

Original Article

The effects of Vaseline gauze strip, Merocel, and Nasopore on the formation of synechiae and excessive granulation tissue in the middle meatus and the incidence of major postoperative bleeding after endoscopic sinus surgery[☆]

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Abstract

Background: Endoscopic sinus surgery (ESS) has become the widely accepted procedure for the treatment of medically refractory chronic rhinosinusitis and nasal polyps. Nasal packing is usually placed after ESS to prevent synechia formation and postoperative bleeding and to support wound healing. The aim of this study was to evaluate the effects of three different nasal packing materials [Vaseline gauze strip, Merocel (Metronic Xomed, Jacksonville, FL, USA), and Nasopore (Polyganics, Rozenburglaan, Groningen, The Netherlands)] on the formation of synechiae and excessive granulation tissue in the middle meatus and incidence of major postoperative bleeding in patients who had undergone ESS.

Methods: A total of 626 patients (1,018 sides) who had undergone ESS were studied retrospectively. Each patient chose one of the three different nasal packing materials according to his or her own preference. The outcome variable was the formation of synechiae and excessive granulation tissue in the middle meatus, which was identified from the medical records of endoscopic evaluations performed 3–4 weeks and 10–12 weeks after surgery. Major postoperative bleeding within 2 weeks after the operation was also documented for analysis. Finally, multiple logistic regression models were used to confirm the results of this study.

Results: We did not observe significant intergroup differences in the effect on the formation of synechiae in the middle meatus. Nasopore packing showed a trend toward causing the formation of excessive granulation tissue during the early stages of wound healing ($p = 0.004$). Patients who had received packing with Nasopore had a greater chance of undergoing readmission or additional packing because of major nasal bleeding within the first 2 weeks after the operation ($p = 0.03$). Multivariable logistic regression models showed that Nasopore was a significant factor for the formation of excessive granulation tissue at 3–4 weeks after the operation ($p = 0.022$) and for major postoperative nasal bleeding within the first 2 weeks after the operation ($p = 0.023$).

Conclusion: Among patients who had undergone ESS for rhinosinusitis with or without polyps, the incidence of synechiae and excessive granulation tissue in the middle meatus and major postoperative bleeding in the patients who received Vaseline gauze packing was equivalent to the incidence of these complications in the patients who received Merocel. Nasopore was not superior to the other two nonabsorbable packing materials.

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Keywords: Endoscopic sinus surgery; Granulation; Nasal packing; Postoperative bleeding; Synechiae

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1. Introduction

Endoscopic sinus surgery (ESS) has become the standard treatment for the management of medically refractory chronic rhinosinusitis and nasal polyps. The common complications of ESS include postoperative formation of synechiae in the middle meatus and nasal bleeding. The former is considered the most common complication of ESS, and the incidence of this complication ranges from 1% to 36%.^{1–3} Synechiae in the middle meatus can block the normal mucociliary drainage pathway of the sinuses and lead to disease recurrence. Numerous techniques, including suture medialization, partial resection of the middle turbinate, and nasal packing in the middle meatus, have been used to prevent postoperative synechia formation. Nasal packing remains the most common procedure to prevent synechia formation and postoperative bleeding. Conventional packing products, such as Vaseline gauze strip and expandable polyvinyl acetate (Merocel; Metronic Xomed, Jacksonville, FL, USA) are nonabsorbable materials. New biodegradable packing materials with various degrees of efficacy have also been developed, for example, Flo-Seal (Baxter International Inc., Deerfield, IL, USA); MeroGel/Meropack (Metronic Xomed); Nasopore (Polyganics, Rozenburglaan, Groningen, The Netherlands); and carboxymethylcellulose (AthroCare, Glenfield, United Kingdom). However, the effects of these packing agents on mucosal healing and postoperative bleeding have not been conclusively determined.

In our department, we use Vaseline gauze strip, Merocel, or Nasopore as the packing material according to the patient's choice. Owing to the limited data on the use of Vaseline gauze strip and Nasopore, we aimed to compare the effects of Vaseline gauze strip, Merocel, and Nasopore on the incidence of major postoperative bleeding and the formation of synechiae and excessive granulation tissue in the middle meatus in patients who had undergone ESS.

