

# Comparison of triamcinolone and mitomycin C nasal pack in functional endoscopic sinus surgery: a randomized, clinical trial

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## Aims and Objectives

Synechia formation in a postoperative nasal cavity is a major factor for suboptimal clinical outcome in functional endoscopic sinus surgery (FESS). Nasal packs medicated with steroids like triamcinolone and topical agents like mitomycin C have been shown to reduce the formation of synechia in postoperative patients. This study attempts to compare the efficacy of mitomycin C and triamcinolone-impregnated nasal pack in the prevention of crusting and synechia formation in patients undergoing FESS.

## Methods

Ninety-eight consenting patients with chronic rhinosinusitis were randomized into two groups of 49 each to receive either triamcinolone-impregnated or mitomycin C-impregnated nasal pack after FESS. Blinded, postoperative endoscopic examination was done at the first and third week and at first and third month and scoring was done according to the Lund Kennedy scoring system. The primary variable for assessing the outcome was synechia formation in the postoperative period, while reduction of crusting, discharge, mucosal edema, polypoidal mucosal changes, and maintenance of ostial patency were secondary variables.

## Results

Significant reduction in synechia formation and crusting at 3 months duration was found in the group receiving triamcinolone nasal pack as compared with mitomycin C nasal pack. Mitomycin C was found to significantly reduce crusting in the first postoperative week. Positive trends in reduction of discharge, mucosal edema, polypoidal changes, and in maintenance of patency of ostia were observed in both the groups, but there was no significant difference between the two groups.

## Conclusion

These results suggest that triamcinolone has a long-term effect in the reduction of synechia formation and crusting in post-FESS patients as compared with mitomycin C, though similar effects were seen in both groups in the immediate postoperative period.

## Keywords:

functional endoscopic sinus surgery, mitomycin C, synechia, triamcinolone

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## Introduction

The chronicity and recurring nature of chronic rhinosinusitis (CRS) pose a challenge to the patient and the doctor alike [1]. Surgical treatment is often required with the main aims being the removal of disease and to establish ventilation and drainage [1]. The positive results of functional endoscopic sinus surgery (FESS) depend on wound healing in the postoperative phase [2]. Best postsurgical outcome depends on the care of mucosa during surgery and the postoperative care accorded to the patient [3]. When looking at the patients requiring revision surgery, synechia have been implicated as a foremost cause for recurrence [4,5].

Of the numerous techniques available in preventing synechia, packing is a very important one. Plain

packing and packing with medication have shown reduction in the formation of synechia postoperatively [6]. Nasal packs medicated with steroids like triamcinolone and topical agents like mitomycin C have been shown to reduce the formation of synechia in a postoperative patient [6,7]. Though there are many studies in the literature evaluating triamcinolone and mitomycin C in synechia prevention, there was no study comparing the superiority of these two agents over one another. We attempted to compare the efficacy of mitomycin C-impregnated and triamcinolone-impregnated nasal pack in the prevention of postoperative

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complications such as synechia formation, crusting, and recurrence in patients undergoing FESS.

### Patients and methods

This single-center, double-blinded parallel group randomized clinical trial was conducted in a tertiary care hospital in India from January 2014 to December 2014. Ethical clearance was obtained from the Institute Ethics Committee (Human Studies), before recruitment of patients into the study. The sample size was calculated using OpenEpi software (Dean AG, Sullivan KM, Soe MM, OpenEpi: Open Source Epidemiologic Statistics for Public Health). The primary variable for assessing outcome was synechia formation in the immediate postoperative period. Considering the percent of synechia among people who received mitomycin C to be 31% [8] and assuming the percentage of synechia among people who received triamcinolone to be 5%, it was estimated that 41 patients in each group would be required. Considering loss to follow-up to be 20%, the final sample size in each group was calculated to be 49. Calculations were done based on 80% power, two-sided 95% confidence interval and ratio of exposed to unexposed to be one. Adult patients aged above 18 years, with bilateral CRS, refractory to medical treatment and requiring bilateral sinus surgery were included in the study. We excluded patients with deviated nasal septum and hypertrophied turbinate, local diseases like invasive fungal sinusitis, suspected malignancy, unilateral rhinosinusitis, history of nasal surgery in the past, patients with uncontrolled hypertension, diabetes or other systemic illness and patients unwilling or unable to comply with regular postoperative visits, patients who developed surgical complications after surgery and those with fungal sinusitis diagnosed by histopathology postoperatively.

