ORIGINAL ARTICLE

Pilot study comparing steroid-impregnated and non-steroid-impregnated absorbable nasal dressing following endoscopic sinus surgery

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ABSTRACT

Introduction: Endoscopic sinus surgery (ESS) is the mainstay for treatment of chronic rhinosinusitis versus maximal medical therapy. We propose a more economical option, by using steroid-impregnated Gelfoam instead of Nasopore post ESS, as it is less expensive and has showed effectiveness in preventing post-operative bleeding.

Materials and methods: A randomised, double-blinded, placebo-controlled trial was carried out in eight patients with chronic rhinosinusitis or nasal polyposis who were planned for bilateral endoscopic sinus surgery. A Peri-operative Sinus Endoscopy (POSE) Score and Lund-Kennedy Endoscopic Score (LKES) were recorded. The use of hydrocortisone-impregnated Gelfoam dressing versus normal saline-impregnated Gelfoam dressing were compared. Scores were repeated post-operatively at one week, three weeks and three months interval.

Results: For LKES, at the end of three months, 50% of the patients had the same score difference, 37.5% had better results on the study side while 12.5% had better results on the control side. Meanwhile, for POSE Score, at the end of three months, 75% of the patients had better score difference on the study side while 12.5% had better results on the control side.

Conclusion: Gelfoam can be used as nasal packing material to deliver topical steroid after endoscopic sinus surgery. Steroid-impregnated nasal dressing after endoscopic sinus surgery may not provide better long-term outcome.

KEY WORDS:
Endoscopic sinus surgery, Rhinosinusitis, Steroid nasal dressing, Gelfoam

INTRODUCTION

Endoscopic sinus surgery (ESS) is considered the treatment of choice for chronic rhinosinusitis refractory to maximal medical therapy. Patient's symptoms and quality of life have been shown to improve after ESS.[1-3] The symptom that improved the most after endoscopic sinus surgery is usually nasal obstruction. Other symptoms such as facial pain, postnasal discharge, hyposmia and headache also improved to a lesser extent.[3]

However, post-operative complications such as adhesion, bleeding, scarring, infection, and oedema may compromise the outcome of the surgery.[4,5] Nasal dressing is commonly applied after ESS to prevent post-operative bleeding, decrease adhesion formation, prevent lateralisation of middle turbinate and subsequent obstruction of the sinus drainage pathway.[6] As non-absorbable nasal dressing has shown some complications such as bleeding and pain upon removal, septal perforation and foreign body granuloma formation, the ideal nasal dressing should be one that is absorbable, haemostatic and improves healing.[6,7] However, the optimal choice of nasal dressing following ESS, or whether nasal dressing are required at all, is still an area of ongoing research.

In order to achieve better outcome following ESS, some surgeons support the use of systemic steroids.[8] As topical steroids carry less systemic adverse effects, nasal dressing impregnated with topical steroid is better if the outcome is comparable. Recently, a randomised, double-blinded, controlled study has suggested that triamcinolone-impregnated nasal dressing using Nasopore® (Polyganics, Netherlands) after ESS provides a significant improvement in early post-operative healing in nasal cavity.[9] We hypothesised that similar results are reproducible with steroid impregnated in other absorbable nasal packing material. Gelfoam® (Pfizer, USA) is less expensive compared to Nasopore®. Literature has shown that Gelfoam® packing is effective in preventing post-operative bleeding with good sinonasal healing comparable to no packing after ESS, therefore Gelfoam® is chosen as the nasal dressing material for this study.[10]

MATERIAL AND METHODOLOGY

Approval from University Malaya's Medical Ethics Committee (reference number 1003.3) was obtained prior to recruitment of subjects. A prospective, randomised, double-blinded, placebo-controlled trial was carried out in Department of Otorhinolaryngology, UMMC, Kuala Lumpur. The objective of the study was to assess the efficacy of steroid-impregnated absorbable intranasal dressing on mucosal healing and surgical outcome post endoscopic sinus surgery (ESS).