2. Methods

2.1. Subjects

We retrospectively reviewed the medical records of 788 patients who had undergone ESS at the Department of Otolaryngology–Head and Neck Surgery of Mackay Memorial Hospital between January 2006 and February 2009. In all the patients, the indication for surgery was chronic rhinosinusitis with or without nasal polyps. Patient exclusion criteria included no postoperative nasal packing (31 patients), nasal malignancy (two patients), and loss during follow-up (129 patients). A total of 626 patients were finally enrolled in this study. In Taiwan's National Health Insurance system (which covers almost the entire population), the insurance plan for the patients who undergo ESS does not provide for free Merocel and Nasopore packing and microdebrider use. Therefore, we explained the costs and differences among the three different packing materials and the benefits of microdebrider use to the patients, and they had complete freedom in selecting

a treatment suited to their budgets and preferences. A written consent was also obtained from each subject.

2.2. Methods

All patients were admitted to our department to undergo the appropriate ESS, and at the end of the surgery, the chosen packing material was impregnated with antibiotics and introduced in the middle meatus. The Vaseline gauze strip and Merocel packing were removed 48–72 hours after surgery. In contrast, Nasopore was left in place until it was suctioned out during the patient's follow-up visit (5–10 days after discharge). The postoperative regimens for the patients were quite similar, including 2-week oral antibiotic therapy along with the administration of a topical nasal steroid and regular follow-up examinations. Excessive granulation tissue and synechiae in the middle meatus were identified from the medical records of the endoscopic evaluations or Picture Archiving and Communication Systems assessments performed 3–4 weeks and 10–12 weeks after surgery. Granulation tissue formation is common during the mucosal healing process; therefore, we considered only those cases that showed excessive granulation tissue involving more than 10% of the middle meatus.⁴ Major postoperative bleeding was defined as severe bleeding that required either readmission or additional nasal packing within 2 weeks after the operation.

The Lund–Mackay computed tomography (CT) staging system (0–12, per side), and the nasal polyp grading system (0, no visible polyps; 1, polyps confined to the middle meatus; 2, polyps that had grown beyond the middle meatus but were not completely obstructing the nasal cavity; 3, polyps completely obstructing the nasal cavity) was used to assess the findings of the preoperative CT and endoscopic evaluations.⁵ We also collected patient data, such as age group (≤ 18 years, 19–65 years, and > 65 years); gender; revision surgery; use of microdebrider; and skill level of the operator (trainee or attending), for further analysis (Table 1).

2.3. Statistical analysis

Statistical analysis of the data obtained in this study was performed using Stata 8.0 (StataCorp, College Station, TX, USA). Comparisons of all the parameters, including the outcome variables for the formation of synechiae and excessive granulation tissue in the middle meatus and the incidence of major postoperative nasal bleeding, for the packing material groups, were performed using Chi-squared tests. Finally, multivariable logistic regression models with stepwise regression procedures were used to confirm the results of our study. Probability values less than 0.05 were considered statistically significant.

3. Results

3.1. Patient characteristics

A total of 626 patients were analyzed in this study; among these, 236 had undergone surgery on one side, whereas 390 had undergone surgeries on both sides; thus, a total of 1,018 ESS

Table 1
Baseline profile of the patients

Characteristic	Vaseline (n = 628)	Merocel (n = 228)	Nasopore (n = 162)	p
Gender				0.229
Male	399	136	92	
Female	229	92	70	
Age group, yr				0.005*
≤18	46	29	17	
18–65	523	189	124	
≥65	59	10	21	
CT Lund–Mackay staging	7.49 ± 2.36	7.73 ± 2.19	7.4 ± 2.17	0.208
Polyp grading				0.668
0	174	73	47	
1	83	36	21	
2	307	96	80	
3	64	23	14	
Revision surgery				0.474
Yes	127	42	38	
No	501	186	124	
Microdebrider use				<0.001*
Yes	173	124	151	
No	455	104	11	
Operator				<0.001*
Attending	284	70	58	
Trainee	344	158	104	

* $p < 0.05$.

procedures were assessed. Vaseline gauze was chosen as the nasal packing material in 628 procedures (61.7%), Merocel in 228 procedures (22.4%), and Nasopore in 162 procedures (15.9%). No significant intergroup differences were observed in the preoperative Lund–Mackay CT staging scores, polyp grades, gender, and proportion of revision surgeries. However, significant intergroup differences were observed in the age group, operator skill, and microdebrider use (Table 1).