A total of, 101 patients were recruited into our study. Randomization was done by the block randomization sequence generated by a computer with a fixed block size of 10 into two groups (ratio 1 : 1) by an investigator with no involvement in the trial and allocation concealment was done by sequentially numbered opaque-sealed envelopes. Enrolment into the study was done by the outpatient department doctors and the group allocation was concealed from the principal investigator and the envelopes were opened only after the enrolled patients completed the baseline assessment and were ready for the procedure. Informed consent was obtained from all participants. Baseline clinical, endoscopic, and radiological examinations in the form of computed tomography of paranasal sinuses were done.

Preoperatively, nasal cavities of all the patients were packed with cotton wicks soaked in 5 ml of 4% lignocaine and 5 ml of one in two lakh adrenaline solution. The packs were removed just before surgery and nasal cavities were infiltrated with 5 ml of 2% lignocaine and 5 ml of one in two lakh adrenaline solution. Functional endoscopic sinus surgery was done either under general or local anesthesia. The extent of surgery was modified according to the patients. The surgeries were done according to the Messerklinger technique. Middle meatal antrostomy, anterior, and posterior ethmoidectomy were invariably done in most of the patients. At the conclusion of surgery, the patient received either polyvinyl acetal (Merocel, Medtronic, United States of America; 8 cm) nasal pack soaked with 1 ml mitomycin C (0.5 mg/ml) or polyvinyl acetal (Merocel; 8 cm) nasal pack soaked with 2 ml of triamcinolone acetonide (40 mg/ml) to both the middle meatus. The nasal pack was removed on second postoperative day. Patients were given saline nasal irrigation twice daily before getting discharged on the third postoperative day. At the time of discharge, patients were instructed to do nasal douching 4–5 times a day. Three patients were excluded from analysis as one of them developed orbital cellulitis postoperatively and in two patients the postoperative histopathology report turned out to be chronic indolent fungal sinusitis.

Patients were reviewed on the first and third week and at the first and third month for endoscopic assessment. Symptom assessment was done at third month follow-up. Both the patients and the person doing the endoscopic assessment were blinded to the group of allocation of the patient. Endoscopic scoring was done during each visit for synechia formation, crusting, discharge, mucosal edema, and polypoidal change.

The following parameters were scored from 0 to 2 according to the postoperative endoscopic findings (each carrying a minimum score of 0 and a maximum score of 2):

- (1) Scarring or synechia (absent: 0; in the middle meatus only: 1; beyond middle meatus: 2).
- (2) Crusting (absent: 0; mild: 1; severe: 2).
- (3) Edema (absent: 0; mild: 1; severe: 2).
- (4) Polypoidal change (absent: 0; mild: 1; severe: 2).
- (5) Discharge (absent: 0; mild: 1; severe: 2).
- (6) Ostial patency.

The primary variable for assessing the outcome was synechia formation in the immediate postoperative period while reduction of crusting, discharge, mucosal edema, polypoidal mucosal changes, and maintenance of

ostial patency were secondary variables. The comparison of variables between the groups was carried out by  $\chi^2$ -test and Fisher's exact test. Statistical analysis was carried out at 5% level of significance and a *P* value of less than 0.05 was considered significant.

## Results

The recruitment for the study started from January 2014 and was completed by December 2014 once the requisite numbers of patients were included in the study (Fig. 1). Baseline data indicate adequate age, sex, and symptom profile matching between the two groups (Table 1). Of the 98 patients who completed the study, 39 (39.7%) were men and 59 (60.2%) were women with a mean age of 36.5 years. The main complaints were nasal discharge (82%), nasal obstruction (71%), headache (74%), postnasal drip (77.5%), and hyposmia (28.5%). Diagnostic endoscopy findings included mucosal congestion (30.6%), middle meatal discharge (24.4%), and polyps (29.5%) (Table 1).

