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Assessment of Hemostatic Efficacy of Feracrylum in Endonasal Surgical Interventions: A Randomized Controlled Study

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ABSTRACT

Background: Endoscopic nasal surgery, a minimally invasive technique, often requires nasal packing to manage bleeding and prevent complications. This study aimed to evaluate Feracrylum's coagulation, antimicrobial, and hygroscopic efficacy in mitigating the drawbacks of nasal packing.

Methods: A randomised controlled study included participants undergoing endonasal surgeries. Group A received topical Feracrylum, while Group B served as the control. On pack removal day, patients were assessed for nasal pack soakage, dressing changes, pain, and the need for tranexamic acid. On postoperative day 7, nasal cavities were examined for crusting and signs of infection. Adhesions and nasal mucosa condition were assessed on postoperative day 14.

Results: The age distribution of the total 40 participants was balanced across the two groups, with 29 (72.5%) patients falling into the second decade of life. In group A, 5 (25%) patients dressings were soaked, compared to 12 (60%) in group B (p=0.05). No dressing changes were needed in group A. Group A showed fewer bleeding and pain scores during pack removal compared to group B (p<0.001). There were significant differences in post-operative day 7 evaluation between the groups, whereas adhesions were less frequent in group A than in group B during post-operative day 14 revaluation.

Conclusions: Topical feracrylum post-endonasal surgeries reduce postoperative hemorrhage, dressing soakage, and the need for other hemostatic agents. It also eases nasal pack removal and decreases repacking incidence.

Key-words: Coagulation, Endonasal surgeries, Hemostatic Efficacy, Nasal package, Topical feracrylum

INTRODUCTION

Endoscopic nasal surgery is a minimally invasive technique that has carved a niche across various surgical domains. Procedures span from common interventions such as endoscopic septoplasty, turbinoplasty, and functional endoscopic sinus surgery to more complex surgeries like endoscopic orbital and/or optic nerve decompression, dacryocystorhinostomy, and endonasal skull base approaches.

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Its merits include the elimination of external scars, minimized impact on normal tissue and bone, and shortened recovery time and hospital stay [1]. The majority of nasal surgeries necessitate the use of nasal packing to manage bleeding, reduce dead space between sub-perichondrial layers and prevent complications such as septal hematoma and synechiae formation. However, these nasal packs can pose challenges, as they may impede nasal breathing, induce headaches, nasal pain, dryness of the mouth, watering of the eyes, ear blockage, difficulty in swallowing and carry the risk of biofilm formation, hypoxemia, hypotension, and hypoventilation [2]. Removal of these packs can be particularly problematic, causing significant pain and bleeding, sometimes requiring repacking [3].

Hemostatic agents play a crucial role in minimizing blood loss and ensuring optimal surgical outcomes. Among

various hemostatic agents, fibrin sealants have gained significant attention due to their ability to promote clotting and seal bleeding vessels [4]. Feracrylum is a type of fibrin sealant that has been extensively studied for its hemostatic efficacy in various surgical applications, including endonasal surgeries. Feracrylum is a two-component system consisting of thrombin and fibrinogen. When mixed together, thrombin catalyzes the conversion of fibrinogen into fibrin, forming a stable clot that seals bleeding vessels [5]. The use of feracrylum in endonasal surgeries has been shown to reduce blood loss and shorten operative time compared to conventional methods such as electrocautery and pressure packing [6].

In an effort to mitigate these untoward effects, various substances were considered. These include topical antifibrinolytics such as epsilon-aminocaproic acid and tranexamic acid, botroclot drops, packs soaked in adrenaline, microporous polysaccharide hemispheres, oxidized methylcellulose, fibrin glue, microfibrillar collagen, gelatine sponges, and saline irrigation during pack removal, none could completely mitigate the adverse events [1,7]. Despite the numerous complications associated with nasal packing, it remains a crucial step in all nasal surgeries. Therefore, we aimed to employ a technique that could minimize the drawbacks of nasal packing while maintaining its effectiveness. In our study, we sought to assess the coagulation, antimicrobial, and hygroscopic efficacy of feracrylum to mitigate the adverse effects commonly associated with nasal packing.

MATERIALS AND METHODS

The study was conducted at the Department of ENT and HNS, Oxford Medical College and Hospital, Bengaluru, Karnataka, India, for over a period of 10 months from 2021 to 2022.

Inclusion criteria- The study included all patients undergoing Endonasal surgeries, such as Septoplasty, inferior turbinate reduction surgeries (PIT, SMD), or FESS, between the ages of 15 and 60.