3.2. Intergroup comparisons

At the follow-up visit performed 3–4 weeks after the operation, synechiae in the middle meatus were found in 50 (8%) sides in the Vaseline group, 20 (8.8%) sides in the Merocel group, and 17 (10.5%) sides in the Nasopore group. No significant intergroup differences were observed in the incidence of synechiae in the middle meatus ($p = 0.584$). The data obtained at 10–12 weeks after the operation also showed no statistically significant intergroup differences.

When the patients were examined 3–4 weeks after the operation, excessive granulation tissue was found in 47 (7.5%) sides in the Vaseline group, 16 (7.0%) sides in the Merocel group, and 25 (15.4%) sides in the Nasopore group. The number of cases in the Nasopore group was significantly higher ($p = 0.004$), thereby indicating a higher incidence of excessive granulation tissue formation in the Nasopore group. However, the difference was not significant at 10–12 weeks after the operation ($p = 0.858$). Furthermore, we did not

observe any significant difference between the incidence of excessive granulation tissue formation in the Vaseline and Merocel groups at any of the time points ($p > 0.05$).

Analysis of the cases of major postoperative nasal bleeding revealed three (0.48%) events in the Vaseline group, one (0.44%) event in the Merocel group, and four (2.5%) events in the Nasopore group. The number of cases in the Nasopore group was significantly higher ($p = 0.03$). Patients who received nasal packing with Nasopore had a greater chance of undergoing readmission or additional packing because of severe nasal bleeding within the first 2 weeks after the operation (Table 2). Furthermore, we did not observe any significant differences between the findings of the Vaseline and Merocel groups ($p > 0.05$).

3.3. Multivariable logistic regression models

To clarify the effects of the packing materials on the incidence of major postoperative nasal bleeding and the formation of synechiae and excessive granulation tissue in the middle meatus, all the parameters in Table 1 were included in the logistic regression models. We found that the packing material did not significantly influence the incidence of synechia formation in the middle meatus at both 3–4 weeks and 10–12 weeks after the operation ($p > 0.05$ for all differences). However, the effect of Nasopore packing on the risk of excessive granulation tissue formation remained important when other factors had been taken into account, and the odds ratio for this effect at 3–4 weeks after the operation was 2.048 ($p = 0.022$). However, no significant intergroup differences were observed at 10–12 weeks. Nasopore packing was a significant predictor of major postoperative nasal bleeding within the first 2 weeks after surgery, and the odds ratio was 10.101 ($p = 0.023$) (Table 3).

4. Discussion

The surgical outcomes in ESS remain dependent on successful wound healing without excessive synechia formation. Many parameters have been used to determine the effect of nasal packing on wound healing. Wormald et al.⁶ set up a sheep model of sinusitis and performed serial mucosal biopsies for light and electron microscopic evaluations. They chose the degree of mucosal reepithelialization, height of the epithelium, percentage of the area covered by cilia, and the maturity of the cilia as the parameters to investigate the

Table 2
Comparison of the effects of the three nasal packing materials

Outcome	Vaseline (n = 628)	Merocel (n = 228)	Nasopore (n = 162)	p
Synechiae (3–4 wk)	50	20	17	0.584
Synechiae (10–12 wk)	20	6	7	0.644
Excessive granulation (3–4 wk)	47	16	25	0.004*
Excessive granulation (10–12 wk)	16	5	3	0.858
Major postoperative bleeding	3	1	4	0.030*

* $p < 0.05$.

Table 3
Multiple logistic regression models

Outcome	OR	Std err	<i>p</i>	95% CI
Synechia (3–4 wk)				
Meroceol	0.849	0.249	0.575	0.478–1.507
Nasopore	1.169	0.410	0.656	0.588–2.324
Synechia (10–12 wk)				
Meroceol	0.631	0.309	0.347	0.242–1.647
Nasopore	1.110	0.581	0.842	0.398–3.099
Excessive granulation (3–4 wk)				
Meroceol	0.808	0.252	0.495	0.438–1.490
Nasopore	2.048	0.641	0.022*	1.109–3.782
Excessive granulation (10–12 wk)				
Meroceol	0.782	0.421	0.648	0.272–2.247
Nasopore	0.827	0.578	0.785	0.210–3.254
Major postoperative bleeding				
Meroceol	1.139	1.350	0.913	0.112–11.628
Nasopore	10.101	10.300	0.023*	1.369–74.536

