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MAIN ARTICLE

Effect of polyvinyl acetal sponge nasal packing on post-operative care of nasal polyposis patients: a randomised, controlled, partly blinded study

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Abstract

Objective: To compare the effects of routine nasal packing with polyvinyl acetal sponge (Merocel) versus no packing, after endoscopic sinus surgery for nasal polyposis.

Subjects and methods: This clinical, randomised, controlled trial was performed in an academic tertiary referral centre between 2008 and 2011. Sixty patients with resistant nasal polyposis underwent endoscopic sinus surgery, and were then randomly divided into two groups: packed and non-packed. The amount of bleeding and pain in each group during pack removal was documented.

Results: There was no significant difference between the two groups in the outcome of surgery and complications. One patient in each group needed extra packing. In the packed group, the mean ± standard deviation pain score on pack removal was 61 ± 3 (using a visual analogue scale in which 0 = no pain and 100 = worst pain imaginable).

Conclusion: This study found no significant difference between polyvinyl acetal packed and non-packed groups, following endoscopic sinus surgery for nasal polyposis. This confirms the findings of similar studies, and supports the reconsideration of routine post-operative packing in selected cases.

Key words: Nasal Polyps; Postoperative Care; Nasal Cavity; Tampons, Surgical; Paranasal Sinuses

Introduction

Endoscopic sinus surgery has become the standard treatment for refractory sinusitis, including nasal polyposis. However, the optimal method of post-operative care is still under investigation. The surgeon's goals are fine haemostasis at the end of surgery and prevention of haemorrhage and other complications during the post-operative period. Surgeons have used different kinds of packing to achieve these goals, but each has its own shortcomings.

Nasal packing may cause breathing problems, infection, pain and even sleep apnoea.[1–3] Moreover, removal of nasal packs can be very painful and may cause bleeding.[4–6]

Many potential solutions to these problems have been published.[7] Different packing materials have been proposed, including absorbable types, to reduce complications associated with packing.[8–10] However, these new materials are relatively expensive and their long term effects are uncertain.[2,4–6,11,12]

On the other hand, some authors are sceptical about the need for routine use of nasal packing.[2–5,13–15] They claim that adequate haemostasis at the end of surgery eliminates the need for packing, which can then be reserved for patients with post-operative epistaxis or special conditions.

Polyvinyl acetal sponge (Merocel; Medtronic Xomed, Bremen, Germany) is considered a standard type of nasal packing material, and is routinely used as a non-absorbable tampon at the end of surgery in our centre.[11,16,17] Some authors have reported that it has better outcomes, compared with other types of non-absorbable packing.[16]

Therefore, we decided to compare routine Merocel nasal packing versus no packing, following endoscopic sinus surgery in patients with nasal polyposis.

Subjects and methods

Study subjects

Sixty patients referred to a tertiary referral hospital (the Imam Khomeini Medical Center) between April 2008 and March 2011 were enrolled in the study. They suffered from nasal polyposis which was resistant to maximal medical treatment (i.e. one puff of fluticasone nasal spray twice daily plus amoxicillin clavulanic acid 625 mg tablet three times daily, for at least one month).

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We excluded from the study any patients with systemic disease (e.g. hypertension, Wegener's granulomatosis, cystic fibrosis or sarcoidosis), immune suppression, bleeding diathesis or coagulopathy, history of trauma, revision surgery, counter-indications for corticosteroid usage (e.g. diabetes or pregnancy), allergy to polyvinyl acetal sponge, or any septoplasty indications.

All patients completed their follow-up period: there was no loss to follow up.

Ethical approval

The study protocol was approved by the institutional review board of Tehran University of Medical Sciences. Detailed information about the study was given to the participants, and written, informed consent was obtained from each one. All aspects of the study were conducted according to the Declaration of Helsinki.

Surgical procedures and medical treatment

All procedures were conducted using Messerklinger's method of endoscopic surgery. Before surgery, oral antibiotics and methyl prednisolone were administered to all patients for at least one week.

In patients with severe polypoidal change or 'floppy' change of the middle turbinate, partial resection of the middle turbinate was performed using punch cutting forceps and a similar technique. All procedures were performed by one of the senior authors, under general anaesthesia.

Complete homeostasis was achieved using disposable number 10 French suction cautery (Erbe, Tubingen, Germany) and temporary nasal packing with cottonoid pledgets soaked in phenylephedrine 0.5 per cent (Osve, Tehran, Iran) at the end of surgery. All packing was subsequently removed. All patients were hospitalised for at least 24 hours after surgery and were then discharged if there were no problems. After surgery, patients were monitored closely to detect any bleeding; extra packing was used if bleeding was uncontrolled.

Post-operatively, all patients received antibiotic prophylaxis (cephalexin 500 mg capsules (Osve) four times daily for 14 days). The only prescribed analgesic was acetaminophen tablets. All patients continued treatment with the same protocol for rhinosinusitis after surgery, including inhaled nasal corticosteroid twice daily (fluticasone propionate), subject to change depending on endoscopic findings, and nasal saline douches three times daily for at least six months.