Exclusion criteria- Patients with hypertension, bleeding diathesis and on epsilon amino caproic acid (EACA), with deranged liver and renal function test and with known drug allergies were excluded from the study. Pregnant and lactating mothers were also not included in the study.

Methodology- A total of 40 participants, matched for age and gender, were enrolled in the study and randomly assigned to two groups using a simple random table. Group A received topical Feracrylum, while Group B served as the control group. Planned nasal surgeries were performed, and complete hemostasis was achieved in all patients. For Patients in Group A, 10 ml of feracrylum was used to flush each nasal cavity after surgery. The nasal cavity was then packed with merocele and was irrigated with the remaining 10 ml of feracrylum to keep the pack in place. In group B, nasal packing was done using merocele and irrigated with equal dilution betadine solution.

Patients were evaluated on the operative day to assess nasal pack soakage, the necessity for changing nasal dressings and the need for tranexamic acid injections to control bleeding. The posterior pharyngeal wall was examined for any signs of blood tinge and the same assessments were conducted on postoperative days 1 and 2. On the 2nd postoperative day, nasal packs were removed for all patients. Throughout the procedure, patients were monitored for bleeding and the potential need for repacking. The pain experienced by patients during pack removal was recorded using the Visual Analogue Scale. All patients were discharged on the 3rd postoperative day with prescriptions for antibiotics, nasal decongestants and nasal douching. On postoperative day 7, nasal cavities were examined for nasal crusting and signs of infection and any reported burning sensations were recorded. Additionally, patients underwent a review on the 14th postoperative day to check for adhesions and assess the condition of the nasal mucosa.

Statistical Analysis- Statistical analysis was conducted on the two randomized groups using the student t-test (two-tailed, independent) to determine the significance of study parameters on a continuous scale between the two groups (inter-group analysis) concerning metric parameters. Levene's test for homogeneity of variance was employed to evaluate the homogeneity of variance. For study parameters on a categorical scale between two or more groups, chi-square/Fisher Exact test was applied. In instances of very small cell samples, fisher exact test was specifically used in the non-parametric setting for qualitative data analysis. A significance level of $p \leq 0.05$ was considered statistically significant.

Ethical approval- This study was carried out at the Department of ENT and HNS, after being approved by the Institutional Ethics Committee.

RESULTS

The age distribution of the 40 participants was balanced across the two groups, with 29 (72.5%) patients falling into the second decade of life (Table 1). The study comprised 21 (52.5%) male patients and 19 (47.5%) female patients. Given the short-term nature of the study, there were no dropouts during the research period (Fig. 1).

Table 1: Demographic details of patients in two study groups.

Parameters	Group A	Group B	p-Value
Age in Years, Mean ± SD	26.8±4.66	26.3±4.58	0.73
Age Category in Years, n(%)			
<20	1(5.0)	1(5.0)	
20-30	14(70.0)	15(75.0)	
31-40	5(25.0)	4(20.0)	
Sex, n(%)			0.97
Female	10 (50.0)	9(45.0)	
Male	10 (50.0)	11(55.0)	

