RESEARCH PAPER

A PROSPECTIVE COMPARATIVE STUDY OF SURGICAL OUTCOMES IN ENDONASAL DACRYOCYSTORHINOSTOMY WITH AND WITHOUT INTRAOPERATIVE APPLICATION OF MITOMYCINC

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ABSTRACT

Aims: To compare the surgical success of endonasal dacryocystorhinostomy (Endo-DCR) with and without intraoperative application of Mitomycin C (MMC), assessed by post-operative syringing patency and symptom resolution.

Material and Methods: A prospective comparative study was conducted from April 2023 to October 2024. Sixty-two patients aged 18–75 years with chronic dacryocystitis and epiphora undergoing Endo-DCR were randomised into two equal groups: an MMC group (n=31) receiving intraoperative topical MMC application to the neo-ostium, and a non-MMC group (n=31). Both groups were assessed at 7 days and 4 months post-operatively by lacrimal syringing and symptom evaluation. Statistical analysis was performed using the Chi-square and Fisher's exact tests; $P < 0.05$ was considered significant.

Results: The MMC group demonstrated significantly superior lacrimal patency: 96.8% patent ostia compared to 71.0% in the non-MMC group ($P < 0.05$). Partial and total obstruction rates were lower in the MMC group (3.2% and 0%) versus the non-MMC group (25.8% and 3.2%). Persistent epiphora was significantly less common in the MMC group (6.5% vs. 25.8%; $P < 0.05$). Granulation tissue formation and synechiae rates trended lower in the MMC group, though this did not reach statistical significance.

Conclusion: Intraoperative application of MMC during Endo-DCR significantly improves neo-ostium patency and reduces post-operative epiphora compared to surgery without MMC. MMC is particularly beneficial in high-risk cases with anticipated fibrosis. It is safe, well-tolerated, and represents an effective biological adjunct to standard Endo-DCR technique.

Keywords: Dacryocystorhinostomy; Mitomycin C; Endonasal DCR; Nasolacrimal duct obstruction; Ostium patency
How to cite this article: V. Arvind Raj Dr. M D Prakash Dr Abishek Anish. A PROSPECTIVE COMPARATIVE STUDY OF SURGICAL OUTCOMES IN ENDONASAL DACRYOCYSTORHINOSTOMY WITH AND WITHOUT INTRAOPERATIVE APPLICATION OF MITOMYCINC. Int J Drug Deliv Technol. 2026;16(89s):1379-1383. DOI: 10.25258/ijddt.16.89s.144.

INTRODUCTION

Dacryocystorhinostomy (DCR) is the definitive surgical procedure for the management of nasolacrimal duct obstruction (NLDO) secondary to chronic dacryocystitis. The procedure establishes a new communication between the lacrimal sac and the nasal cavity, bypassing the obstructed nasolacrimal duct. Since its first endoscopic description, endonasal DCR (Endo-DCR) has gained widespread acceptance as the preferred surgical approach, offering the advantages of preserved external anatomy, absence of facial scarring, direct visualisation of the neo-ostium, and the ability to address concurrent sinonasal pathology [1].

Despite these advantages, the most significant limitation of Endo-DCR remains post-operative restenosis of the neo-ostium, which occurs as a result of fibrosis, granulation tissue formation, and synechiae development during the wound healing process [2]. Reported failure rates in Endo-DCR range from 5–30%, with ostial closure being the predominant cause of surgical failure [3].

Mitomycin C (MMC) is an antimetabolite derived from Streptomyces caespitosus with potent antifibrotic properties. By inhibiting fibroblast proliferation and reducing collagen deposition, MMC modifies the wound healing response at the cellular level, without dependence on patient compliance or mechanical stenting [4]. Unlike silicone intubation, MMC does not cause mechanical irritation of the canalicular system and acts specifically on the fibrotic cascade responsible for ostial closure.