Eight patients were recruited into the study based upon the following criteria: Inclusion criteria: patients with chronic

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rhinosinusitis or nasal polyposis of equal severity in both nostrils, who were planned for endoscopic sinus surgery, planned surgery in both nasal cavity and written consent and willing participation from subjects. Exclusion Criteria: patients who are ineligible to give informed consent and patients who are unwilling or unable to comply with the postoperative visits necessary for data collection.

Patients were randomised to receive hydrocortisone-impregnated Gelfoam® dressing in one nasal cavity and normal saline-impregnated Gelfoam® dressing in the contralateral nasal cavity (patient's own nasal cavity, served as a control). Randomisation was carried out by a medical officer whom was not involved in the surgery. Both the patient and the surgeon are blinded as to which nasal cavity served as the test site, and which nasal cavity served as the control site throughout the entire study. Only upon completion of the study, for data analyses purposes, was the control and test site revealed. Baseline assessment using Peri-operative Sinus Endoscopy (POSE) Score[8,11] (Table I) and Lund-Kennedy Endoscopic Score (LKES)10 was recorded and repeated post-operatively at one week, three weeks and three months interval. Data analysis was done using Wilcoxon signed-rank test using SPSS version 22, with a significance level of $p<0.05$.

RESULTS

Preoperative Lund-Kennedy Endoscopic Score and POSE Score showed no statistically significant difference between the study and control cavities. At one week and three months post-surgery, the mean Lund Kennedy Score and mean Perioperative Sinus Endoscopy (POSE) Score for both study and control groups were very similar. No statistically significant difference was noted postoperatively in the study and control groups using both scoring system (Table II, III).

In order to reflect the true significance of the post-operative scores, the authors propose to calculate the score difference whereby;

Postoperative Score – Preoperative Score = Score Difference.

Lund Kennedy Score Difference

At one-week post-surgery, six out of eight patients (75%) had better score difference on the study side. The score difference was worse in one patient, while the other patient had the same score difference. At three weeks post-surgery, the control group showed better outcome than the study group. At the end of three months, 50% of the patients had the same score difference, 37.5% had better results on the study side while 12.5% had better result on the control side. Statistically, these score differences were not significant (Table IV).

POSE Score Difference

One week after surgery, seven out of eight patients (87.5%) had better score difference on the study side, one patient showed no difference between control and study side. At three weeks post-surgery, the control group had better score difference than the study group. At the end of three months, 75% of the patients had better score difference on the study side while 12.5% had better results on the control side. The remaining one patient showed no difference in both sides.

Based on the score difference using POSE scores, better improvement was observed in the study group compared to the control group at one week and three- month post-surgery with $p=0.016$ and 0.040 respectively (Table V).

DISCUSSION

Postoperative care is crucial in management of patients after ESS. Regular suction cleaning and rinsing or washing are routinely done in order to achieve better surgical outcome.[11] The optimal choice of nasal dressing and the benefit of systemic versus topical steroid during perioperative or immediate postoperative period are still being researched.

Conventionally, non-absorbable nasal dressing is used after endoscopic sinus surgery to prevent bleeding. In recent years, several absorbable nasal dressing materials have been manufactured. Studies have shown that absorbable nasal packing is safe, well-tolerated and favour better healing in the nasal cavity with less synechiae formation compared to those who received standard non-absorbable nasal packing.[12,13] These studies used MeroGel® (a non-woven pad composed of a benzylic ester of hyaluronic acid) or Nasopore® (fully synthetic biodegradable fragmentable foam) as the absorbable material for nasal packing. Another absorbable nasal packing material available is Gelfoam®. A study by Wee showed that sinonasal healing after Gelfoam® nasal packing was as good as without packing.[10]

Administration of short term systemic steroids during perioperative period (five days pre-surgery and nine days post-surgery) would give rise to healthier nasal cavities postoperatively with the best effects seen at two weeks after surgery.[8] As systemic steroids come with side effects such as gastrointestinal disturbances causing peptic ulceration and increase plasma glucose levels, steroid-impregnated nasal dressing was suggested to replace systemic steroid. According to More et al., triamcinolone-impregnated absorbable nasal dressing is comparable to oral steroid in the management of early nasal polyposis after sinus surgery.[14] Another study showed that triamcinolone-impregnated nasal dressing using Nasopore provides significant improvement in early post-operative healing in nasal cavity after ESS.[9]

The Lund-Kennedy Endoscopy Scale (LKES) is a widely accepted scoring system for chronic rhinosinusitis developed in 1995. The Perioperative Sinus Evaluation Scoring System (POSE), is a newer scoring system validated by Erin D. Wright in 2007, which correlates strongly with the Lund-Kennedy Endoscopy Scale (LKES). The authors have chosen to utilise both scoring system as they complement each other, and also as a reference for comparison of results to other studies that may have only used LKES or POSE.

