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RESEARCH PAPER

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A randomized controlled trial on triamcinolone versus saline impregnated merocel post endoscopic sinus surgery: Our experience in a tertiary care centre

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Abstract

Purpose: To assess the potential benefit of impregnating Merocel (a non-absorbable nasal dressing) with a topical steroid solution, for use as a direct and slow local delivery system of steroids after sinus surgery to improve postoperative wound healing.

Methods: In this randomized controlled trial, 40 patients with bilateral chronic rhinosinusitis with nasal polyposis were subjected to functional endoscopic sinus surgery. Following the completion of the surgery, Merocel packs were inserted in the bilateral nasal cavities and infiltrated with 4 mL triamcinolone (40 mg/mL) in one nasal cavity (treatment group) and 4 mL normal saline in the other (control group). Nasal packs were removed on the third postoperative day and postoperative healing assessment was done on postoperative Weeks 1, 2, 4, and 12. The findings were noted as per Lund Kennedy (LKES) and perioperative sinus endoscopy (POSE) scores and compared on both sides.

Results: Significant ($P < 0.05$) improvement was noted in Lund Kennedy score for crusting and polyp at Week 12, for edema at Week 1, and nasal discharge at Weeks 1 and 12, but there was no significant improvement in scarring at any week. Overall, the difference between the treatment and control arms was statistically significant at all postoperative visits except at Week 4. Also, there was a significant improvement in POSE scores at Weeks 1, 2, and 12 but not at Week 4.

Conclusion: This study positively concludes that the nasal cavity packed with drug-soaked packs had less scarring and edema in the postoperative period and the overall wound healing was much better as compared to saline-soaked packs.

KEYWORDS

chronic rhinosinusitis, functional endoscopic sinus surgery, Lund Kennedy, merocele, perioperative sinus endoscopy, triamcinolone

INTRODUCTION

Chronic rhinosinusitis (CRS) is one of the most common health problems that lead to frequent visits to ENT specialists around the world. It causes a significant amount of healthcare expenditure as a result of direct costs arising from hospital visits and medications, as well as indirect costs related to frequent leaves from work and a decrease in general productivity.[1]

The primary goal of treatment in these patients is to manage symptoms and improve their quality of life. Management aims at enhancing mucociliary clearance, improving sinus drainage/outflow, treating local infection and inflammation, and providing access to topical medications. Treatment can be medical or surgical in the form of endoscopic sinus surgery (ESS) if appropriate medical management is unsuccessful.[2]

ESS for the treatment of CRS aims at providing ventilation and drainage of the paranasal sinuses by widening the ostia to create greater access to topical medications.[3] The successful outcomes in ESS are determined by adequate wound healing. Factors like scarring/synechiae, ostial or middle-meatal obstruction, infection, and persistent inflammation in the opened sinus cavities can lead to poor surgical outcomes. Among these, postoperative crusting and synechiae formation are two major factors for the failure of surgery. Although there has been an ongoing debate regarding optimal postoperative stenting or dressing materials following ESS, previously published literature has shown that absorbable nasal dressing leads to improved wound healing and has been subjectively preferred by patients as compared to standard nasal sponges.[4,5] Also, rigorous postoperative care with regular nasal douching prevents nasal crusting and adhesions profoundly.[6]

The preoperative use of topical steroids has previously been evaluated in the literature and showed a lesser rate of bacterial recovery which thus suggested a plausible beneficial role in postoperative outcomes. Also, clinical trials with intranasal triamcinolone acetonide have shown that it is beneficial in minimizing nasal secretory response and reducing inflammation when used for the medical treatment of rhinosinusitis. Further, it has been associated with markedly few adverse side effects in a risk–benefit analysis.[7] It has been previously suggested that the use of nasal packs may also be used to deliver topical antibiotics in the postoperative period.[8]

There is no consensus in the literature regarding optimal perioperative nasal dressing and packing and the optimal postoperative medical regimen. Evidence-based practice and meta-analysis have suggested that a course of postoperative systemic steroids is of value but still there is no strong evidence regarding the benefit of topical steroids as sufficient concentration is not achieved at the surgical site.[9] It has only been hypothesized that direct delivery of topical steroids in the immediate postoperative time for a prolonged period may achieve the improved objective, that is, endoscopic appearance of nasal cavity which is achieved with systemic steroids.[10] Endoscopic scoring systems like the Lund Kennedy endoscopic score (LKES) and perioperative sinus endoscopy (POSE) score are used for this purpose. The POSE scoring system is favorably comparable with the LKES and it may be advantageous in terms of face/content validity and responsiveness to change and is worthy of further validation. These objective endoscopic scoring systems for sinonasal cavities include assessments of features such as crusting, mucosal edema, polyposis, secretions, and scarring (LKES, two points for each category), as well as additional assessments of the middle turbinate, middle meatal antrostomy, and secondary sinuses (POSE).