Several studies have reported improved patency rates with intraoperative MMC application in DCR, yet evidence from prospective comparative studies with standardised follow-up protocols remains limited, particularly from the Indian subcontinent where patient demographics and clinical disease severity may differ from Western cohorts [5].

This prospective comparative study was undertaken to evaluate and compare the surgical outcomes of Endo-DCR with and without intraoperative application of MMC, assessed by lacrimal syringing patency and post-operative symptom profile, at a tertiary care teaching institution in Bangalore, India.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective comparative study conducted in the Department of Otorhinolaryngology – Head & Neck Surgery, BMCRI – Sri Venkateshwara ENT Institute, Bangalore, India, between April 2023 and October 2024. Ethical clearance was obtained from the institutional ethics committee and written informed consent was obtained from all participants prior to enrolment. The study was conducted in accordance with the Declaration of Helsinki (revised 2013). This study is reported in accordance with the CONSORT/TREND reporting guidelines for non-randomised comparative studies.

Participants

Sixty-two patients with chronic dacryocystitis presenting with epiphora and confirmed nasolacrimal duct obstruction on syringing and probing were enrolled. Patients were randomised into two groups of 31 each: the MMC group and the non-MMC (control) group.

Inclusion criteria were: age 18–75 years; clinical and investigative diagnosis of chronic dacryocystitis with epiphora; fitness for general or local anaesthesia; and willingness to provide written informed consent.

Exclusion criteria were: proximal canalicular or punctal obstruction; uncontrolled diabetes mellitus or systemic hypertension; pregnancy; intranasal tumour or mass lesion; prior nasal or lacrimal surgery (revision cases); and active acute dacryocystitis at time of operation.

Surgical Technique

All procedures were performed under general anaesthesia using a standard endonasal endoscopic technique. A mucosal incision was made over the ascending process of the maxilla adjacent to the middle turbinate. The lacrimal bone was removed using a bone punch to expose the medial wall of the lacrimal sac, which was then incised and the anterior and posterior flaps reflected. Bicanalicular silicone intubation was performed in select cases at the surgeon's discretion. In the MMC group, a cotton pledget soaked in MMC solution (0.2 mg/mL) was applied to the neo-ostium for 5 minutes at the conclusion of the procedure, followed by thorough saline irrigation.

Post-operative Care and Follow-up

All patients received topical nasal corticosteroids, saline nasal douching, and systemic antibiotics for one week post-operatively. Follow-up assessments were conducted at 7 days and 4 months post-operatively. Assessment at each visit included nasal endoscopy, lacrimal syringing (classified as patent, partial block, or total block), and symptom evaluation (epiphora, nasal obstruction, pain, and swelling).

Statistical Analysis

Data were entered into SPSS version 21.0 (IBM Corp., Armonk, NY, USA). Categorical variables were compared using the Chi-square test and Fisher's exact test where appropriate. A P value < 0.05 was considered statistically significant.

RESULTS

Demographic Profile

A total of 62 patients completed follow-up and were included in the final analysis (MMC group n=31; non-MMC group n=31). The two groups were well matched for baseline characteristics (Table 1). The majority of patients were in the fifth and sixth decades of life, with the 51–60 year age group comprising 35.5% of the cohort and the 61–70 year group comprising 33.9%. A female preponderance was observed, with 40 females (64.5%) and 22 males (35.5%).