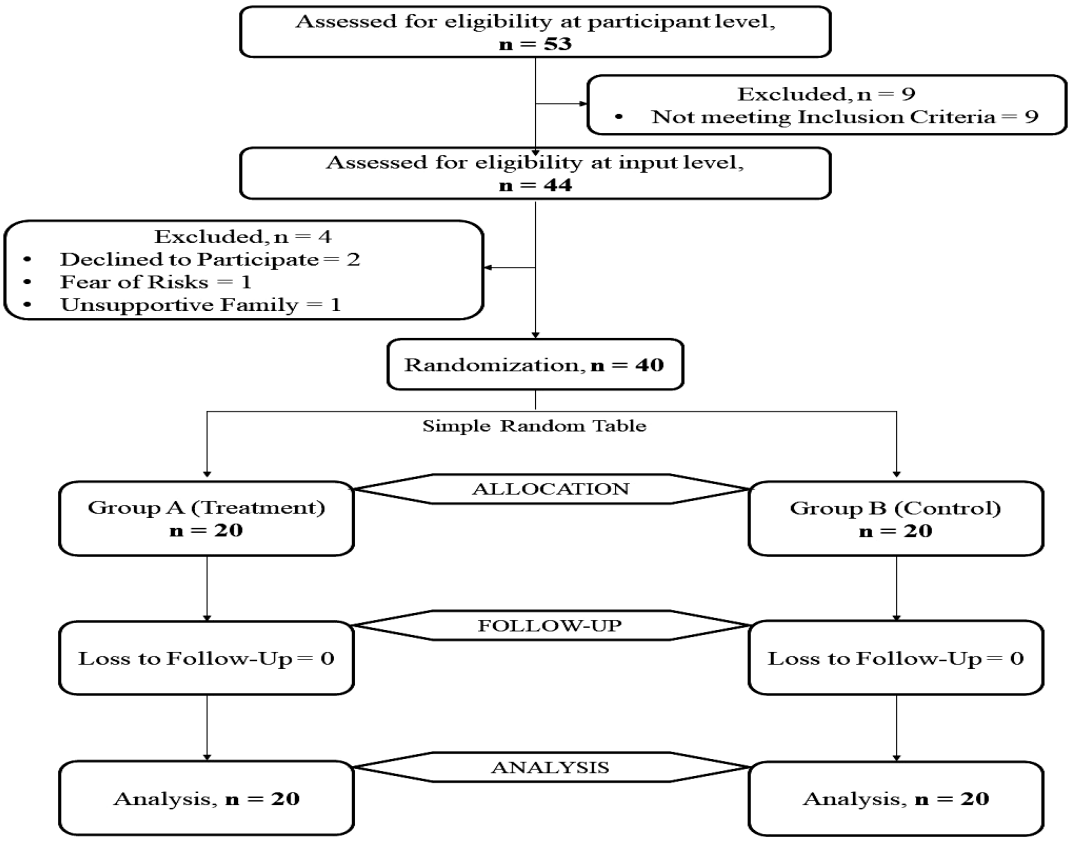

Fig. 1: CONSORT diagram for the study.

Nasal dressing soakage was utilised as a parameter to evaluate nasal bleeding on both the operative day and postoperative day 1. In group A, only 5(25%) patients' dressings were soaked, whereas in group B, 12(60%) patients' dressings were soaked. A significant statistical difference between the groups was observed on the operative day, with a p-value of 0.05. However, there was no statistical significance noted on postoperative day 1. On the operative day, 4(20%) patients in group B and 1(5%) patient on postoperative day 1 in the same group needed a change of the nasal dressing due to soakage. No patients in group A required a change of nasal dressing. Tranexamic acid injection was administered to patients experiencing severe nasal bleeding; none in group A required this treatment, while 3(15%) patients in group B received tranexamic acid on the operative day, as indicated in Table 2.

Table 2: Post-operative nasal dressing soakage, need for change of dressing and use of tranexamic acid usage in two study groups, Chi-Square Test/Fisher Exact Test.

Parameter	Group A		Group B		p-value
	Yes	No	Yes	No	
Post-operative nasal dressing soakage, n(%)					
Day 0	5(25)	15(75)	12(60)	8(40)	0.05
Day 1	1(5%)	19(95)	4(20)	16(80)	0.341
Post-operative need to change the dressing, n(%)					
Day 0	0(0)	20(100)	4(20)	16(80)	0.106
Day 1	0(0)	20(100)	1(5)	19(95)	0.936
Post-operative need to use tranexamic acid, n(%)					
Day 0	0(0)	20(100)	3(15)	16(80)	0.230
Day 1	0(0)	20(100)	0(0)	20(100)	1

During the post-operative posterior pharyngeal wall assessment, 3(15.0%) patients in group A and 7(35.0%) patients in group B displayed a blood tinge on the operative day. However, on postoperative day 1, none of the study patients in either group showed any signs of postnasal bleeding. The difference between the two groups was not statistically significant at both day 0 (p=0.27) and day 1 (p=1).

On the second postoperative day, nasal packs were removed for all patients, and the occurrence of rebleeding during pack removal, as well as the need for repacking, was evaluated. In group A, mild bleeding was observed in 2(10%) patients, which decreased with the use of xylometazoline nasal drops. In group B, 9(45%) patients experienced mild bleeding, and 1(5%) patient had moderate bleeding, requiring repacking in 2(10%) cases to control the bleeding. Pain during pack removal was assessed using the Visual Analogue scale. In group A, 50% of patients reported a pain score of 3, 30% had a score of 2, and only 20% had a score of 4. In contrast, in group B, 45% of patients had scores of 4, 25% had a score of 5, and one patient complained of a score of 6. Intergroup analysis revealed a statistically significant difference with a p<0.001. Table 3 provides an overview of patient characteristics on the day of pack removal.

On the seventh post-operative day, patients were evaluated for nasal crusting, burning sensation, and infections, revealing no significant differences between the groups. By the fourteenth day, the nasal mucosal appearance was comparable in both groups. The occurrence of adhesions was lower in group A compared to group B.

Table 3: Bleeding, need for repacking and pain assessment on pack removal day in two study groups, Chi-Square Test/Fisher Exact Test.

