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Intranasal Oxidized Cellulose (Surgicel®) Sheet Application after Partial Inferior Turbinectomy, Can It Make A Difference?

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ABSTRACT

Background: hemostasis, throughout and after endonasal surgery, still raise loads of debates as regarding the foremost optimal technique as regard the efficacy, patient comfort, risks and costs.

Objective: assessment of the worth of applying the intranasal surgicel® sheet after partial inferior turbinectomy (PIT) surgery

Patients and Methods: a prospective, randomized comparative study was conducted from July 2015 to July 2018 at Al-Azhar University hospitals. A total of hundred and twenty patients underwent bilateral PIT. They were randomly divided into a pair of groups; group A enclosed sixty patients had PIT with intranasal surgicel® sheet application and group B enclosed sixty patients had PIT without surgicel® sheet. A comparison was made between the two groups at three time points; forty eight hours, one week, and four weeks postoperatively.

Results: at forty eight hours after surgery, number of patients reported milder pain before and after pack removal in group A were significantly higher than patients within the group B. Patients in Group A bled less with shorter hemostasis time than those in group B. At one week postoperatively; visual analogue score (VAS) for pain was significantly less in group A with a better healing. At four weeks postoperatively; healing was significantly better in group A.

Conclusion: the utilization of intranasal surgicel® sheet after PIT can decrease pain and bleeding and lessen hemostasis duration during pack removal and decreased postoperative pain with decreasing rates of intranasal adhesions.

Keywords: Partial inferior turbinectomy, Intranasal pack, Nasal obstruction, Surgicel®.

INTRODUCTION

The nasal turbinate is an organ that regulates the airflow in the nasal cavity and plays a crucial role in respiration. It is part of the nasal valve and plays the foremost important role in the biological activity of the nasal cavity[(1)]. It additionally encompasses a wide mucus membrane for external antigens to access, and it is very vulnerable to inflammation and hyperemia. The turbinate thickens chiefly because of its body structure and additionally due to nasal septal deviation or rhinitis[(2)]. Turbinate hypertrophy result in chronic nasal obstruction, pain and sleep disorder [(3)]. These symptoms in individuals with turbinate hypertrophy impair their quality of life and induce functional disorders[(4)]. Thus, they need to be correctly managed.

When conservative management is not enough to permit a good nasal permeability, surgical management ought to be indicated. Whereas turbinate surgery is frequently practiced, there has been a protracted disagreement over its clinical efficacy and long-term benefit[(1)].

Many of surgical procedures are performed for management of hypertrophic inferior turbinates such as total, partial or submucous turbinectomies, and turbinoplasties, besides alternative procedures like electrocautery, chemocautery, cryosurgery, and laser surface surgery. A recently added is endoscopic shaver turbinectomy and coblation[(2)]. However, the surgery ordinarily practiced in our setup is "bilateral partial inferior turbinectomy". Any surgical procedures performed upon the nasal turbinates are absolute to disrupt with their physiological function. This disruption in addition to postoperative complications are main reasons for the arguable attitudes toward this operation[(3, 4)].

Nowadays, nasal packing is employed as a step of the nasal surgery so as to forestall hemorrhage and to ensure a normal wound healing process. The vary of materials used for these procedures are wide, including removable and absorbable materials. Because there is no standardization in this matter, the selection is within the surgeon's hand, according to his capabilities, beliefs or technical possibilities[(5)].

Hemostasis, throughout and after nasal surgery, still raise loads of debates regarding the foremost appropriate technique as regard the efficacy, patient comfort, risks, benefits and costs. Each endonasal surgical procedure such as septoplasty, rhinoplasty, as well as endoscopic sinus surgery, specifically when combined with turbinectomy and/or submucous resection of the septum, could cause bleeding and/or postoperative hematoma requiring postoperative

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hemostasis[6]. There are no generally accepted standards as regard the materials that ought to be used in nasal packing, duration the packing ought to be left in situ or the indications for nasal packing[7].