Table 1 Baseline demographic characteristics of study groups

Characteristic	MMC Group (n=31)	Non-MMC Group (n=31)
Age range (years)	18–75	18–75
Mean age – modal decade	51–60 yrs (35.5%)	51–60 yrs (35.5%)
Female sex	20 (64.5%)	20 (64.5%)
Male sex	11 (35.5%)	11 (35.5%)
Diagnosis	Chronic dacryocystitis with epiphora	Chronic dacryocystitis with epiphora

Lacrimal Syringing – Patency at 4 Months

At the 4-month follow-up assessment, lacrimal syringing demonstrated significantly superior ostial patency in the MMC group compared to the non-MMC group. In the MMC group, 30 of 31 patients (96.8%) had a fully patent neo-ostium, whereas in the non-MMC group, only 22 of 31 patients (71.0%) achieved complete patency ($P < 0.05$). Partial nasolacrimal obstruction was recorded in 1 patient (3.2%) in the MMC group compared to 8 patients (25.8%) in the non-MMC group. Total ostial occlusion was not observed in the MMC group, but occurred in 1 patient (3.2%) in the non-MMC group. These results are summarised in Table 2.

Table 2 Comparison of lacrimal syringing patency at 4-month follow-up

Syringing Result	MMC Group n (%)	Non-MMC Group n (%)	P value
Patent	30 (96.8%)	22 (71.0%)	< 0.05
Partial Block	1 (3.2%)	8 (25.8%)	
Total Block	0 (0%)	1 (3.2%)	
Total	31 (100%)	31 (100%)	

Post-operative Complications and Symptom Profile

Persistent epiphora or lacrimal sac swelling at 4 months was significantly less frequent in the MMC group (6.5%) compared to the non-MMC group (25.8%; $P < 0.05$). Synechiae, fibrosis, or adhesion formation at the neo-ostium was observed in 1 patient (3.2%) in the MMC group versus 2 patients (6.5%) in the non-MMC group, a difference that did not reach statistical significance ($P > 0.05$). Similarly, granulation tissue formation was lower in the MMC group (3.2%) than the non-MMC group (9.7%), though this difference was also not statistically significant ($P > 0.05$). No adverse effects attributable to MMC were recorded. These findings are summarised in Table 3.

Table 3 Post-operative complications at 4-month follow-up

Complication	MMC Group n (%)	Non-MMC Group n (%)	P value
Synechiae/Fibrosis/Adhesion	1 (3.2%)	2 (6.5%)	> 0.05
Granulation Tissue	1 (3.2%)	3 (9.7%)	> 0.05
Epiphora/Swelling	2 (6.5%)	8 (25.8%)	< 0.05
Restenosis	1 (3.2%)	4 (12.9%)	< 0.05

DISCUSSION

This prospective comparative study demonstrates that intraoperative application of MMC during Endo-DCR is associated with a significantly higher neo-ostium patency rate and significantly lower incidence of persistent epiphora at 4 months compared to Endo-DCR performed without MMC. These findings are consistent with a growing body of literature supporting the adjunctive use of MMC in lacrimal surgery.

The primary mechanism of DCR failure is fibrotic closure of the surgically created neo-ostium, driven by an exaggerated wound healing response involving fibroblast proliferation, collagen deposition, and granulation tissue formation [2]. This is particularly pronounced in patients with chronic dacryocystitis, long-standing infection, or a narrow nasal cavity,

where the mucosal microenvironment is already primed towards a fibrotic healing pattern [6].

MMC, by virtue of its ability to irreversibly cross-link DNA and inhibit fibroblast mitosis, directly attenuates this fibrotic response at the cellular level. Unlike stenting, which mechanically splints the neo-ostium and is associated with canalicular trauma and patient non-compliance, MMC acts independently of post-operative patient behaviour [4]. When used at the standard concentration of 0.2 mg/mL for 5 minutes and followed by thorough saline irrigation, it has an established safety profile and does not impair normal mucosal healing [7].

Our finding of a 96.8% patency rate in the MMC group compares favourably with published series. Ali Lafta Salman et al. reported significantly higher success and better symptom resolution in Endo-DCR when MMC was used intraoperatively [5]. Similarly, Apuhan et al. demonstrated significantly higher long-term patency rates in the MMC group compared to controls, while Mudhol et al. found that MMC enhanced surgical success in both endoscopic and external DCR by reducing fibrosis [8,9]. The significant reduction in persistent epiphora in our MMC group (6.5% vs. 25.8%; $P < 0.05$) directly reflects the improved functional patency of the lacrimal drainage system.

