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Original Article

Ear,Nose and Throat Section

Comparison of the Efficacy of Ivalon® Nasal Pack and Ribbon Gauze Pack Following Nasal Surgeries- A Randomised Clinical Trial

K GOWTHAME[1], S PRABAKARAN[2], RB NAMASIVAYA NAVIN[3], KARTHIKA RANGANATHAN[4]

ABSTRACT

Introduction: Nasal bleeding is one of the Ear, Nose and Throat (ENT) emergencies which are usually managed by the Hippocratic maneuver. Anterior nasal packing is unavoidable after nasal surgeries and refractory anterior nasal bleeding. There are wide variety of newer nasal packs available and easily acceptable by the patients. The most commonly used nasal packs in day to day practices are Ivalon® and vaseline soaked ribbon gauze pack.

Aim: To compare the difference between Ivalon® nasal pack with a traditional ribbon gauze pack in terms of efficacy, feasibility, patient comfort, cost and need for repacking postremoval in patients undergoing nasal surgeries.

Materials and Methods: This randomised clinical trial involved 144 patients who required nasal packing after nasal surgeries, like septoplasty, Functional Endoscopic Sinus Surgery (FESS) and nasal bone fracture reduction in the Department of ENT, Head and Neck surgery at a Tertiary Care Centre, Chennai, India. Patients were categorised into two groups- Ribbon gauze group and Ivalon® group. The patient's comfort was quantified based on nasal discharge, pain on removing the pack, stuffiness of the nose, and irritability were compared. After pack removal, mucosal oedema, congestion, and synechiae formation were assessed by using a diagnostic nasal endoscopy after 1 week.

Results: Out of 144 patients, in Ivalon® group, 37 (51.4%) were males and 35 (48.6%) were females. The incidence of nasal symptoms with nasal surgery i.e nasal discharge was significantly higher in the ribbon gauze packing group (68.1%) compared to Ivalon® pack (31.9%) (p-value=0.044). Pain on pack removal was also more in the former (76.4%) compared to Ivalon® group (23.6%) which were statistically significant (p-value=0.005). Pain on pack removal was significantly more in the former (76.4%) compared to Ivalon® group (23.6%). Other symptoms like anxiety, discomfort, stuffiness, local irritation, and congestion were lesser in the Ivalon® group. Mucosal oedema was higher in ribbon gauze group (59.7%) compared to Ivalon® pack (40.3%) which was statistically significant (p-value= 0.019).

Conclusion: As a postnasal surgery pack, Ivalon® pack is a better option due to less pain, anxiety, stuffiness, local irritation, congestion, synechiae formation and gives better comfort when compared to the ribbon gauze packs.

Keywords: Anterior nasal packing, Pain, Repacking, Septoplasty, Synechiae

INTRODUCTION

Epistaxis ('nasal bleeding'in Greek) is one of the most alarming symptoms and emergency situation which are being managed in the field of Otorhinolaryngology. Most nasal bleeds are managed by the Hippocratic maneuver [1].The initial conservative management is applying digital pressure, compression with ice, or cautery of the bleeding vessel [2]. Hippocrates (5th century BC) found that the effective measure for control of nasal bleeding is to apply the pressure over the alae nasi [3]. However, few cases of anterior nasal bleed and all postoperative nasal surgeries like septoplasty, Functional Endoscopic Sinus Surgeries (FESS), and nasal bone fracture reduction, nasal packs are used to control anterior nasal bleeding [4]. Nasal packing is useful in the prevention of postoperative complications like bleeding, septal haematoma or synechiae formation, approximation of mucoperichondrial flap, and stabilisation of septal cartilage [5]. These nasal packs also improve the healing of nasal mucosa, avoidance of mucosal adhesion, and re-establish normal mucociliary clearance after sinus surgery [6]. Easy insertion and removal, less pain and discomfort are the characteristics of an ideal nasal pack [6]. The advantage of postsurgery nasal packing is to give the tamponade effect to prevent the complications of surgery [2].