This study, therefore, sought to assess the potential benefit of using a nonabsorbable nasal dressing impregnated with topical steroid solution, which here is triamcinolone, in comparison with normal saline as a mode of slow- delivery system after sinus surgery to enhance postoperative wound healing.

KEY POINTS

- The significant finding of the study is a significant improvement in the Lund-Kennedy endoscopic scores and perioperative sinus scores on the treatment side which received a triamcinolone infiltrated nasal pack as compared to the control arm which received saline infiltrated nasal pack.
- This study being a Level 2 study adds to inadequate data on the benefits of soaking nasal packs with a steroid solution post endoscopic sinus surgery.

MATERIAL AND METHODOLOGY

This study was a prospective, randomized, double-blinded, placebo-controlled study conducted in the department of ENT, Government Medical College and Rajindra Hospital, Patiala on 40 subjects undergoing functional endoscopic sinus surgery (FESS) for CRS with bilateral nasal polyposis. The study was conducted over a period of 2 years.

The study protocol was approved by the Institutional Review Board for Ethical Clearance of Government Medical College and Rajindra Hospital and it was performed in accordance with the Code of Ethics of the World Medical Association according to the Declaration of Helsinki of 1975, as revised in 2000.

Inclusion criteria included adults of both sexes aged between 15 and 60 years with CRS with nasal polyposis requiring bilateral FESS. Exclusion criteria included patients requiring unilateral FESS, history of previous sinus surgery, or any history of intolerance to triamcinolone.

After selection of study subjects, all participants' parents and guardians were properly informed about the tests that he/she would undergo and a written informed consent was taken. Each patient was subjected to detailed clinical examination, anterior and posterior rhinoscopy, and diagnostic nasal endoscopy. Routine investigations were performed. computed tomography (CT) scan nose and PNS (axial and coronal sections) was done in all patients to look for the extent of the disease. The decision to perform surgery was based on patients' history, clinical examination, and the CT scan.

Preoperatively, LKES[11] and POSE[12] scores were noted. Bilateral FESS was done to remove all the polyps and sufficiently widen the natural ostia of all the affected sinuses to allow access for topical medication.

After the surgery was completed, Merocel packs were inserted in the nasal cavities bilaterally between the middle turbinate and septum. Four milliliter triamcinolone (40 mg/mL) was infiltrated in one nasal cavity (treatment group) and 4 mL normal saline in the other (control group). The allocation of nasal cavity receiving the triamcinolone infiltration was randomized. It was done discreetly by the surgical staff as per instructions from the primary investigator and this information was concealed from both the primary investigator and the operating surgeon. This information was sealed by the nursing staff in an envelope which was opened at the end of the postoperative data collection. Postoperatively, systemic antibiotic was prescribed and nasal packs were removed on the third postoperative day. Following this, alkaline nasal douching was advised at discharge. Steroid sprays were prescribed at the third postoperative week.

The assessment of postoperative wound healing and surgical outcomes was done on postoperative first, second, fourth, and 12th weeks with 0° 4 mm rigid endoscopes by a single person to avoid observer bias. Although the guide and the co-guide were also present with the student at the time of assessment to confirm the findings. Findings were noted as per LKES and POSE scores on every follow-up to compare the difference in healing between the treatment and control groups.

The sample size was estimated based on a previous study, using the formula: $n = z^2_{(1-\alpha/2)} \times SD^2/(d)^2$, where n is the sample size; $Z = 1.96$; $d = 5$; SD = 16. Statistical analysis was done using the paired t-test for intragroup and unpaired t-test for intergroup comparison using a significance level of $P < 0.05$.

RESULTS

In this study, the majority of patients (45%) were in the age group of 31–40 years. The mean age of the study population was 34.62 ± 8.23 years with a range of 21–51 years (Table 1).

The study population showed male preponderance with 28 male patients out of a total of 40 with an M:F ratio of 2.33:1 (Table 1),

Among patients with comorbidities, diabetes mellitus was seen in 20% and hypertension was present in 10% of the patients.

Among presenting symptoms, nasal obstruction and postnasal discharge were the most common symptoms followed by anterior nasal discharge and anosmia.