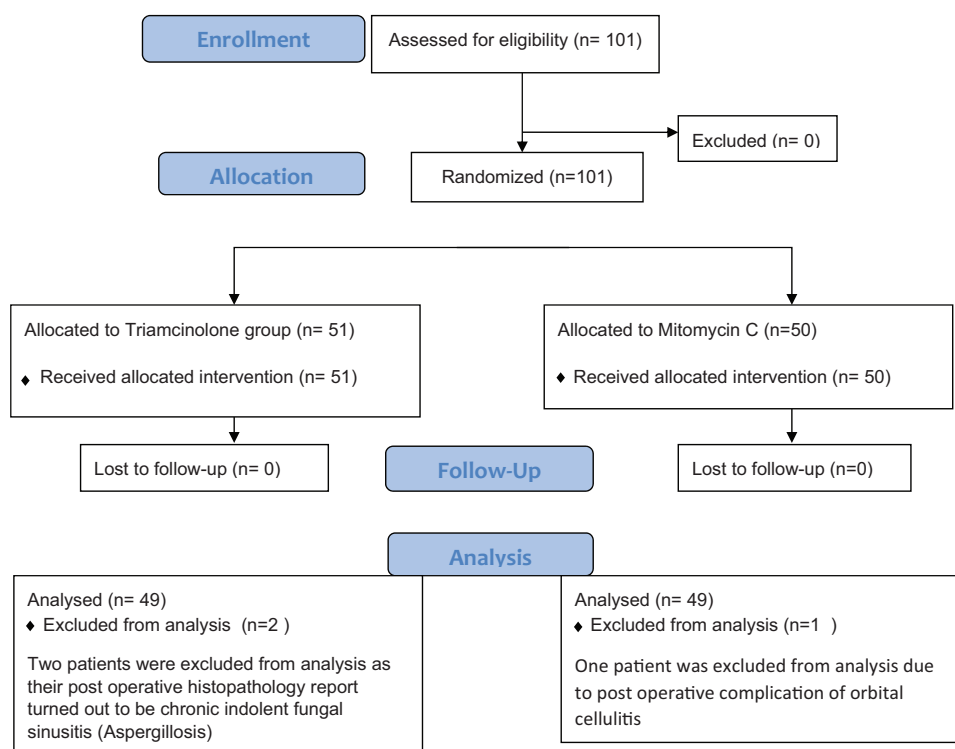
With respect to synechia formation, there was no significant difference in its incidence in the two groups during the first and third weeks and during the first month follow-up. But during the third month follow-up around 16.3% had synechia formation in the

triamcinolone group whereas in the mitomycin C group, 38.7% had synechia formation. There was a

**Table 1 Demographic and clinical characteristics for each group**

Demographic data	Triamcinolone (n=49) [n (%)]	Mitomycin c (n=49) [n (%)]
Age group (years)		
18–25	11 (22.4)	7 (14.2)
26–40	20 (40.8)	19 (38.7)
41–55	18 (36.7)	23 (46.9)
Sex		
Male	19 (38.7)	20 (40.8)
Female	30 (61.2)	29 (59.1)
Symptoms		
Nasal obstruction	36 (73.4)	34 (69.3)
Discharge	40 (81.6)	41 (83.6)
Postnasal drip	39 (79.5)	39 (79.5)
Headache	38 (77.5)	34 (69.3)
Polyps/mass	15 (30.6)	13 (26.5)
Smell abnormalities	16 (32.6)	12 (24.4)
Endoscopic findings		
Congested mucosa	15 (30.6)	15 (30.6)
Polyps	17 (34.6)	12 (24.4)
Mucosal edema	6 (12.2)	5 (10.2)
Discharge	11 (22.4)	15 (30.6)
Others	–	2 (4.08)

**Figure 1**



Participant flow chart in the study.

**Table 2 Synechia formation during follow-up**

Follow-up	Grade	Triamcinolone (n=49) [n (%)]	Mitomycin C (n=49) [n (%)]	P value
First week	Absent	49 (100)	48 (97.9)	>0.999
	Present	0	1 (2.04)	
Third week	Absent	46 (93.8)	44 (89.7)	0.714
	Present	3 (6.12)	5 (10.2)	
First month	Absent	37 (75.5)	34 (69.3)	0.6516
	Present	12 (24.4)	15 (30.6)	
Third month	Absent	41 (83.6)	30 (61.2)	0.0228
	Mild	8 (16.3)	19 (38.7)	

**Table 3 Crusting during follow-up**

Follow-up	Triamcinolone (n=49) [n (%)]			Mitomycin C (n=49) [n (%)]			P value
	Absent	Mild	Severe	Absent	Mild	Severe	
First week	0	3 (6.1)	46 (93.8)	0	11 (22.4)	38 (71.5)	0.0404
Third week	3 (6.1)	12 (24.4)	34 (69.3)	5 (10.2)	13 (26.5)	31 (63.2)	0.7123
First month	14 (28.5)	26 (53.06)	9 (18.3)	15 (30.6)	21 (42.8)	13 (26.5)	0.5237
Third month	41 (83.6)	8 (16.3)	0	30 (61.2)	19 (38.7)	0	0.0228