There are wide variety of nasal packs available worldwide. The removable nasal packs include ribbon gauze coated with either vaseline or antibiotic cream, custom-made glove pack, merocel or Ivalon® pack, and now-a-days biodegradable materials are available [6]. The conventional nasal packing is ribbon gauze coated with vaseline or antibiotic cream, but the patient experiences pain and discomfort during insertion and removal. Absorbable materials are gel foam, oxicel, or surgicel [7]. Pain during insertion and removal, discomfort, mouth breathing, dry mouth, reduced sleep, and anxiety are the commonly reported problems after packing [8].There are newer packs, foam type injected into the nasal cavity which dissolve after 24-48 hours with the effect of hemostasis, good healing and prevention of adhesion [9,10]. Surgicel is also used for postoperative nasal packing-which is oxidised regenerated cellulose and procoagulative causes platelet aggregation and activates clotting mechanism [11]. Few patients stated the most painful experience in their lifetime is nasal pack removal [12]. Recently some surgeons avoid nasal packing after minor nasal surgeries.

Merocel or Ivalon® pack material is the most commonly used, which is made of cross-linked polyvinyl alcohol [6]. It is a foam-type non absorbable material that improves platelet aggregation and prevents bacteria or fungal growth [13]. The expandable nasal tampons are available in three sizes: 6 cm, 8 cm, and 10 cm, 8 cm is used for anterior nasal packing and 10 cm is for posterior nasal packing [14]. The advantage of Ivalon® pack is its easy insertion, less pain and discomfort for the patient and effectively control the bleeding. The disadvantage is chances of repacking after removal and expensive (Rs.375/-) compared to ribbon gauze (Rs.50/-).

The significance of the current study is the comparison of both conventional vaseline soaked ribbon gauze and Ivalon® nasal

pack exclusively in patients undergoing major nasal surgeries. This study comprehensively assessed parameters like anxiety, comfort, pain, stuffiness, local irritation, chances of repacking during and immediately after pack removal and congestion, synechiae, and mucosal oedema were assessed endoscopically. The present study aimed to compare the difference between Ivalon® nasal packs with a traditional ribbon gauze pack in terms of efficacy, feasibility, patient comfort, cost and need for repacking postremoval in patients undergoing nasal surgeries. Primary outcome variable was patient comfort, and secondary outcome variables were efficacy, feasibility, cost, and need for repacking.

MATERIALS AND METHODS

This randomised clinical trial included a total of 144 patients who underwent nasal surgeries in the Department of ENT, Head and Neck surgery at a Tertiary Care Centre, Chennai, Tamil Nadu, India. This study was conducted from May, 2021 to April 2022, after getting approval from the Ethical Committee (Proposal No. 158/IHEC/March 2021) and informed consent were obtained.

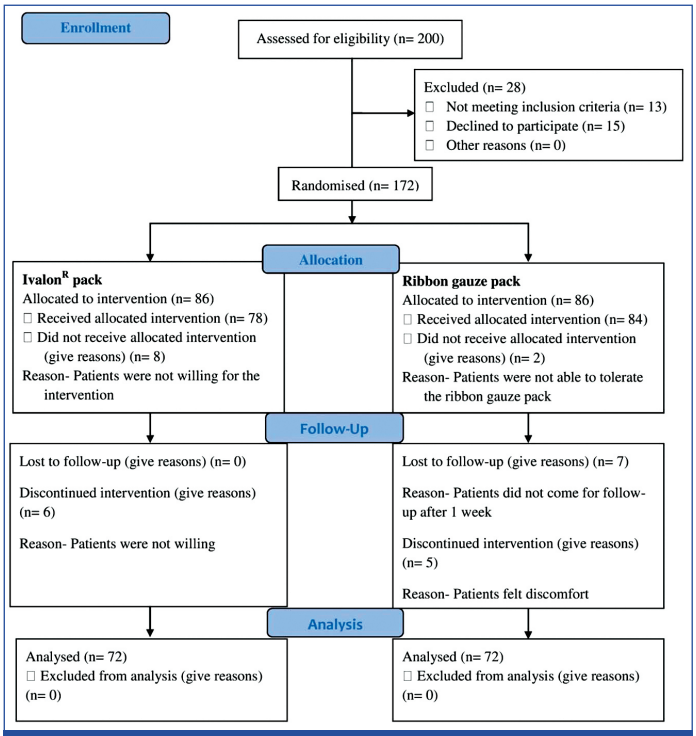
Inclusion criteria: Patients of any age group, both the sex, and patients who underwent transnasal surgeries like septoplasty, FESS, and nasal bone fracture reduction were included in this study.