In our study, LKES was calculated preoperatively and compared at Weeks 1, 2, 4, and 12 postoperatively. The average LKES preoperatively was 5.42 in the treatment arm and 5.50 in the control arm. The statistical difference between the two groups was not-significant ($P = 0.698$). The average score at Week 1 was 2.35 in the treatment arm and 3.07 in the control arm ($P = 0.001$). The average score at Week 2 was 0.8 and 1.27 in the steroid group and saline group, respectively ($P = 0.008$). The average score at Week 4 was 0.25 both in the treatment and control arm ($P = 0.566$). The average score at Week 12 was 0.025 in the treatment arm and 0.52 in the control arm ($P = 0.00$). The difference between the treatment and control arms was statistically significant at all postoperative visits except at Week 4. There was some scarring seen in a few patients in both the treatment and control arms, which may be the reason for statistically insignificant results at Week 4 (Table 1).

TABLE 1 Comparison of patient data.

Clinical characteristics	Treatment group	Control group	*P* value
No. of patients	40		
Mean age	34.62 ± 8.23 years		
No. of males	28		
No. of females	12		
Nasal polyps	40		
Asthma	2		
AERD	0		
LKES			
Preoperative	5.43 ± 0.87	5.50 ± 0.85	0.698
Week 1	2.35 ± 0.86	3.08 ± 0.83	0.001
Week 2	0.83 ± 0.71	1.30 ± 0.85	0.008
Week 4	0.33 ± 0.53	0.40 ± 0.63	0.566
Week 12	0.03 ± 0.16	0.53 ± 0.82	0.000
POSE score			
Preoperative	16.83 ± 1.53	16.90 ± 1.65	0.834
Week 1	2.35 ± 0.83	3.08 ± 0.83	0.001
Week 2	0.88 ± 0.76	1.28 ± 0.85	0.029
Week 4	0.25 ± 0.44	0.25 ± 0.44	1.000
Week 12	0.33 ± 0.62	0.79 ± 1.15	0.026

LKES was also compared individually for each of its components. For nasal crusting and polyps, the difference was statistically insignificant at postoperative follow-up at Weeks 1, 2, and 4 but statistically significant at Week 12 between treatment and control groups (Tables 2 and 3). For edema, it was statistically significant at the first postoperative visit (Week 1) only (Table 4). When compared for nasal discharge, the LKES was statistically significant at postoperative Weeks 1 and 12 and insignificant at Weeks 2 and 4 (Table 5). And lastly for scarring, the difference was not significant at postoperative Week 1 and Week 2 but insignificant at Week 4 and Week 12 between treatment and control arms (Table 6).

The mean preoperative POSE score was 16.83 and 16.90 in the treatment and control arms, respectively. The difference between the two was statistically insignificant ($P = 0.834$). The score at Week 1 reduced to 2.35 in the treatment arm while in the control arm it was 3.08 ($P = 0.001$). At Week 2, the mean score was 0.88 and 1.28 in the treatment and control arms, respectively ($P = 0.029$). At Week 4 and Week 12, the mean POSE score was 0.25 and 0.33 in the treatment arm

TABLE 2 Lund Kennedy score crusting (postoperative follow-up at Week 1 and Week 2).

	Week 1	Week 2	Week 4	Week 12
Treatment (steroid) group	1.20	0.65	0.25	0.00
Control (saline) group	1.40	0.80	0.25	0.18
P value (significance < 0.05)	0.052	0.136	1.000	0.005 (significant)

TABLE 3 Lund Kennedy score polyp (postoperative follow-up at Week 1 and Week 2).

	Week 1	Week 2	Week 4	Week 12
Treatment (steroid) group	0.00	0.00	0.00	0.00
Control (saline) group	0.00	0.00	0.00	0.15
P value (significance < 0.05)	1.000	1.000	1.000	0.010

and 0.25 and 0.78 in the control arm, respectively ($P = 1.000$ and 0.026 at Week 4 and Week 12, respectively). The difference between the two study groups was statistically significant at all post-op visits except at Week 4.

Thus, the difference in POSE scores between the treatment and control arms was statistically significant at postoperative visits at Weeks 1, 2, and 12 but not at Week 4 (Table 7).

DISCUSSION

FESS is perhaps the most commonly used surgical approach for managing CRS and aims to improve/restore drainage and airflow throughout the affected sinuses.[13,14] Although FESS is effective in more than 90% of patients and significantly improves quality of life, postoperative complications, in particular bleeding and adhesions, are quite common.[15] As a consequence, the nasal cavity is packed after FESS with material designed to control any ongoing bleeding, reduce clot formation, decrease the risk of synechia, and promote healing. Once this nasal pack is removed, the patients usually present with excessive crusting, inadequate removal of which may lead to infections, while traumatic removal may cause synechiae formation which consequentially may obstruct the sinus drainage and eventually cause recurrence of disease. Thus, to prevent these complications, patients are prescribed sino-nasal douching at discharge and regular follow-ups are required for suction clearance.