Some complications in endonasal surgery are caused by nasal packing; these are the result of exaggerated swelling inflicting an obstruction in endonasal lymph and venous drainage. These complications embody mucosal injury and loss of ciliary function even in absence of surgical incisions, sleep respiratory disturbances[8], decreased arterial oxygen saturation throughout sleep[9], displacement and aspiration of various packing materials, allergy; toxic shock syndrome, eustachian tube dysfunction, and paraffin-induced granuloma. Nasal packs are un-comfortable whereas they are in situ and cause pain and bleeding upon removal[10].

Many different advanced local hemostatic agents are employed in addition to conventional surgical bleeding control methods, including oxidized cellulose (Surgicel®). Surgicel® is applied in one or two layers, absorb water from the application site and expand to provide an artificial clot from forming cellulosic acid. It forms a gel upon contact with blood. Although the mechanism of action has not nevertheless utterly understood, it produces a plug-like layer that may cease the bleeding once it becomes hydrated on the surface of hemorrhagic vascular structures. Histological studies have shown that surgicel® produces no inflammation apart from connective tissue proliferation [11,12].

AIM OF THE STUDY

It is to assess the role of intranasal surgicel® sheet to attain hemostasis, decreasing postoperative pain, and forestall intranasal adhesions after partial inferior turbinectomy.

PATIENTS AND METHODS

Study Design and Population:

The present study is a prospective, double-blinded, randomized, comparative study. It conducted over a period of three years ranging from July 2015 to July 2018 at Otolaryngology, Head and Neck Surgery Department, Al-Azhar University hospitals, Cairo, Egypt. This study involved hundred and twenty cases. These cases were chosen for bilateral partial inferior turbinectomy as they were stricken by inferior turbinate hypertrophy refractory to medical treatment. Patients were divided in two groups (A and B); each group involved sixty patients randomly divided using table of randomization. Group A had bilateral partial turbinectomy with the utilization of intranasal surgicel® sheet and group B had bilateral partial turbinectomy without use of intranasal surgicel® sheet.

For each patient a full medical history was taken with special attention to nasal symptoms (nasal obstruction, nasal discharge, sneezing and snoring).

Nasal examination with nasal endoscope (4 mm diameter; 0° and 30°) was used for assessment of the turbinate size in keeping with **Yanez and Mora**[13] classification; grade **1:** normal sized inferior turbinate fully retracted, grade. **2:** moderate size turbinate engorgement filling half of the nasal cavity not touching nasal septum with nasal obstruction that responds to local decongestant, and grade **3:** inferior turbinate engorgement reaching the nasal septum with nasal obstruction that doesn't respond to local decongestant. Each patient had an axial and coronal computed tomography (CT) for the nose and paranasal sinuses.

Inclusion criteria:

We chose patients with grade 2 or 3 hypertrophy of their turbinates and not responding to medication within the form of three months of local corticosteroids nasal sprays (2 puffs in each nostril once daily), systemic decongestants in the form of pseudoephedrine (45–120 mg every 12 h).

Exclusion criteria:

Any patient with alternative explanation for nasal obstruction was excluded e.g. patients with marked septal deviation undergoing septoplasty, patients with nasal polyposis, antrochoanal polyps or sinonasal tumors and patients with previous nasal operation.

Preoperative Investigation:

All the patients had a complete blood count (CBC), Prothrombin time (PT) and activated partial thromboplastin time (aPTT) to exclude any coagulation disorder, none of the patient were receiving any Non-Steroidal Anti-Inflammatory Drugs or anticoagulants before surgery.

Partial Inferior Turbinectomy Procedure and Postoperative Care:

General anesthesia with orotracheal intubation and the throat was packed in a very customary fashion to prevent trickle down of blood into the hypopharynx. The nose was packed with gauze soaked in a mixture of 4 dimensional xylocaine solution with Xylometazoline prior to the surgery and pack was left for a minimum of 5–7 min. Once packs were removed the inferior turbinates were medialized employing a blunt freer type of elevator and were trimmed by an angled turbinectomy scissors. Resection of mucosa likewise as part of the bone, the extent of resection rely on the

degree of hypertrophy. In both cases the hemostasis was secured by putting ribbon gauze soaked in Xylocaine and Xylometazoline solution. Within the last stages of the procedure, the surgeon was informed whether the patient had been allotted to the intranasal surgicel® sheet or non-intranasal surgicel® sheet group through the method of 4 block randomization. If the patient was enrolled within the intranasal surgicel® sheet group, 2 layers of surgicel® (Ethicon, Somerville, USA) sheets were spread over the bleeding area of medial wall of inferior turbinate. After the surgery, anterior merocel nasal packs in each nasal cavity (8 or 10 cm long, Medtronic, Tallahassee, Florida, USA) were left in situ for 2 days and the intranasal surgicel® sheet were sucked out after 48 hrs.