Pack Removal Day	Group A	Group B	p-value
Bleeding, n (%)			
No	18 (90)	10 (50)	015*
Yes	2 (10)	10 (50)	
Bleeding severity, n (%)			
Mild	2 (10)	9 (45)	
Moderate	0 (0)	1 (5)	
Severe	0 (0)	0 (0)	
Need for repacking due to bleeding, n (%)			
No	20 (100)	18 (90)	0.487
Yes	0 (0)	2 (10)	
Pain assessment during pack removal using VAS (Visual Analogue Scale for pain), n (%)			
1	0 (0)	0 (0)	<001
2	6 (30)	0 (0)	
3	10 (50)	0 (0)	
4	4 (20)	9 (45)	
5	0 (0)	5 (25)	
6	0 (0)	1 (5)	

DISCUSSION

Postoperative hemorrhage following endonasal surgeries is reported to range between 23% to 39% [8,9]. Nasal packing is considered a primary method to manage hemorrhage after these surgeries. However, the use of nasal packing remains a contentious issue due to associated problems such as nasal pain, headache, dryness of the mouth, watering of the eyes, ear blockage, difficulty in swallowing and the potential risks of biofilm formation, hypoxemia, and hypoventilation [10-15]. Despite these challenges, there are instances where nasal packing alone may not suffice to halt hemorrhage, necessitating the use of hemostatic agents. Feracrylum, an incomplete ferrous salt of polyacrylic acid, functions as a topical hemostatic agent. When applied topically, it serves as a hemostatic agent, demonstrates antimicrobial effects and exhibits hygroscopic properties. Its mechanism of action involves the activation of thrombin, which converts fibrinogen into fibrin, thereby facilitating clot formation. Additionally, when Feracrylum combines with blood proteins, particularly albumin, it creates a gel-like substance that forms a physical barrier on the wound surface, effectively halting capillary oozing [16]. The antimicrobial effects of Feracrylum have been similar to those of povidone-iodine, leading to microbial cell wall lysis [17,18].

The hemostatic properties of the Feracrylum have undergone extensive examination in tonsillar surgeries, wound healing in oral surgeries and deep partial-thickness burns [19,20]. We applied it in endonasal surgeries and observed superior hemostasis in group A, where Feracrylum was utilised, compared to group B. This was evident through considerations such as nasal dressing soakage, the necessity for changing nasal dressings, and the requirement for injectable tranexamic acid, all of which were lower in group A patients than in group B. These findings substantiate the hemostatic potential of the Feracrylum molecule.

Nasal pack removal is often challenging due to associated severe pain and bleeding, sometimes requiring repacking [10]. In our study, the average pain score using the Visual Analog Scale in group A ranged from 2 to 4, while in group B, it was between 3 and 6. The pain score during pack removal in group B aligned with other studies, where scores ranged from 4.65 to 6.17 depending on the type of packs used [10-13]. Significantly, the pain score was lower in group A, attributed to Feracrylum forming a gel-like layer upon combining with blood proteins, exhibiting hygroscopic properties, and making pack removal less painful. The hygroscopic nature of Feracrylum, maintaining the wound site's moisture and facilitating easy dressing removal, was noted by Meenakshi et al. in their study [19]. Reactive hemorrhage during nasal pack removal has been reported in other studies to be between 2.8% and 7.1%, depending on the type of pack used [11-13]. Our study mirrored these findings, with group B experiencing a 5% incidence of moderate hemorrhage, leading to repacking in 2(10%) patients. In contrast, group A had no instances of moderate hemorrhage, showcasing a significant difference between the two groups. The systemic absorption of Feracrylum is minimal compared to other coagulants, given its molecular weight of 500,000–8,000,000 Daltons, resulting in fewer or no side effects [19-21]. The incidence of nasal adhesion was also lower in group A.

CONCLUSIONS

Despite the numerous complications associated with nasal packing, it remains essential after most endonasal surgeries. This study aimed to assess the efficacy of Feracrylum in reducing nasal packing complications, allowing for the achievement of its purpose with fewer drawbacks. Our conclusions suggest that topically applying Feracrylum solution after nasal surgeries before packing reduces the incidences of postoperative hemorrhage, nasal dressing soakage, and the need for other hemostatic agents. Additionally, it makes nasal pack removal less painful and decreases the incidence of repacking. Postoperative crusting and adhesion occurrences were also reduced. In conclusion, the topical use of the Feracrylum molecule post endonasal surgeries proves to be beneficial. However, further large-scale studies are warranted to confirm these findings.