The nasal packs that have been used postoperatively are usually saline soaked. Although they do promote healing in ways as described above, this healing can be further enhanced by adding an anti-inflammatory action to them. Steroids have always been known for their anti-inflammatory action and for this reason, soaking the nasal pack with a steroid seems logical. When healing is improved in the early postoperative period, early complications like crusting and synechiae are prevented, thus, further preventing disease recurrence in the long run. As there are only limited studies in the literature endorsing the merits of steroid-soaked nasal packs, this study was aimed at providing better evidence in establishing the primacy of triamcinolone soaked merocele as a drug eluding packing material for reduction of postoperative sequelae of ESS.

Postoperative follow-up LKES

Radiologic and endoscopic scoring systems have been used as the primary modes for assessment of outcomes following sinus surgery. These are the objective measures of the disease burden. In 1995, Lund and Kennedy[11] proposed an endoscopic scoring system, the LKES system based on the degree of scarring, crusting, edema, polyps, and discharge.

In our study, the LKES difference between the treatment and control arms was statistically significant at all postoperative visits except at Week 4. There was some scarring seen in a few patients in both the treatment and control arms, which may be the reason for statistically insignificant results at Week 4.

Similar results were obtained in a study which observed 19 patients for 6 months postoperatively. This study found a significant difference between the treatment and control arms at Days 7 and 14. The difference lacked statistical significance at postoperative Day 28, but a significant difference was detected between the groups at 3 and 6 months observations.[12]

In another study, the follow-up was done at 3 weeks postoperative period. LKES in the third postoperative week showed statistically highly significant improvement ($P = 0.0001$).[9]

However, in the study by Rudmik et al.[16] where dexamethasone eluting spacer was used, endoscopic evaluation in the fourth postoperative week showed no significant difference on LKES between treatment and control group with an equivalent range of 2–10. This discordance may be due to the variation in treatment modalities followed by various centers in the postoperative period after ESS. In our center we administered nasal douching after pack removal and topical intranasal steroid sprays (2 puffs twice a day) after 3 weeks till 3 months follow-up. The changes seen in the nasal cavity can be the effect of these adjunctive treatments and, hence, it is difficult to ascertain if the drug eluding nasal pack has any effect in the long term.

Variations in the LKES

Nasal crusting

In our study, the difference in evidence of nasal crusting between the treatment and control arm was statistically significant at

TABLE 4 Lund Kennedy score edema (postoperative follow-up at Weeks 1, 2, 4, and 12).

	Week 1	Week 2	Week 4	Week 12
Treatment (steroid) group	0.35	0.10	0.00	0.00
Control (saline) group	0.68	0.25	0.00	0.00
P value (significance < 0.05)	0.003 (significant)	0.079	1.000	1.000

TABLE 5 Lund Kennedy score nasal discharge (postoperative follow-up at Weeks 1, 2, 4, and 12).

	Week 1	Week 2	Week 4	Week 12
Treatment (steroid) group	0.80	0.10	0.00	0.03
Control (saline) group	1.00	0.23	0.00	0.25
P value (significance < 0.05)	0.003 (significant)	0.133	1.000	0.003 (significant)

TABLE 6 Lund Kennedy score scarring (postoperative follow-up at Weeks 1, 2, 4, and 12).

	Week 1	Week 2	Week 4	Week 12
Treatment (steroid) group	0.00	0.00	0.08	0.00
Control (saline) group	0.00	0.03	0.15	0.00
P value (significance < 0.05)	0.00	0.320	0.034 (significant)	0.00

TABLE 7 POSE score (postoperative follow-up at Weeks 1, 2, 4, and 12).

	Week 1	Week 2	Week 4	Week 12
Treatment (steroid) group	2.35	0.88	0.25	0.33
Control (saline) group	3.08	1.28	0.25	0.78
P value (significance < 0.05)	0.001 (significant)	0.029 (significant)	1.000	0.045 (significant)

postoperative Week 12 only. Only one other study in the literature has evaluated nasal crusting which also did not find significant difference between the two study arms.[9] Proper saline douching and regular suction clearance on follow-ups must be performed to tackle crusting.

Polyp

In our study, polypoidal change in the postoperative period was reduced in both the treatment and control arms at all follow-ups but was statistically significant only at postoperative follow-up at week 12. Polypoidal mucosa is one of the major causes of recurrence for which intranasal steroid sprays are usually prescribed in the postoperative period. Infiltration of nasal pack with a steroid gives this additive effect, potentially reducing the need for postoperative intranasal sprays.