Exclusion criteria: Patients having a postnasal bleed, any nasal or paranasal mass, anterior nasal bleeding due to causes other than surgeries, and patients who are not willing for the study were excluded from this study.

Sample size calculation: It is determined from discomfort score during pack removal by Mamta S et al., with mean scores of 3.6 and 4.65 in two groups [15]. With 95% confidence interval and 80% power the sample size is calculated using OpenEpi Software and a sample size of 72 was arrived in each group.

Procedure

All patients were evaluated preoperatively using Computed Tomography Paranasal Sinuses (CT-PNS) to know which of the sinuses were involved and scoring was done using the Lund-Mackay score for chronic rhinosinusitis [16]. All the patients were randomised into two groups by block method of randomisation. After nasal surgery, one group was packed with Ivalon® nasal pack and other group with ribbon gauze pack by the surgeon [Table/Fig-1,2].



[Table/Fig-1]: CONSORT flow chart.

[Table/Fig-2]: Anterior nasal packing with Ivalon® nasal pack.

After the nasal surgical procedure, when the patient was under general anaesthesia, ribbon gauze was packed. It was soaked with vaseline. Then, using Tilley's forceps and nasal speculum, the gauze was packed in both the nasal cavities in a step ladder pattern from floor to the roof of the nasal cavity. Another group of patients were packed with Ivalon® nasal pack along the floor of nasal cavity in septoplasty and nasal bone fracture reduction, and between middle turbinate and lateral nasal wall in case of FESS. Ivalon® pack was injected with saline to keep it in position.

The anterior nasal pack was removed on the first postoperative day. Nasal discharge, pain on removing the pack, stuffiness of the nose, and irritability were analysed. The pain was analysed by a visual analog scale. Anxiety, discomfort, stuffiness, and local irritation were recorded. Score 1 was given if each of the symptoms was present and score 0 if asymptomatic. After pack removal, mucosal oedema, congestion, and synechiae formation were assessed by diagnostic nasal endoscopy after 1 week by the investigator.

STATISTICAL ANALYSIS

Statistical analysis was carried out using Statistical Package for the Social Sciences (SPSS) version 21.0 and Microsoft Excel software. The means and proportions were used. The association between two groups were assessed by Chi-square test. The statistical significance was considered when p-value <0.05.

RESULTS

In both the groups males constituted majority while, the mean age was similar.

Variables	Ivalon® pack (n,%)	Ribbon gauze (n,%)
Age (in years)		
18-30	20 (27.8 %)	14 (19.4%)
31-40	20 (27.8%)	23 (31.9%)
41-50	17 (23.6%)	19 (26.5%)
51-60	12 (16.7%)	14 (19.4%)
61 and above	3 (4.1%)	2 (2.8%)
Mean±SD	38.74±12.16	36.2±11.14
Gender		
Male	37 (51.4%)	39 (54.2%)
Female	35 (48.6%)	33 (45.8%)

[Table/Fig-3]: Distribution of age and gender (N=72).

Based on the Lund-Mackay scoring, majority of the patients had a score of less than 5 (61.1%) in Ivalon® group and underwent septoplasty (43.1%) [Table/Fig-4] [15,16].

After nasal packing, 23 (31.9%) patients complained about nasal discharge on the Ivalon® pack group and 49 (68.1%) patients complained on the ribbon gauze group (p-value=0.01). In the Ivalon® group, 17 (23.6%) patients experienced pain during pack removal whereas, 55 (76.4%) patients had pain on removal in the ribbon gauze group (p-value=0.01).

Parameters	Ivalon® pack n (%)	Ribbon gauze n (%)
Lund- Mackay CT score (N=72)		
<5	44 (61.1%)	41 (56.9%)
≥5	28 (38.9%)	31 (43.1%)
Surgery done		
Septoplasty	31 (43.1%)	31 (43.1%)
Functional endoscopic sinus surgery	27 (37.5%)	27 (37.5%)
Nasal bone fracture reduction	14 (19.4%)	14 (19.4%)

[Table/Fig-4]: Lund- Mackay CT score and type of nasal surgeries.