All the patients received antibiotics post-operatively in the form of cephalosporin (500 mg twice daily) and analgesics in the form of paracetamol (500 mg three times per day) for 7–10 days, and they were instructed to use alkaline nasal douching with sodium bicarbonate for 4 weeks postoperatively.

Postoperative Evaluation:

We evaluated patients postoperatively at three time-points (48 hours, 1 week, and 4 weeks) as regard the postoperative pain, amendment of nasal obstruction and also the degree of intranasal adhesions. During removal of merocel nasal pack, bleeding and time to hemostasis were scored from zero to three by the surgeon. Postoperative pain was analyzed according to visual analogue score (VAS) system[(14)] by asking the patient to score pain from 1–10 and was classified as the following; mild pain: 1–3, moderate pain: 4–7 and severe pain: 8–10. Nasal obstruction conjointly was assessed according to VAS system[(14)] by asking the patient to score the relief of nasal obstruction from 1–10 and was categorized as follows; no improvement: VAS 1–3, partial improvement: VAS 4–7 and complete improvement: VAS 8–10.

Tissue healing was evaluated objectively by the author in all patients by using nasal endoscope (4 mm diameter; 0° and 30°) according to **Lund and Kennedy [(14)]** score; ***good healing***: minimal crustations and no nasal synichae, ***moderate healing***: mild to moderate crustations with mild nasal synichae, and ***poor healing***: delayed mucosal re-epithelization, severe crustations and nasal synichae. It hadn't been tried to divide the preformed intranasal adhesions to assess the natural tissue healing, there have been no variations in methods of postoperative care in the patients of both groups.

Based on the protocol of Al-Azhar University hospitals, patients underwent removal of packing at forty eight hours after surgery. At that time, merocel was removed utterly and degraded sheets of surgical® were sucked out partially. Intranasal crusts in each side were removed cautiously. Then, patients were asked to score from zero (no symptoms) to ten (maximal symptoms) using the visual analog score[(14)] (VAS), concerning degrees of pain before and through removal of the pack. Throughout removal, bleeding and time to hemostasis were scored from zero to three by the surgeon.

Ethical and Approval Considerations:

The study protocol was approved by the local Ethics and Research Committee of Faculty of Medicine, Al-Azhar University. All eligible patients signed consents for participation in the study after full explanation of the study protocol.

Statistical Analysis:

All analyses were done using SPSS software (Version 20.0, Statistical Package for Social Science, Chicago, IL, USA). The level of significance was always set at $P<0.05$. Chi square (χ^2) and Student's *t*-tests were used to get statistical information after data analysis. Descriptive approaches were used to evaluate the age and gender distribution.

RESULTS

Characteristics of Enrolled Patients:

After completion of follow-up; all the patients (120) were eligible for final analysis. Out of them; 48(40%) were males and 72(60%) were females and age range varied from eighteen to forty five years. There had been sixty patients within the surgicel® group (group A) and sixty patients within the non-surgicel® sheet group (group B). In group A, 28(46.7%) patients were males and 32 (53.3%) were females. The mean age was 24.6 years. In group B, 27(54%) patients were males and 23(46%) were females with mean age 27.3 years with no statistically significant differences between the two groups regarding the sex and age distribution. In group A, there have been 27(45%) patients with bilateral hypertrophied turbinates grade 2 and 33(55%) patients with grade 3. In group B, 30(50%) patients had grade 2 of turbinate hypertrophy and 30(50%) patients with grade 3. There was no statistically significant difference relating to the stage of turbinate hypertrophy between the two groups.

Table (**1**) illustrates the preoperative distribution of different nasal symptoms in the both groups. All the differences regarding nasal symptoms were statistically insignificant.