Edema

The reduction in edema was statistically significant in the treatment arm only at follow-up at postoperative Week 1. At rest of the follow-up visits, the edema was reduced in both treatment and control arms equally, hence the difference was statistically not-significant. Other studies also showed similar results.[9,17]

Nasal discharge

In our study, nasal discharge was significantly reduced in the treatment arm at postoperative Week 1 and Week 12. In a study conducted by Dekhil et al.,[18] they found a significant reduction in nasal discharge at 1-week postoperative period ($P = 0.048$) but the difference at postoperative 1 month and 3 months was not significant ($P = 0.097$ and 0.26, respectively).[18]

Scarring

Synechiae formation is the most frequently occurring complication after FESS, ranging from 6% to 27%.[19] In the present study, the scarring was statistically insignificant between the treatment group and the control group at all postoperative follow-ups. The patients who had scarring at Week 4 underwent synechiolysis, hence the reason why there was no scarring observed at Week 12. In the literature, variable results have been obtained on scarring; thus, further studies may be required to ascertain whether scarring is actually reduced by steroid infiltration in nasal packs.

Thus, summarizing the LKES results of our study, we found that the nasal pack soaked with triamcinolone showed significant favorable outcome in terms of decreased crusting and edema in comparison to the control group where normal saline was used to soak the nasal pack. Even though every component of LKES was not significantly reduced, there was a significant overall improvement in this score suggesting their beneficial effect on postoperative healing. Further studies with longer follow-ups (in years) can be done to further evaluate the role of drugs used to soak the nasal packs as a significant improvement was seen in LKES at 12th week follow-up as well even though nasal packs were removed after 3 days. This shows that the initial effect of steroids affects the long-term healing as well. Also, drug-eluding stents or packs that can be kept for a longer duration without causing discomfort can help in understanding the effect of these drugs on long-term health of the nasal cavity.

POSE score

The POSE scoring system is a newer sinonasal scoring system employed by Wright and Agrawal[10] to evaluate the outcomes in a randomized trial of perioperative systemic steroids on surgical patients of CRS with polyposis. POSE scoring provided richer measures of inflammation in the ethmoid cavity, scarring and obstruction in outflow, as well as evaluation of secondary sinuses, thus enhancing face validity and responsiveness to change. It also included instructions for baseline assessments. Furthermore, it was seen that the POSE seemed to be more sensitive to subtle changes over time and it also correlated better with the symptom scores than LKES.

The difference in mean preoperative POSE score was insignificant between the treatment and control arms. When compared at postoperative Week 1, 2, 4, and 12, the difference was statistically significant at Weeks 1, 2, and 12 but not at Week 4.

In the study conducted by Cote and Wright,[10] the baseline POSE score was 13.16 and 13.05. Similar to our study, they found statistically significant differences at all post-op visits except at post-op Day 28. Similarly, Gyawali et al.[9] observed POSE scores ranged from 0 to 8 in the treatment site with an average of 1.21, and 0-8 with an average of 1.95 in the control site. This difference was also statistically significant ($P = 0.004$).

The POSE score being a more precise and better objective measurement of postoperative status of nasal cavity than the LKES further consolidates the evidence of the efficacy of steroids in reducing inflammation and improving healing in postoperative period as a significant improvement has been seen in this study. Although the packs were in situ for only 3 days, this significant improvement was seen not only at the initial postoperative weeks but also at 3 months in both the LKES and the POSE scores despite both the treatment and the control arms receiving topical steroids. This gives the affirmation that early healing is a major factor in eliminating the risk for recurrence. When the mucosa has already started healing and inflammation is reduced, the effect of medications given thereafter is also improved, especially that of topical sprays due to enhanced absorption as given in our study.

CONCLUSION

In conclusion, we found that both the LKES and the POSE score were significantly reduced in the postoperative period in the steroid group as compared to the saline group. This shows that the triamcinolone-soaked nasal cavity is superior to saline-soaked nasal packs in accelerating postoperative healing. However, as this was a short-term follow-up study, further evidence with more studies and a longer follow-up is required.

LIMITATIONS

This was a short-term follow-up study and the sample size was small. Thus, further evidence with more studies with a greater sample size and a longer follow-up is required to study that the initial positive effect of steroids on wound healing may prevent recurrence in the long term.

AUTHOR CONTRIBUTIONS

All the authors have contributed to the preparation of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Research data are not shared.

ETHICS STATEMENT

The study protocol was approved by the Institutional Review Board for Ethical Clearance of Government Medical College and Rajindra Hospital and it was performed in accordance with the Code of Ethics

of the World Medical Association according to the Declaration of Helsinki of 1975, as revised in 2000.

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