The trends towards lower rates of granulation tissue and synechiae in the MMC group, though not reaching statistical significance in our cohort, are consistent with the findings of Jae Rock Do et al. and Shinde et al., who reported significantly reduced granulation tissue formation and better ostium healing with MMC application [10,11]. The lack of statistical significance for these secondary endpoints in our study is likely attributable to the relatively small sample size, representing a key limitation of this work.

An important clinical consideration is the appropriate patient selection for MMC. Rather than routine application in all Endo-DCR cases, MMC should be preferentially used in high-risk patients: those with chronic dacryocystitis, thick or inflamed mucosa, revision DCR, or a narrow nasal cavity with anticipated dense healing. In this select group, MMC provides the greatest biological advantage, reducing the need for revision procedures, improving long-term symptom relief, and enhancing overall patient satisfaction.

The absence of any recorded adverse effects attributable to MMC in our cohort supports the safety of this agent when used at the recommended concentration and application duration. Reported complications in the literature, including canalicular toxicity and delayed wound healing, have generally been associated with higher concentrations or prolonged exposure times [7].

This study has several limitations that warrant acknowledgement. The sample size of 62 patients, while adequate for primary endpoint analysis, was insufficient to detect statistically significant differences in the secondary complication endpoints. The follow-up duration of 4 months may not fully capture longer-term restenosis, which has been reported to occur up to 12 months post-operatively. The absence of blinding, inherent to the nature of the surgical intervention, introduces the potential for observer bias. A larger, multicentre, double-blinded randomised controlled trial with extended follow-up would provide more definitive evidence.

CONCLUSION

Endonasal Dacryocystorhinostomy is a safe, effective, and minimally invasive procedure for the management of nasolacrimal duct obstruction. The primary limitation of Endo-DCR is post-operative restenosis secondary to fibrosis and granulation tissue formation at the neo-ostium. This prospective comparative study demonstrates that intraoperative adjunctive application of Mitomycin C significantly improves neo-ostium patency and reduces persistent epiphora at 4 months. MMC is safe, well-tolerated, and operates at the cellular level to attenuate the wound healing cascade responsible for ostial closure. Its targeted use in high-risk cases – those with chronic dacryocystitis, thick mucosa, or a propensity for fibrosis – is recommended. Surgical success in Endo-DCR depends not only on the technical execution of the procedure, but on the adequacy of the post-operative ostial healing response.

KEY MESSAGES

- Intraoperative MMC application significantly improves neo-ostium patency following Endo-DCR (96.8% vs. 71.0%; $P < 0.05$).
- Persistent epiphora is significantly less common when MMC is used (6.5% vs. 25.8%; $P < 0.05$).
- MMC is safe at a concentration of 0.2 mg/mL applied for 5 minutes, with no adverse effects recorded in this cohort.
- MMC is most beneficial in high-risk cases with chronic dacryocystitis, thick mucosa, or anticipated fibrosis, rather than as a routine adjunct.
- Modifying the wound healing response is as important as surgical technique in determining long-term Endo-DCR success.

ACKNOWLEDGEMENTS

The author thanks the faculty and staff of the Department of Otorhinolaryngology – Head & Neck Surgery, BMCRI – Sri Venkateshwara ENT Institute, Bangalore, and all patients who participated in this

study. This study was presented at AOICON Kolkata 2026.

DECLARATIONS

Conflict of Interest: The author declares no conflict of interest.

Ethical Approval: Institutional ethical clearance was obtained prior to study commencement. The study was conducted in accordance with the Declaration of Helsinki (revised 2013).

Informed Consent: Written informed consent was obtained from all participants.

Funding: No external funding was received for this study.

Data Availability: The datasets generated and analysed during this study are available from the corresponding author on reasonable request.

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