Frequent endoscopic debridement was carried out for at least three months after surgery, to induce and maintain a normal cavity.

Tests and outcome evaluation

In addition to demographic data, each patient's duration of sinusitis, history of asthma and aspirin sensitivity were evaluated.

All patients underwent axial and coronal computed tomography scanning before surgery, and scans were categorised by Lund–Mackay score.

Each patient's nasal pain, nasal obstruction and headache were graded using a visual analogue scale (with 0 = no symptoms and 100 = most severe symptoms imaginable), at three time points: before surgery, three to four weeks after surgery, and 12 to 14 weeks after surgery.

Complications (including crusting, synechiae, antrostomy obstruction and lateralisation of the middle turbinate) were evaluated by post-operative nasal endoscopy, at the above-mentioned time points.

The amount of post-operative bleeding was also evaluated, categorised into four grades (0 = no bleeding, 1 = intra-nasal bleeding, 2 = extra-nasal oozing and 3 = severe bleeding requiring extra packing). All evaluations were conducted by one of the authors, using the same method.

Finally, pain severity during pack removal (on the fifth post-operative day) was documented based on the patient's declaration, using a visual analogue scale (with 0 = no pain and 100 = most severe pain imaginable). All packs were removed by one of the authors, using the same method.

The number of awakenings during sleep in the first five days after surgery and the amount of required analgesia were also evaluated.

Blinding and randomisation

Enrolled patients were randomly divided into two groups. The method of randomisation was block randomisation. No packing was used in the first group. In the second group, polyvinyl acetal sponge (Merocel) was placed in the middle meatus at the end of surgery.

Surgeons were blinded to whether their patient was to receive polyvinyl acetal sponge packing or no packing, until the end of surgery. In addition, the author who evaluated the outcome of the surgery in both groups was blinded to whether each patient had received polyvinyl acetal packing or no packing.

Statistical method

Data were analysed using the Statistical Package for the Social Sciences version 11.5 for Windows software program (SPSS Inc, Chicago, Illinois, USA). The chi-square test and *t*-test were used to evaluate pre- and post-operative data. Values were evaluated using descriptive statistical methods (mean ± standard deviation (SD)). Results were considered significant if p values were less than 0.05.

Results

During the study period, 60 patients were enrolled and randomly divided into two similar groups. Their characteristics are summarised in Table I.

There was a statistically significant difference in post-operative bleeding between the two groups

TABLE I
PATIENT CHARACTERISTICS

Variable	Packed	Not packed	*p*
Sex (male/female; *n* (%))	21 (70) / 9 (30)	17 (56.7) / 13 (43.3)	0.239*
Age (mean ± SD; y)	36.1 ± 13	36.2 ± 16	0.994†
Sampter triads	None	None	None
Asthma history (*n* (%))	4 (13.3)	1 (13.3)	0.126*
Sinusitis duration (mean ± SD; y)	4.9 ± 2.6	4.3 ± 2.4	0.779†
Lund–Mackay score (mean ± SD)	16 ± 6	14 ± 7	0.313†

*Chi-square; †*t*-test. SD = standard deviation; y = years

($p = 0.005$, chi-square); however, one patient in each group needed extra packing to control bleeding. The severity of bleeding in each group is shown in Table II.

There were no significant differences between cases and controls as regards nasal obstruction, nasal pain or headache, when assessed pre-operatively, at three to four weeks post-operatively and at 12 to 14 weeks post-operatively. These results are shown in Table III.

On pack removal, the mean pain score in the packed group was 61 ± 3.2.

In the first five days after surgery, only one of the patients in the non-packed group woke from sleep because of pain ($p = 0.31$).

The mean duration of analgesia consumption was 4.1 ± 2.9 days in the packed group and 2.5 ± 1.2 days in the non-packed group ($p = 0.089$).

No major complications were seen in either group. Minor complications were evaluated endoscopically at three to four weeks and 12 to 14 weeks after surgery, and are summarised in Table IV.

All patients underwent endoscopic follow up 26 weeks after surgery. Medical records for this follow up showed that synechiae were found in two patients, one in the packed group and one in the non-packed group. Therefore, the final results did not differ after six months, suggesting stable results thereafter. Moreover, none of the patients needed revision surgery in the follow-up period.

Discussion

Endoscopic sinus surgery has become the standard procedure for sinusitis treatment. However, there is no general agreement regarding the standard post-operative care of these patients. Of the various issues currently debated in this area, packing at the end of surgery is especially controversial.

