study of Duggal P et al^[15] and Wadgonkar SP et al^[16]. The reason for affecting the females more commonly is probably due to hormonal changes that cause generalised de-epithelialisation in the body including lacrimal sac and duct. This may lead to obstruction of the narrow lacrimal fossa in the women as pointed by Groessl SA and Sires BN^[17].

In our study the incidence of the dacryocystitis was more in the rural population as compared to the urban population. The result was in concurrence with the study of Duggal P et al^[15].

In our study the post operative patency of the rhinostomy stoma was better in the group of the patients receiving application of the Mitomycin-C at the time of the surgery. At one month of the follow up the rhinostomy stoma was patent in 24 out of 25 patients in the Mitomycin-C group (Group-A) as compared to the 19 out of 25 in the Merocele group (Group-B), the difference being statistically significant with a p value of ($P=0.04$). The difference in the ostial patency was also significant with p

values of (P=0.03) and (P=0.01) at three months and six months of the follow up respectively.

Our result for osteal patency was in concurrence with the result of Camara JG et al^[18], who mentioned that the success rate of the Mitomycin-C application was statistically significant and concluded by stating that the intraoperative use of Mitomycin-C in the endoscopic dacryocystorhinostomy is safe and also effective. Our result for osteal patency was also in concurrence to the study of Prabhakar SK et al^[19].

The result of our study was not in concurrence to the result of Zilelioglu et al^[20] and Prasannaraj T et al^[21]. According to their study Mitomycin-C did not appear to influence the formation of granulations, synachiae and it did not significantly affect the success rate.

The effect of Merogel packing on the maintenance of the osteal patency as given by W Wu et al^[22] was statistically significant, but in our study the Merocel packing alone gave poor result as compared to the Mitomycin-C application. This difference in the result could be due to the different chemical composition of the Merogel and Merocel

CONCLUSION

The endoscopic dacryocystorhinostomy is the standard surgical procedure for the management of the dacryocystitis. The results of the endoscopic dacryocystorhinostomy are comparable to the external dacryocystorhinostomy but the endoscopic procedure has minimal morbidity and possibility to treat the sinonasal disease simultaneously. The endoscopic dacryocystorhinostomy with the Mitomycin-C application gave better results than with the Merocel packing. The difference in the results was statistically significant at one month, three months and six months of the follow up. We conclude that Mitomycin-C application at the time of surgery has significant beneficial effect in preventing the synachiae and granulation tissue formation, thus preventing the reclosure of the rhinostomy stoma after the primary endoscopic dacryocystorhinostomy. Merocel packing helps in the reposition of mucosal and/or lacrimal sac flap but on long term follow up it has poor results as compared to the Mitomycin-C application in preventing the reclosure of rhinostomy stoma.

Compliance with Ethical Standards:

- The authors declare that they have no conflict of interest.
- All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
- Informed consent was obtained from all individual participants included in the study.

- Approval was taken from the Institutional Ethics Committee before starting this prospective study.

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