Table (1): Distribution of preoperative nasal symptoms in the 2 patient's groups

Nasal symptoms	Group A (surgicel® sheet group) N=60	Group B (non-surgicel® sheet group) N=60	χ^2* FE**	P-value
Nasal obstruction	60(100%)	60(100%)	---	---
Postnasal discharge	30(50%)	33(55%)	0.13	0.714
Headache	15(25%)	12(20%)	0.19	0.661
Change of smell	3(5%)	3(5%)	**FE**	1.000
Halitosis	3(5%)	3(5%)	**FE**	1.000
Snoring	15(25%)	18(30%)	0.17	0.682

:** Chi-square test, *:** Fisher Exact test

The procedure outcome:

Table (2): Comparison between the 2 groups at 48 hours postoperatively

Variable	Group A (surgicel® sheet group) N=60	Group B (non-surgicel® sheet group) N=60	χ^2* FE**	P-value
	N (%)	N (%)		
Pain before pack removal				
Mild	36(60)	12(20)	18.37	0.000#
Moderate	18(30)	22(36.7)	0.34	0.561
Severe	6(10)	26(43.3)	15.38	0.000#
Pain after pack removal				
Mild	24(40)	8(13.3)	9.59	0.001#
Moderate	22(36.7)	15(25)	1.41	0.235
Severe	14(23.3)	37(61.7)	16.5	0.000#
Bleeding				
No bleeding	12(20)	2(3.3)	6.55	0.01#
Minimal bleeding	38(63.3)	12(20)	21.43	0.000#
Moderate bleeding	8(13.3)	40(66.7)	33.37	0.000#
Severe bleeding (needs packing again)	2(3.3)	6(10)	**FE**	0.272
Hemostasis				
Required time<5 min	50(83.3)	14(23.3)	41.02	0.000#
Required time ≥5 - <10 min	4(6.7)	10(16.7)	2.02	0.155
Required time 10≥ - <20 min	4(6.7)	28(46.7)	22.54	0.000#
Required time≥20 min	2(3.3)	8(13.3)	2.73	0.09
Nasal obstruction				
No improvement	42(70)	39(65)	0.15	0.696
Partial improvement	18(30)	21(35)	0.15	0.696

:** Chi-square test, *:** Fisher Exact test, **#:** Statistically significant difference

At 48 hours after surgery, percent of patients with mild pain before pack removal in the surgicel® sheet group was significantly higher (60%) than patients (20%) in the non-surgicel® sheet group (P=0.000). Also, percent of patients with mild pain after pack removal in the surgicel® sheet group was significantly higher (40%) than patients (13.3%) in the non-surgicel® sheet group (P=0.001). Regarding bleeding, percent's of no and minimal bleeding were significantly higher in the surgicel® sheet group than patients in the non-surgicel® sheet group (P=0.0 and 0.000, respectively). Also, percent of short hemostasis time (<5 min) was significantly (83.3%) higher in the surgicel® sheet group than patients (23.3%) in the non-surgicel® sheet group (P=0.000). Lastly, there was no statistically significant difference between the 2 groups regarding improvement in nasal obstruction (Table **2**).

Table (3): Comparison between the 2 groups at 1 week postoperatively

Variable	Group A (surgicel® sheet group) N=60	Group B (non-surgicel® sheet group) N=60	χ^2* FE**	P-value
	N (%)	N (%)		
Pain				
Mild	18(30)	6(10)	6.3	0.01#
Moderate	36(60)	30(50)	0.84	0.358
Severe	6(10)	24(40)	12.84	0.000#
Nasal obstruction				
No improvement	0(0)	0(0)	---	---
Partial improvement	30(50)	33(55)	0.13	0.714
Complete improvement	30(50)	27(45)	0.13	0.714
Healing				
Good	42(70)	12(20)	28.32	0.000#
Moderate	15(25)	42(70)	22.59	0.000#
Poor	3(5)	6(10)	**FE**	0.49

***:** Chi-square test, ***:** Fisher Exact test, **#:** Statistically significant difference

After one week postoperatively, the comparison of postoperative pain revealed that there was 30% of patients with mild pain in group Acomparedwith10% of patients in group B with a statistically significant difference (P=0.01). Also, there was 10% of patients with severe pain in group Acomparedwith40%ofpatients in group B with a statistically significant difference (P=0.000). On the other hand, there was no significant difference as regard partial and complete improvement of nasal obstruction (P=0.714). Regarding the intranasal adhesions; in group A there was 70% of patients had good healing and 25% of patients had moderate healing compared with 20% of patients had good healing and70% of patients had moderate healing in group B. The differences between the 2 groups was statistically significant differences (P=0.000 for each of them) **(**Table **3)**.