As the preoperative scores differ between subjects (preoperative POSE scores in the study group range from 5 to 12 while the control group scores range from 2 to 8), the average postoperative POSE scores may not be the best indicator in showing the improvement in each study subject. Therefore, the score difference pre and postoperatively was calculated.

Table I: Summary of Scoring Criteria for Peri-Operative Sinus Endoscopy (POSE) Score

Middle Turbinate		
Synechia/Lateralized	Synechia to lateral wall or lateralized MT = 1 point each	
	Score = 1	**Score = 2**
Middle Meatus/MMA		
Narrowing/Closure	MMA narrow (scar or oedema)	MMA closed (scar or oedema)
Maxillary Sinus Contents	Mucoid secretions/oedema	Purulent
Ethmoid Cavity		
Crusting	Mild (few isolated)	Extensive (diffuse or occluding)
Mucosal Oedema	Loss of discernible underlying bony contours in some areas	Diffuse loss of discernible underlying bony contours
Polypoid Change	Discernible outpouchings beginning to narrow or partly fill the cavity	Discernible outpouchings fill the ethmoid cavity
Polyposis	Extending beyond middle meatus but not to the inferior turbinate	Beyond the upper border of the inferior turbinate
Secretions	Thin/mucoid	Purulent
Secondary Sinuses		
Frontal Recess/Sinus	Narrowed/oedema present	Obstructed/infected/severely inflamed
Sphenoid Sinus	Narrowed/oedema present	Obstructed/infected/severely inflamed

Table II: Statistical Description and Analysis of Post-surgery Lund-Kennedy Postoperative Score

N=8

	Study			Control		
	Range	**Mean**	**Median**	**Range**	**Mean**	**Median**
Pre Op	3-6	4.500	4.0	1-6	3.875	4.0
1 week	1-4	2.500	2.5	1-4	2.625	3.0
3 weeks	0-4	2.125	2.5	0-3	1.250	1.5
3 months	0-2	1.125	1.0	0-2	1.125	1.0

	Study				Control				p value
	IQR	**SE**	**95% CI**		**IQR**	**SE**	**95% CI**		
			lower	**upper**			**lower**	**upper**	
Pre Op	2	0.378	3.61	5.39	2	0.515	2.66	5.09	0.180
1 week	1	0.327	1.73	3.27	1	0.324	1.86	3.39	0.792
3 weeks	2	0.479	0.99	3.26	2	0.412	0.28	2.22	0.222
3 months	2	0.295	0.43	1.82	2	0.295	0.43	1.82	1.000

IQR : Interquartile Range
SE: Standard Error
CI: Confidence Interval

Table III: Statistical Description and Analysis of Post-surgery Perioperative Sinus Endoscopy (POSE) score

N=8

	Study			Control		
	Range	**Mean**	**Median**	**Range**	**Mean**	**Median**
Pre Op	5-12	7.750	8.0	2-8	6.500	7.0
1 week	1-4	2.75	2.5	1-5	3.125	3.0
3 weeks	0-6	3.125	3.5	0-4	1.625	1.5
3 months	0-4	1.750	1.5	0-5	2.375	2.0

	Study				Control				p value
	IQR	**SE**	**95% CI**		**IQR**	**SE**	**95% CI**		
			lower	**upper**			**lower**	**upper**	
Pre Op	2	0.726	6.03	9.47	2	0.707	4.83	8.17	0.109
1 week	2	0.412	1.78	3.72	2	0.441	2.08	4.17	0.476
3 weeks	4	0.718	1.43	4.82	3	0.565	0.29	2.96	0.105
3 months	2	0.453	0.68	2.82	4	0.680	0.77	3.98	0.236