**p* < 0.05. CI = confidence interval; OR = odds ratio.

process of wound healing.⁷ However, serial biopsies cannot be easily performed in a human clinical study. Wormald et al.⁶ then selected synechia formation, mucosal edema, and infection as the parameters for analyses. Other authors have used synechia in the middle meatus and formation of granulation tissue as the parameters to assess healing.^{1,8–10} In the present study, we adopted the formation of synechia and excessive granulation tissue in the middle meatus and major postoperative bleeding as the outcome variables to assess the effects of the three different packing materials.

To assess the effect of packing materials on synechia prevention, Miller et al.¹ conducted a blinded randomized controlled trial to compare the effects of MeroGel and Meroceol packing in 37 patients who had undergone ESS. They found that the rate of synechia formation in both groups at 8 weeks after the operation was approximately 8%, and the intergroup difference was not statistically significant.¹ Berlucchi et al.¹¹ performed a prospective randomized controlled study comparing the effects of MeroGel and standard nonabsorbable nasal packing at 2, 4, and 12 weeks after ESS in 66 patients. They found lower rates of nasal synechia formation in the MeroGel group at both 4 and 12 weeks after the operation.¹¹ Similarly, Chandra et al.¹⁰ performed a double-blinded randomized controlled trial comparing the effects of FloSeal (Baxter, Alexander Court Hayward, CA, USA) and thrombin-soaked gelatin foam in 20 patients, and they found that FloSeal significantly increased adhesion (*p* = 0.006) and granulation tissue formation (*p* = 0.007). Bugten et al.⁸ compared the effects of nonabsorbable packing with no packing after ESS; in their study, endoscopic video recordings obtained 10–14 weeks after surgery showed seven (7/62) adhesions in the nonabsorbable packing group and 29 (29/54) adhesions in the control (no packing) group (*p* < 0.001). In a prospective randomized controlled study published in 2006, Wormald et al.⁶ tested the effects of MeroGel on one side and no packing on the other side in 42 patients with chronic rhinosinusitis who had undergone ESS. The researchers did not find any significant differences

among the incidence of synechia formation on the two sides at 2 weeks, 4 weeks, and 6–8 weeks after surgery. Overall, the incidence of synechia formation after ESS differs considerably from trial to trial, and the optimal material for nasal packing is still a matter of debate. Because none of the previous studies has compared the effects of Meroceol and Nasopore with those of the Vaseline gauze strip, we retrospectively analyzed our data and found no significant differences among these three materials with regard to their ability to reduce synechia formation (8%, 10.5%, and 8.8%, respectively).

Granulation tissue formation is an essential stage during the mucosal healing process after ESS, and assessment of this process can indicate the healing status. Some authors have compared the wound-healing efficacies of absorbable packing and no packing in patients who had undergone ESS. Ksatl et al. performed a study in 26 patients who underwent ESS; these patients were randomized to receive carboxymethylcellulose on one side and no packing on the opposite side. No significant differences were found between the wound-healing outcome measures, including granulation tissue formation, for the two sides.¹² Hu et al.¹³ performed a study to compare the effects of Meropack and no packing in 60 children who had undergone ESS. They did not observe any statistically significant difference in granulation tissue formation. However, none of these studies directly compared the granulation tissue formation observed after packing with absorbable material with that observed after packing with traditional nonabsorbable material. In the present study, we defined excessive granulation tissue formation (>10% of the middle meatus) as one of the outcome variables. We did not consider the cases showing mild granulation tissue formation, because mild granulation tissue was less likely to obstruct the sinus drainage pathway and impede the healing process. We observed excessive granulation tissue formation in the Nasopore packing group at 3–4 weeks after the operation, and this difference disappeared 10–12 weeks after the operation. Compared with the other two nonabsorbable nasal packings, Nasopore is retained in the sinus after operation for a longer period of time. Mucosal irritation by undegraded Nasopore or incorporation of Nasopore into the healing sinus mucosa in the initial postoperative period may be a causative factor for this phenomenon, but further pathological studies are required to confirm this hypothesis. Notably, Maccabee et al.¹⁴ performed trials with a rabbit model and showed that the use of absorbable packing materials, such as FloSeal and MeroGel, was associated with increased incidence of fibrosis of the maxillary sinus mucosa, incorporation of packing materials into the healing mucosa, and infiltration of lymphocytes. They concluded that MeroGel and FloSeal appeared to impair the mucosal healing process. Shoman et al.¹⁵ conducted a study to compare the effects of Nasopore and Meroceol placed in a vinyl glove finger after ESS.¹⁵ They graded the degree of mucosal edema by performing endoscopic examinations. Interestingly, they also found that the mucosal healing in patients receiving Nasopore packing was significantly worse at 4 weeks after the operation, and this difference was not observed at 12 weeks after the operation. Taken together, these findings suggest that Nasopore may be associated with a higher incidence of mucosal swelling