Table (4): Comparison between the 2 groups at 4 weeks postoperatively

Variable	Group A (surgicel® sheet group) N=60	Group B (non-surgicel® sheet group) N=60	χ^2	P-value
	N (%)	N (%)		
Pain				
Mild	2 (40)	42(70)	9.73	0.001#
Moderate	36(60)	18(30)	9.73	0.001#
Severe	0(0)	0(0)	---	---
Nasal obstruction				
No improvement	0(0)	0(0)	---	---
Partial improvement	18(30)	24(40)	0.92	0.338
Complete improvement	42(70)	36(60)	0.92	0.338
Healing				
Good	48(80)	33(55)	7.45	0.006#
Moderate	9(15)	18(30)	3.06	0.08
Poor	3(5)	9(15)	2.31	0.128

***:** Chi-square test, **#:** Statistically significant difference

After 4 weeks postoperatively, we revealed that 40% of patients had mild pain in group A compared to 70% of patients in group B with a statistically significant difference (P=0.001). Also, 60% of patients had moderate pain in group A compared to30% of patients in group B with a statistically significant difference (P=0.001). Regarding the intranasal adhesions, there was 48(80%) patients had good healing in group A and 33(55%) patients had good healing in group B with better healing in group A and with statistically significant difference (P=0.006) **(**Table **4)**.

DISCUSSION

Nasal obstruction as a subsequent of enlarged inferior turbinates is a common presentation in Otorhinolaryngology. The inferior turbinates hypertrophy may be due to many various causes as well as allergy, vasomotor rhinitis or drug-induced rhinitis[15,16]. Mucosal swelling of the inferior turbinates is an element of the physiologic vascular changes that occur throughout the normal nasal cycle. Infection, hyper-reactivity, and allergy could enhance these changes. Enlargement of the inferior turbinates can occur secondary to either an enlargement of the osseous or mucosal component of the turbinate[17]. Surgical reduction of inferior turbinate is commonly performed in patients after failed medical treatment of the turbinate hypertrophy. This reduction can be performed by different techniques that resect, displace or literally minimize the volume of the turbinate[15]. The aim of surgery are to increase the nasal airway, to preserve the mucosal integrity and to decrease the chance of the complications. One of the main risks of surgery is hemorrhage; patients with coagulopathies are specifically at exaggerated risk of complication[18]. The surgery of the inferior turbinate reduction has been modified and enhanced within the previous few years[19]. These changes are essential to attain better outcome within the post-surgical period, as well as make the surgery less painful and annoying to the patients.

The use of intranasal packing after turbinate surgery is vital, in study done by **Velasco *et al.*[20]** it had been ascertained that the post-surgical bleeding degree of the patients group submitted to bilateral partial inferior turbinectomy who used the nasal pack was not up to the group not using a pack, However the utilization of nasal packs carry loads of complications chiefly the tissue injury. In study done by **Shaw *et al.*[21]** on mucosa of nasal cavity of sheep reported that the utilization of nasal packs resulted in a significant loss of the ciliated surface of the mucosa in comparison with the control group and they attributed the formation of nasal synichae postoperatively thanks the loss of the normal mucosa.

Intranasal splints are usually used after nasal septal surgery for prevention of intranasal synichae and support of central septal position. However, the role of surgicel® sheet in turbinate reduction surgery acting as hemostatic and separating material between medial surface of the turbinate and septum was not rumored within the literature before to best of our knowledge.

Currently, different hemostatic agents have been utilized in the management of nasal bleeding. For instance, surgicel® (oxidized regenerated cellulose) and FloSeal have showed success in promoting clot stabilization[22].