**Table 4 Symptoms at third week of follow-up**

Symptoms	Triamcinolone (n=49) [n (%)]	Mitomycin C (n=49) [n (%)]
Nasal obstruction	10 (20.4)	20 (40.8)
Discharge	3 (6.1)	11(22.4)
Postnasal drip	0	1 (2.04)
Headache	17 (34.6)	21 (42.8)
Polyps/mass	8 (16.3)	7 (14.2)
Smell abnormalities	4 (8.1)	3 (6.1)

**Table 5 Ostial patency on follow-up**

Follow-up	Grade	Triamcinolone (n=49) [n (%)]	Mitomycin C (n=49) [n (%)]	P value
First week	Patent	48 (97.9)	48 (97.9)	1.5052
	Not patent	1 (2.04)	1 (2.04)	
Third month	Patent	46 (93.8)	41 (83.6)	0.1991
	Not patent	3 (6.12)	8 (16.3)	

statistically significant difference between the two groups (Table 2). As patients in both the groups were treated with similar postoperative care, these findings show that triamcinolone significantly has an effect on long-term prevention of synechia formation when compared with mitomycin C. With respect to crusting, during the first week follow-up around 94% had severe crusting in the triamcinolone group. In the mitomycin C group, only 77.5% had severe crusting. There was a statistically significant difference between the two groups in reduction of crusting in the immediate postoperative period (Table 3). At the third month of follow-up, only 16.3% of patients in the triamcinolone group had crusting as compared with 38.7% of patients in the mitomycin C group. Though mitomycin C had a better chance in reducing crusting at 1 week postoperatively, triamcinolone had a long-term effect on reducing crusting when compared with mitomycin C.

There was no statistically difference between the two groups in reduction of polypoidal changes, discharge, mucosal edema in the first, third weeks, first and third months' postoperatively even though positive trends in

reduction of these parameters were observed in both the groups during the study. Symptom assessment at the third month showed improvement in both the groups (Table 4). At 3 months of follow-up, ostial patency was maintained in around 94% of patients in the triamcinolone group but only in 83.6% of patients in the mitomycin C group. This was not statistically significant (Table 5).

## Discussion

FESS has been shown to be effective in treating patients who do not respond to medical therapy in around 85% cases [9]. Even though there is a marked improvement in the technique of FESS, recurrence of the disease is a major issue. Failure of FESS has been reported to be close to 20% [10]. Synechia is reported to be the leading cause of failure of FESS in around 10–40% [4]. Along with possible residual disease, synechia formation was regarded as an important cause of recurrence or failure of FESS. Lateralization of middle turbinate in the postoperative period predisposes one to synechia formation. Stability of the middle turbinate is essential for preventing synechia formation. Many techniques

have been tried in stabilizing the middle turbinate. These include suturing of middle turbinate to the nasal septum, creation of raw surface over the lateral surface of the middle turbinate, and the corresponding area over the septum and middle meatal stenting.

Both nonabsorbable and absorbable packing has been used postoperatively. While offering advantages in terms of hemostasis and lack of pain, these have their share of problems. They are expensive and their biocompatibility has not been tested. Also impairment of mucosal healing and promotion of scar formation has also been attributed [11].

Rowe-Jones *et al.* [12] and Jorissen *et al.* [13] noted that steroid (mometasone) improves the endoscopy score in the postoperative phase. Stjarne *et al.* [14] noted a significant increase in time to relapse in the control group using steroids. Dijkstra *et al.* [15] who studied the effect of fluticasone spray in preventing recurrence of nasal polyps as compared with a placebo noted an improvement in symptoms and reduction in recurrence rates but it was not significant. Côté *et al.* [7] noted a reduction in synechia formation in the control group.

Mitomycin C is an antitumor antibiotic used mainly in bladder cancer and anal squamous cell carcinoma. It has an apoptotic effect on fibroblasts. As fibroblasts play a very important role in healing and fibrosis, it is thought to prevent scarring of nasal cavity when used topically. Konstantinidis *et al.* [16] found that mitomycin C significantly reduces adhesion formation and chance of restenosis in the postoperative period. Safety concerns regarding the use of mitomycin C were alleviated in a study by Chung *et al.* [6]. Venkatraman *et al.* [17] found that there was significant reduction in the incidence of synechia by using mitomycin C.