IQR : Interquartile Range
SE: Standard Error
CI: Confidence Interval

Table IV: Score Difference (Lund-Kennedy Score) – statistical description and analysis

	Study			Control		
	Range	Mean	Median	Range	Mean	Median
1 week	-5 to 0	-2.000	-2.0	-4 to 1	-1.250	-1.0
3 weeks	-7 to -1	-2.375	-2.5	-7 to -1	-2.625	-3.0
3 months	-11 to -4	-3.375	-3.0	-6 to -2	-2.750	-3.0

	Study				Control				p value
	IQR	SE	95% CI		IQR	SE	95% CI		
			lower	upper			lower	upper	
1 week	3	0.598	-3.41	-0.59	1	0.491	-2.41	-0.09	0.058
3 weeks	2	0.532	-3.63	-1.12	3	0.532	-3.88	-1.37	0.527
3 months	2	0.460	-4.46	-2.29	2	0.366	-3.62	-1.88	0.197

IQR : Interquartile Range
SE: Standard Error
CI: Confidence Interval

Table V: Score Difference (POSE Score) – statistical description and analysis

	Study			Control		
	Range	Mean	Median	Range	Mean	Median
1 week	-8 to -2	-5.000	-4.5	-5 to 0	-3.375	-3.5
3 weeks	-7 to -1	-4.625	-4.5	-7 to -1	-4.875	-5.0
3 months	-11 to -4	-6.000	-5.0	-6 to -2	-4.125	-4.0

	Study				Control				p value
	IQR	SE	95% CI		IQR	SE	95% CI		
			lower	upper			lower	upper	
1 week	3	0.681	-6.61	-3.39	3	0.625	-4.85	-1.90	0.016
3 weeks	4	0.730	-6.35	-2.90	2	0.639	-6.39	-3.36	0.577
3 months	7	0.779	-7.84	-4.16	3	0.515	-5.34	-2.91	0.040

IQR : Interquartile Range
SE: Standard Error
CI: Confidence Interval

The postoperative outcome was better in the study group at one-week post-surgery when scored with POSE=87.5%(p=0.016) and LKES=75%(p=0.058). This improvement is comparable to the usage of perioperative systemic steroid which had its best effect at two weeks post operation.8 At three weeks follow up, the study group did not perform better than the control group in terms of healing in the nasal cavities. We postulate that this is because, topical steroids were only given once in the operating theatre post-surgery. In addition, patients underwent regular nasal suction and nasal douching after the first follow up. At three months post-surgery, the outcome in the study group was noted to be slightly better than the control group but the results were not statistically significant with LKES (p=0.197). The results from POSE Scores and LKES were not completely the same in our study. It showed that POSE Scores and Lund-Kennedy Endoscopic Scores may not attain similar result patterns despite all assessments being done by a single blinded observer.

In clinical practice, topical steroid is considered safer than systemic steroid as it is localised with markedly less adverse effects. However, there are some degree of systemic absorption of topical steroids. Hong et al., reported that triamcinolone-impregnated nasal dressing suppressed serum cortisol levels during early postoperative period. The systemic effect recovered gradually and normalised after 10 days.[15]

There were several limitations in our study. Firstly, our sample size was small. Secondly, it is very difficult to recruit patients with equal severity of preoperative nasal conditions, thus rendering our preoperative LKES and POSE scores different. If we were to emphasise on that, we would require a longer period of time to collect subjects to obtain a significant sample size. By calculating the score difference pre and postoperatively, we can get a better representation of the improvement in each nasal cavity. A larger sample size will definitely conceive more conclusive results. Thirdly, a multicentre randomised control trial, would allow a more accurate representation of the studied population. Aside from that, a longer follow up period would determine if there were any long-term benefits such as reduce rates of recurrence of disease, by using steroid-impregnated Gelfoam.

CONCLUSION

The healing of the nasal cavity after ESS is better in early postoperative period with steroid-impregnated nasal dressing. Topical steroids may be an option to replace oral steroids during postoperative period. Gelform can be used as nasal packing material to deliver topical steroids after endoscopic sinus surgery. Steroid-impregnated nasal dressing after endoscopic sinus surgery, may not provide better long-term outcome.

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