In the Ivalon® group anxiety was seen in 20 (27.8%), comfort in 57 (79.2%), stuffiness in 32 (44.5%), local irritation in 34 (47.2%), and the chance of repacking in 2 (2.8%) patients. In the ribbon gauze group, anxiety was seen in 52 (72.2%), comfort in 15 (20.8%), stuffiness in 40 (55.6%), local irritation in 38 (52.8%) patients [Table/Fig-5]. The pain on removal was analysed by visual analog scale in which majority of patients belonged to scale 0 (55) and 1 (9) on Ivalon® group and scale 3 (26) and 4 (23) on ribbon gauze group [Table/Fig-6].

Symptoms	Ivalon® pack (n=72)	Ribbon gauze (n=72)	p-value
Nasal discharge	23 (31.9%)	49 (68.1%)	<0.01
Anxiety	20 (27.8%)	52 (72.2%)	<0.01
Comfort	57 (79.2%)	15 (20.8%)	<0.01
Pain on removal	17 (23.6%)	55 (76.4%)	<0.01
Stuffiness	32 (44.5%)	40 (55.6%)	0.18
Local irritation	34 (47.2%)	38 (52.8%)	0.50
Repacking	2 (2.8%)	0 (0%)	NA

[Table/Fig-5]: Nasal symptoms after packing.
p-value <0.05 was considered to be significant

Groups	Scale 0 No pain	Scale 1 Just noticeable	Scale 2 Mild pain	Scale 3 Uncomfortable pain	Scale 4 Annoying pain	Mean score	p-value
Ivalon® R pack (n,%)	55 (76.39%)	9 (12.5%)	5 (6.94%)	2 (2.78%)	1 (1.39%)	0.4	<0.01
Ribbon gauze pack (n,%)	17 (23.61%)	2 (2.78%)	4 (5.56%)	26 (36.11%)	23 (31.94%)	2.5	

[Table/Fig-6]: Pain assessment (Visual Analog Scale) (N=72).
*Chi-square test applied; p-value <0.05 was considered to be significant

The patients were assessed using nasal endoscopy after one week and showed mucosal oedema [Table/Fig-7] in 29 (40.3%) patients, congestion [Table/Fig-8] in 31 (43.1%) patients, and synechiae formation [Table/Fig-9] in 33 (45.8%) patients on the Ivalon® pack group. On the ribbon gauze group, the mucosal oedema was seen in 43 (59.7%) patients, congestion in 41 (56.9%) patients and synechiae formation in 39 (54.2%) patients [Table/Fig-10]. All these symptoms and endoscopic findings were evaluated and found independent of nasal surgeries like septoplasty, FESS, and nasal bone fracture reduction [Table/Fig-11,12]. Patient's comfort postoperative FESS, septoplasty, nasal bone fracture reduction are mentioned in [Table/Fig-11]. In FESS the normal mucociliary mechanism and the mucosa

[Table/Fig-7]: Showing mucosal oedema on Ivalon® group and on Ribbon gauze group (Left to Right).

[Table/Fig-8]: First image showing congestion on Ivalon® group and second image on Ribbon gauze group.

[Table/Fig-9]: First image showing synechiae on Ivalon® group and second image on Ribbon gauze group.

Nasal endoscopy finding	Ivalon® pack (n,%)	Ribbon gauze (n,%)	p-value
Mucosal oedema	29 (40.3%)	43 (59.7%)	0.019
Congestion	31 (43.1%)	41 (56.9%)	0.095
Synechiae	33 (45.8%)	39 (54.2%)	0.317

[Table/Fig-10]: Nasal endoscopy finding after 1 week (N=72).