Oxidized regenerated cellulose (Surgicel Nu-knit, Ethicon Inc, USA) has been enclosed in several studies for its effects on hemostasis after endoscopic sinus surgery. In this regard, in study done by **Shinkwin *et al.*[23]**, which was a randomized, prospective trial that enclosed sixty patients, comparing Surgicel Nu-knit (placed in one nostril) with Vaseline ribbon gauze and merocel packs (randomized within the comtralateral nostril). Twenty-four hours, patients were asked postoperatively to assess the discomfort reported in either side of the nose whereas the packs were in position and upon its removal. The duration and estimated amount of bleeding following packs removal were additionally assessed and concluded that surgicel Nu-knit caused less significant discomfort each whereas in position and on removal than Vaseline gauze.

Another study published by **Bhatnagar and Berr[11]** ended that the advantage of surgicel® sheet packing in the management of recurrent posterior epistaxis; eight patients with posterior epistaxis years were managed by selectively packing only the bleeding site with surgicel®. Following successful treatment, the patients' average duration of hospital stay was less than twenty four hours compared to an average hospital stay following conventional packing of 3.25 days and patients reported no pain.

In 2019, another updates published by **Sözen *et al.*[24]** who conducted a retrospective observational study to evaluate the effectiveness and tolerability of surgicel® application with transseptal suturing in epistaxis, and comparing it with anterior nasal packing and they ended that surgicel® application with transseptal suturing ought to be considered an alternative management in nasal packing, in cases of anterior septal epistaxis. In the current study, Patients were assessed three time-points to score the pain, amount of bleeding and hemostasis throughout the nasal pack removal and the postoperative pain and also the degree of mucosal healing and adhesion formation in both groups of patients had bilateral partial inferior turbinectomy. Within the present study it had been clear that the utilization of intranasal surgicel® sheet application resulted in significant reduction of nasal pain throughout the first week of postoperative follow-up, these results mismatched the results of published studies that found patients who had septoplasty (group with intranasal splints and another group without splints) with inferior turbinectomy or not, experienced a similar degree of pain among the primary forty eight hours, however at one week the mean pain score was higher in the splint group[25,26]. However, in study done

by **Jung *et al.*** [27] it had been rumored that at one week, the nasal discomfort score was not significantly completely different on the splint and non-splint sides deeming the results of the current study. Within the early postoperative period, mucosal swelling of the nasal cavity and crust formation can be causes of nasal discomfort.

The use of surgicel® sheet, that separates the medial surface of the inferior turbinate and nasal septum acts as a splint within the current study resulted in a significant decrease in the degree of intranasal adhesions formation after partial turbinectomy surgery that maintained all over the first postoperative month. These results match the results addressing the utilization of splints after septoplasty with or without turbinectomy. In study done by **Malki *et al.*** [26], which used cut Silastic splints, and located at half-dozen weeks, 1.8% of the splint group had intranasal adhesions compared to 7.7% of the no-splint group, however this distinction was not significant. In study done by **von Schoenberg *et al.*** [28] it had been found the very best incidence of intranasal adhesions occurred in patients who had surgery at the same time on each of the septum and the lateral nasal wall, of these, 31.6% of the no-splint group had adhesions at one week compared to 3.6% in the splint group and at 3 months, both groups solely had one patient each with adhesions under topical anesthesia as part of routine postoperative nasal toilet, therefore the results of this study emphasized that the role of surgicel® in minimizing nasal adhesions maybe comparable to the role of nasal splints.

The results of the present study may be attributed to the fact that nasal packing either as a preliminary before the operative steps, frequent suctioning with sharp suction tips and nasal packs at the end of the operation would end up in minor trauma to the nasal septal mucosa and loss of ciliated epithelium that promote the postoperative adhesions and will have an effect on the procedure outcome. It had been additionally clear from the result of this study that the degree of intranasal adhesions decreased by the time and this might be viewed according to **Paul *et al.*** [29]; they showed the importance of using alkaline nasal douching in promoting mucosal re-epithelization and healing.

CONCLUSION AND RECOMMENDATION

It can be concluded that the use of intranasal surgicel® sheet application after partial inferior turbinectomy without septal surgery can cause decreased bleeding and cut back the duration of hemostasis additionally, decrease postoperative pain in the short term follow-up period with significant evidence of decreasing rates of intranasal adhesions, which mimics the role of intranasal splints. The current study can open a new era for further research. So, more studies on large number of patients with longer periods of follow up regarding the role of intranasal surgicel® sheet application in turbinate surgery ought to be conducted.

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