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REFERENCES

[1] Thongrong C, Kasemsiri P, Carrau RL, Bergese SD. Control of Bleeding in Endoscopic Skull Base Surgery: Current Concepts to Improve Hemostasis. ISRN Surg., 2013; 2013: 1-11.
[2] Awan MS, Iqbal M. Nasal Packing after Septoplasty: A Randomized Comparison of Packing versus no Packing in 88 Patients. Ear Nose Throat J, 2008; 87(11): 624-27.
[3] Mane RS, Patil B, Mohite A. Comparison of Septoplasty with and Without Nasal Packing and Review of Literature. Indian J Otolaryngol Head Neck Surg., 2013; 65(S2): 406-08.
[4] Daud A, Kaur B, McClure GR. Fibrin and Thrombin Sealants in Vascular and Cardiac Surgery: A Systematic Review and Meta-analysis. Eur J Vasc Endovasc Surg., 2020; 60(3): 469-78.
[5] Spotnitz WD. Fibrin Sealant: The Only Approved Hemostat, Sealant, and Adhesive-a Laboratory and Clinical Perspective. ISRN Surg., 2014; 2014: 203943.
[6] Rai S, Rattan V. Efficacy of Feracrylum as Topical Hemostatic Agent in Therapeutically Anticoagulated Patients Undergoing Dental Extraction: A

Comparative Study. J Maxillofac Oral Surg., 2019; 18(4): 579-83.

[7] Vaiman M, Sarfaty S, Eviatar E. The use of fibrin sealant as a glue for septoplasty and conchotomy. Rhinol., 2009; 47(3): 297-300.

[8] Stankiewicz JA, Lal D, Connor M, Welch K. Complications in endoscopic sinus surgery for chronic rhinosinusitis: a 25-year experience. Laryngoscope, 2011; 121(12): 2684-701.

[9] Bloom JD, Kaplan SE, Bleier BS, Goldstein SA. Septoplasty Complications: Avoidance and Management. Otolaryngol Clin North Am., 2009; 42(3): 463-81.

[10]Bernardo MT, Alves S, Lima NB, Helena D, Condé A. Septoplasty with or without postoperative nasal packing? Prospective study. Braz J Otorhinolaryngol., 2013; 79(4): 471-74.

[11]Shanmugam DVU. A Comparison of Conventional Nasal Pack with Merocel Nasal Pack in the Management of Epistaxis. J Med Sci Clin Res., 2019; 7(10): 904-12.

[12]Saedi B, Sadeghi M, S Farschi. Effect of polyvinyl acetal sponge nasal packing on post-operative care of nasal polyposis patients: a randomised, controlled, partly blinded study. J Laryngol Otol., 2012; 126(4): 380-84.

[13]Schoenberg MV, Robinson P, Ryan R. Nasal packing after routine nasal surgery—is it justified?. J Laryngol Otol., 1993; 107(10): 902-05.

[14]Tunkel DE, Anne S, Payne SC, et al. Clinical Practice Guideline: Nosebleed (Epistaxis). Otolaryngol Head Neck Surg., 2020; 162(1_suppl): S1-S38.

[15]Fairbanks DNF. Complications of Nasal Packing. Otolaryngol Head Neck Surg., 1986; 94(3): 412-15.

[16]Laddha A, Mulla M, Sharma S, Lahoti BK, Mathur R. A prospective comparison of topical feracrylum citrate versus adrenaline as haemostatic agent in hypospadias surgery in children. Afr J Paediatr Surg., 2014; 11(3): 215.

[17]Moenadjat Y, Setiabudy R, Astrawinata DAW, Gumay S. The safety and efficacy of feracrylum as compared to silver sulfadiazine in the management of deep partial thickness burn: A clinical study report. Med J Indonesia, 2008; 17(4): 259-71.

[18]Bhagwat AM, Save S, Burli S, Karki SG. A study to evaluate the antimicrobial activity of feracrylum and its comparison with povidone-iodine. Indian J Pathol Microbiol., 2001; 44(4): 431-33.

[19]Chauhan MK, Kumari M. Feracrylum: An Effective and Save Topical Haemostatic Agent. World J Pharmaceut Res., 2017; 6(10): 319-25.

[20]Sathyaki DC, Roy MS, Kumar V, Jyothiswarup R. Use of feracrylum in tonsillectomy. Int J Otorhinolaryngol Head Neck Surg., 2018; 4(3): 663.

[21]Singh K, Dhruv K, Patle RD, Paikra SU. Role of local instillation of one percent feracrylum and haemocogulase on wound healing. Int J Res Med Sci., 2016; 4(1): 169-76.