Symptoms	Septoplasty	Functional endoscopic sinus surgery	Nasal bone fracture reduction	p-value
Nasal discharge				
Ivalon® pack	14 (45.16%)	4 (14.81%)	5 (35.71%)	0.044
Ribbon gauze	17 (54.84%)	23 (85.19%)	9 (64.29%)	
Anxiety				
Ivalon® pack	7 (22.58%)	8 (29.63%)	5 (35.71%)	0.636
Ribbon gauze	24 (77.42%)	19 (70.37%)	9 (64.29%)	
Comfort				
Ivalon® pack	27 (87.1%)	20 (74.07%)	10 (71.43%)	0.347
Ribbon gauze	4 (12.9%)	7 (25.93%)	4 (28.57%)	
Pain on removal				
Ivalon® pack	3 (9.68%)	12 (44.44%)	2 (14.29%)	0.005
Ribbon gauze	28 (90.32%)	15 (55.56%)	12 (85.71%)	
Stuffiness				
Ivalon® pack	14 (45.16%)	12 (44.44%)	6 (42.86%)	0.989
Ribbon gauze	17 (54.84%)	15 (55.56%)	8 (57.14%)	
Local irritation				
Ivalon® pack	15 (48.39%)	13 (48.15%)	6 (42.86%)	0.935
Ribbon gauze	16 (51.61%)	14 (51.85%)	8 (57.14%)	
Repacking				
Ivalon® pack	1 (3.23%)	1 (3.7%)	0	NA
Ribbon gauze	0	0	0	

[Table/Fig-11]: Relationship between the type of surgery and symptoms.
p-value <0.05 was considered to be significant

is preserved as much as possible. Even though matching was not done, the prevalence of synechiae was more in nasal bone fracture reduction (57.14%) than FESS (55.56%) and septoplasty (51.61%) in ribbon gauze group. However, all these were statistically insignificant [Table/Fig-12]. Pain on pack removal was more in septoplasty patients with ribbon gauze (90.32%) than FESS (55.56%) and nasal bone fracture reduction (85.71%) patients with ribbon gauze [Table/Fig-11]. This study was done to assess and compare efficacy between Ivalon® and Ribbon gauze nasal pack in various nasal surgeries. It did not compare the symptoms and complications between nasal surgeries, hence the best surgery can not be commented upon.

Symptoms	Septoplasty	Functional endoscopic sinus surgery	Nasal bone fracture reduction	p-value
Mucosal oedema				
Ivalon® pack	13 (41.94%)	10 (37.04%)	6 (42.86%)	0.896
Ribbon gauze	18 (58.06%)	17 (62.96%)	8 (57.14%)	
Congestion				
Ivalon® pack	14 (45.16%)	13 (48.15%)	4 (28.57%)	0.463
Ribbon gauze	17 (54.84%)	14 (51.85%)	10 (71.43%)	
Synechiae				
Ivalon® pack	15 (48.39%)	12 (44.44%)	6 (42.86%)	0.926
Ribbon gauze	16 (51.61%)	15 (55.56%)	8 (57.14%)	

[Table/Fig-12]: Relationship between the type of surgery and nasal endoscopic finding after 1 week.

DISCUSSION

Nasal bleeding is a common symptom that affects all the age groups with an incidence of 5-10% per year [1]. Nasal surgeries usually requires nasal packing to control the bleeding. Ribbon gauze soaked with vaseline or antibiotic cream and Ivalon® nasal pack are most commonly used nasal packs in the recent days. The current study was aimed to compare the difference between Ivalon® nasal packs with a traditional ribbon gauze pack in terms of efficacy, feasibility, patient comfort, cost and need for repacking post removal in patients undergoing nasal surgeries.

In this study, the incidence of nasal discharge (p=0.044) was significantly higher due to ribbon gauze packing (68.1%) compared to Ivalon® pack (31.9%) and pain on pack removal (p=0.005) also more in ribbon gauze side (76.4%) than Ivalon® pack (23.6) which were statistically significant. Other symptoms like anxiety and discomfort are lesser in Ivalon® pack compared to ribbon gauze but not statistically significant. Stuffiness, local irritation, mucosal oedema, and congestion due to Ivalon® pack is as the same as ribbon gauze. But the chance of repacking after removal is slightly higher in the Ivalon® pack. There is less chance of synechiae formation in the Ivalon® pack. Every patient experiences or perceives varied pain thresholds.

Shanmugam D compared the effectiveness of the conventional nasal pack with the Meroce® nasal pack and found that later to be a favorable technique in terms of easy insertion, lesser insertion time, and short learning curve. But the conventional pack had less chance of repacking [1]. This study compared the conventional pack with Meroce®/ Ivalon® in different patients with epistaxis but the current study compared both the ribbon gauze pack and Ivalon® pack in patients who underwent nasal surgeries.