and excessive granulation tissue formation in the first month after ESS; this difference becomes insignificant at 3 months after the operation.

In this study, we observed that the incidence of major postoperative bleeding in the Nasopore group was significantly higher than that in the Merocel or Vaseline gauze groups. In contrast, Shoman et al.¹⁵ compared the postoperative bleeding after packing with Nasopore and Merocel and found no significant difference between the two materials. However, a closer inspection of the methods used in their study reveals that they used a nonvalidated questionnaire (0–10; 0, no bleeding; 10, maximal bleeding) to assess the severity of postoperative bleeding in the first week. In contrast, we used a different perspective on this issue and considered only the cases that showed major bleeding and required readmission or additional packing. We think that this parameter will also have to be considered when choosing the packing material. In our practice, we do not use a bipolar cauterization to control bleeding at the end of surgery; thus, nasal packing materials that exert a significant amount of direct pressure onto bleeders play an important role in hemostasis. Nasopore provides less compression pressure onto mucosa and possibly predisposes to a higher rate of postoperative major nasal bleeding. New nasal packing materials composed of hemostatic agents have been developed and claim to have better efficacy in stopping postoperative bleeding. Baumann and Caversaccio performed a prospective study to compare the efficacies of FloSeal and Merocel after ESS. They calculated the incidence of postoperative nasal bleeding and found no significant difference between FloSeal (1/50) and Merocel (2/50).¹⁶ Pomerantz and Dutton performed a retrospective study and compared the efficacy of platelet gel with that of Merocel. In their study, none of the patients showed postoperative bleeding that required packing.¹⁷ To date, no conclusive evidence has been obtained for an optimal packing material that is superior to all the others with respect to prevention of postoperative bleeding.

Our study had some limitations; the most important limitation was the nonrandomized allocation in the three groups. A nonrandomized design is more prone to show significant imbalances that may reduce the validity of the results. In Taiwan's National Health Insurance system, the insurance plan for patients who undergo ESS covers Vaseline gauze packing but does not cover Merocel and Nasopore packing. We explained the extra costs and differences among the three different packing materials to the patients, and they were allowed to select the ideal packing material according to their budgets and preferences. The three groups appeared to be adequately balanced, because disease severity (which was assessed by both Lund–Mackay CT staging system and polyp grading), gender, and number of revision surgeries were equivalent among the three groups. However, we observed imbalances in age group, microdebrider use, and operator skill levels. Other factors, such as surgical technique and postoperative management regimens, were similar in our department. To ensure the robustness of our conclusions, we used multivariable logistic regression models to confirm our results. We demonstrated that the results obtained from the logistic regression models were consistent with the results obtained

from Chi-squared tests. Notably, 62% of the patients chose the free Vaseline packing after undergoing ESS in our department. The results of our study showed that the ability of this cheap conventional nasal packing material to prevent major postoperative nasal bleeding and the formation of synechiae and excessive granulation tissue is at least equivalent to those of newer materials.

In conclusion, no significant difference was observed in the formation of synechiae in the middle meatus in patients who had received nasal packing with Vaseline gauze, Merocel, or Nasopore after undergoing ESS for rhinosinusitis with or without polyps. Although Nasopore tended to induce excessive granulation tissue formation during the early stages of wound healing, this difference was not observed 10–12 weeks after the operation. Furthermore, Nasopore showed a significantly greater association with bleeding-related admission and additional nasal packing. Overall, the outcome measures in the patients who received Vaseline gauze were equivalent to those in the patients who received Merocel. However, Nasopore was not superior to the two nonabsorbable packing materials in our study.

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