TABLE II
BLEEDING SEVERITY

Group	Bleeding (pts; *n* (%))			
	None	Intra-nasal	Oozing	Severe*
Packed	20 (66.7)	3 (10)	6 (20)	1 (3.3)
Not packed	2 (3.3)	7 (23.3)	21 (35)	1 (3.3)

*Requiring extra packing. Pts = patients

TABLE III
SYMPTOM SEVERITY OVER TIME

Time point	Symptom	Group	Score (mean ± SD)	*p*
Pre-op	Nasal obstrn	Case	81 ± 17	0.43
		Control	73 ± 30	
	Nasal pain	Case	15 ± 6	0.56
		Control	19 ± 7	
	Headache	Case	40 ± 13	0.45
		Control	33 ± 10	
3–4 wk post-op	Nasal obstrn	Case	26 ± 9	0.29
		Control	19 ± 5	
	Nasal pain	Case	13 ± 9	0.26
		Control	8 ± 4	
	Headache	Case	21 ± 14	0.14
		Control	13 ± 5	
12–14 wk post-op	Nasal obstrn	Case	14 ± 7	0.56
		Control	11 ± 3	
	Nasal pain	Case	4 ± 1	0.25
		Control	2 ± 1	
	Headache	Case	12 ± 6	0.50
		Control	9 ± 5	

SD = standard deviation; Pre-op = pre-operative; obstrn = obstruction; wk = weeks; post-op = post-operative

Over the years, many authors have reported their results for routine use of different packing materials following sinus surgery. Moreover, newer products are continuously being launched on the market, with manufacturers claiming optimal results. However, many authors have found that frequent nasal packing is bothersome, with no significant benefits.[1]

Therefore, we decided to compare two groups of highly selected nasal polyposis patients, one treated with post-operative nasal packing and one without. We found no significant difference in these patients' outcomes and complications, apart from relatively severe pain during pack removal in the packed group (mean visual analogue scale pain score ± SD = 61 ± 3).

Our findings agree with those of similar studies, which are elaborated in the following paragraphs.[1]

Eliashar *et al.* found that packing was not necessary in all patients who underwent endoscopic sinus surgery. They proposed that it was possible to reduce patients' discomfort, and the cost of the procedure, by eliminating nasal packing.[15]

Ji-Hun Mo *et al.* also suggested that packing could be safely used less frequently in cases of routine endoscopic sinus surgery.[4]

TABLE IV
POST-OPERATIVE ENDOSCOPIC FINDINGS

Time point	Finding	Group	Pts (*n* (%))	*p**
3–4 wk post-op	Crusting	Packed	24 (80)	0.128
		Not packed	18 (60)	
	Synechiae	Packed	5 (16.7)	0.246
		Not packed	2 (6.7)	
	Antrost obstrn	Packed	3 (10)	0.97
		Not packed	2 (6.7)	
	Lat of MT	Packed	2 (6.7)	0.116
		Not packed	6 (20)	
12–14 wk post-op	Crusting	Packed	2 (6.7)	0.116
		Not packed	6 (20)	
	Synechiae	Packed	2 (6.7)	0.612
		Not packed	3 (10)	
	Antrost obstrn	Packed	3 (10)	0.97
		Not packed	2 (10)	
	Lat of MT	Packed	0	0.143
		Not packed	2 (6.7)	

*Chi-square. Pts = patients; wk = weeks; post-op = post-operative; Antrost obstrn = antrostomy obstruction; Lat of MT = lateralisation of middle turbinate

Kastl *et al.* found no significant difference between patients treated with no packing and with carboxymethylated cellulose packing.[6]

Orlandi and Lanza studied patients with chronic sinusitis who underwent different types of endoscopic surgery.[2] They concluded that routine tamponade was not necessary in the majority of endoscopic sinus surgery cases.

On the other hand, Bugten *et al.* found an increasing incidence of adhesion in non-packed patients, in a randomised, clinical study.[7] Most adhesions were observed in the middle meatus of the evaluated patients in the non-packed group, and could have been due to lateralisation of the middle turbinate, mucosal abrasion or mucosal inflammation.

In our series, the middle turbinate was partially resected in patients with floppy change, which may have reduced the incidence of adhesions.

Also, there was a significant difference in post-operative bleeding between our two groups; however, this was mostly in the form of oozing which did not require intervention.

- **After endoscopic surgery for nasal polyps, patients received either packing or no packing**
- **Polyvinyl acetal sponge nasal tampons (Merocel) were used**
- **There were no significant differences between the groups, including for post-operative bleeding**

In the aforementioned studies, the final surgical outcome could have been affected by the different types of patients and different types of surgery included, and also by the wide range of adjunctive surgical procedures performed.[2] Our series included only nasal polyposis patients; as a result, our findings can be interpreted more easily and generalised more safely to other patients.

We believe that the possible impact of nasal packing on wound healing, and the pain and discomfort associated with removal of non-absorbable packing, should be considered before their mandatory use in the post-operative care of sinus surgery cases.[14]

This study, like many similar ones, failed to show any significant benefit associated with routine packing after endoscopic sinus surgery. However, we strongly recommend the performance of more in-depth studies to establish a standard protocol for post-operative care following this type of surgery.

Conclusion

This study found no significant difference between patients receiving polyvinyl acetal sponge nasal packing and no packing following endoscopic sinus surgery. This result confirms the findings of similar studies, and supports the reconsideration of routine post-operative packing in selected cases. We believe that functional endoscopic sinus surgery can be performed safely without packing at the end of surgery.

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