Mohan A et al., compared the conventional framycetin ribbon packs with nasal tampons and found that both packs are equally effective in the control of postoperative bleeding and tampon were more comfortable among the patients. No difference in crusting and adhesions in the two packs. Less pain, less trauma, and less congestion and pain are seen in nasal tampons [4]. The current study compared vaseline-soaked gauze pack with Ivalon® pack and concluded that there was less chance of nasal discharge, discomfort, anxiety, congestion, mucosal oedema, and synechiae in the Ivalon® nasal pack.

Alam MJ et al., compared the conventional anterior nasal pack with the modified ventilated nasal pack in terms of anxiety and concluded that ventilated nasal pack causes less anxiety than conventional nasal packs [8]. In the current study, Ivalon® nasal pack caused less anxiety compared to vaseline-soaked gauze pack.

Thomas I et al., conducted a study on using a sponge for postoperative nasal packing and concluded that commonly available and commercially-prepared sponge was as good as Meroce® in terms of efficacy in hemostasis, less mucosal trauma, less pain during removal, and may be used in developing countries to reduce the cost [6]. The current study results showed Ivalon® nasal pack caused less mucosal oedema, less pain on removal but expensive and chances of repacking was high compared to ribbon gauze pack.

Dutta S et al., studied the modified technique of anterior nasal packing and found that aluminium foil from the cover of suture material was very useful, cost-effective, and also reduces complications like synechiae formation, reducing mucosal injury and less chance of re-bleeding after packing [2]. In the current study, Ivalon® nasal pack was expensive and the high chances of rebleeding after removal but causes less synechiae formation and mucosal injury.

Watson MG et al., compared three packs, pneumatic balloon pack, paraffin ribbon gauze, and polythene glove packs, and found paraffin pack was more uncomfortable for the patients and the pneumatic balloon is easy to insert and comfortable but causes adhesion and crusting [17]. In this study, Ivalon® nasal pack was easy to insert and more comfortable and acceptable to the patient compared to ribbon gauze pack.

These are the most commonly used packs in other similar studies. The novelty of this study was to compare the efficacy of Ivalon® and ribbon gauze in the patients who are exclusively undergoing nasal surgeries and it comprehensively assessed parameters like anxiety, comfort, pain, stuffiness, local irritation, chances of repacking during and immediately after pack removal and congestion, synechiae, mucosal oedema were assessed endoscopically.

Limitation(s)

Pain perception is subjective. Hence, pain scores could not be quantified better. Immunological and tissue reaction to nasal packs would be different for each individual. Patient's acceptability and comfort level at the time of nasal packing was not assessed as all the patients were packed under general anaesthesia.

CONCLUSION(S)

In the developing world, newly available packs are equally as efficacious as traditional packs and better accepted by patients. This study compared the efficacy of Ivalon® pack and conventional ribbon gauze following nasal surgeries. There is less chance of nasal discharge, discomfort, anxiety, congestion, mucosal oedema, and synechiae in the Ivalon® nasal pack. The disadvantage is the incidence of repacking and its cost. Ivalon® pack is acceptable to the patients due to less pain, anxiety, short learning time and provides better comfort when compared to the ribbon gauze.

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PARTICULARS OF CONTRIBUTORS:
1. Senior Resident, Department of Otorhinolaryngology, Chettinad Academy of Research and Education, Chettinad Hospital and Research Institute, Chennai, Tamil Nadu, India.
2. Associate Professor, Department of Otorhinolaryngology, Chettinad Academy of Research and Education, Chettinad Hospital and Research Institute, Chennai, Tamil Nadu, India.
3. Assistant Professor, Department of Otorhinolaryngology, Chettinad Academy of Research and Education, Chettinad Hospital and Research Institute, Chennai, Tamil Nadu, India.
4. Junior Resident, Department of Otorhinolaryngology, Chettinad Academy of Research and Education, Chettinad Hospital and Research Institute, Chennai, Tamil Nadu, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. RB Namasivaya Navin,
Assistant Professor, Department of Otorhinolaryngology, Chettinad Academy of Research and Education, Chettinad Hospital and Research Institute,
Chennai, Tamil Nadu, India.
E-mail: navin.rajasekar@gmail.com

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