Studies by Gupta *et al.* [18] and Yamaoka *et al.* [19] showed a reduction in synechia formation. In our study, under the mitomycin C group 38.7% had synechia after 3 months, while 61.22% of patients were synechia free as compared with 21.43% in the study by Yamaoka *et al.* [19]. The higher incidence of synechia in our study can be attributed to the lower dose of topical mitomycin C used in our study (0.5 mg/ml) and due to shorter follow-up duration. Similar results were demonstrated in the study by Anand *et al.* [8].

In a randomized, double-blind, placebo-controlled study on the effect of triamcinolone packing following

FESS [7], it was reported that there was a lesser incidence of synechia formation in the treatment group at 6 months follow-up period but the difference was not statistically significant. But in our study, at 3 months follow-up period statistically significant reduction in synechia formation was noted in the triamcinolone group as compared with mitomycin C. Karkos *et al.* [20] in a review of the literature noted a short-term effect of mitomycin C but could not find a satisfying long-term action. Our study echoes similar results with respect to long-term action of mitomycin C.

Studies by Venkatraman *et al.* [17] and by Côté *et al.* [7] demonstrated a significant decrease in crusting in the postoperative period by using mitomycin C and triamcinolone pack, respectively. The results are similar to our study. In our study, though both the groups had similar number of patients with crusting at the end of the first week, more number of patients in the mitomycin C group had mild crusting (22.4%) as compared with the triamcinolone group (6.1%). This was a significant difference between the two groups. This can be attributed to the facilitation of rapid return of normal respiratory epithelium by mitomycin C [21].

Only 16.3% of patients in the triamcinolone group had crusting as compared with 38.7% of patients in the mitomycin C group at the third month of follow-up. Though mitomycin C had a better chance in reducing crusting at 1 week postoperatively, triamcinolone had a long-term effect on reducing crusting when compared with mitomycin C. This can be attributed to the long-term anti-inflammatory action of topical steroids over nasal mucosa.

Studies by Venkatraman *et al.* [17] and by Côté *et al.* [7] demonstrated a significant decrease in polypoidal mucosa, discharge, and mucosal edema in the postoperative period by using mitomycin C and triamcinolone pack, respectively. In our study, positive trends in reduction of postoperative polypoidal change, discharge, and mucosal edema were observed in both the groups during the study. But a significant difference between triamcinolone and mitomycin C could not be established.

In a study by Ingrams *et al.* [21], a dose-dependent maintenance of ostial patency was demonstrated by the use of mitomycin C. In this study, ostial patency was maintained in around 94% of patients in the triamcinolone group, but only in 83.6% of patients in the mitomycin C group at the end of the study. Though there was a positive trend in maintaining patency of ostia the result was not statistically significant.

Possible limitations in this study are the lack of control group for the agents, lack of intragroup analysis with controls and shorter follow-up period. The control group could not be added as the study period was short during which the inclusion of the requisite number of patients would have been impossible. But since proper randomization could be achieved, lack of control group did not affect the outcome of the study. Preoperative steroid usage, pre-existing allergy and atopy in the patients were not taken into account during analysis. Though there are many studies in the literature evaluating triamcinolone and mitomycin C in synechia prevention, there was no study comparing these two agents. This study was primarily done to compare these two agents. Reduction of synechia and crusting is seen in the two groups, but triamcinolone is superior when compared with mitomycin C. Triamcinolone had statistically significant improvement in synechia and crusting in the long run unlike mitomycin which had short-term favorable outcomes. We can conclude that regular use of triamcinolone in nasal packs will result in improved postoperative period after FESS and result in decreased synechia formation.

## Conclusion

Triamcinolone reduces synechia formation and crusting in the late postoperative period in patients who have undergone FESS. Mitomycin C causes significant reduction in crusting in the immediate postoperative period when compared with triamcinolone. Triamcinolone causes significant long-term reduction in synechia formation and crusting when compared with mitomycin C. Studies incorporating control groups, preoperative steroid usage, allergy and underlying atopy and with longer follow-up period can be undertaken to assess the positive effects of triamcinolone and mitomycin C over wound healing after FESS.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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