Negative pressure drainage vs. nasal packing after septoplasty: a randomized clinical trial

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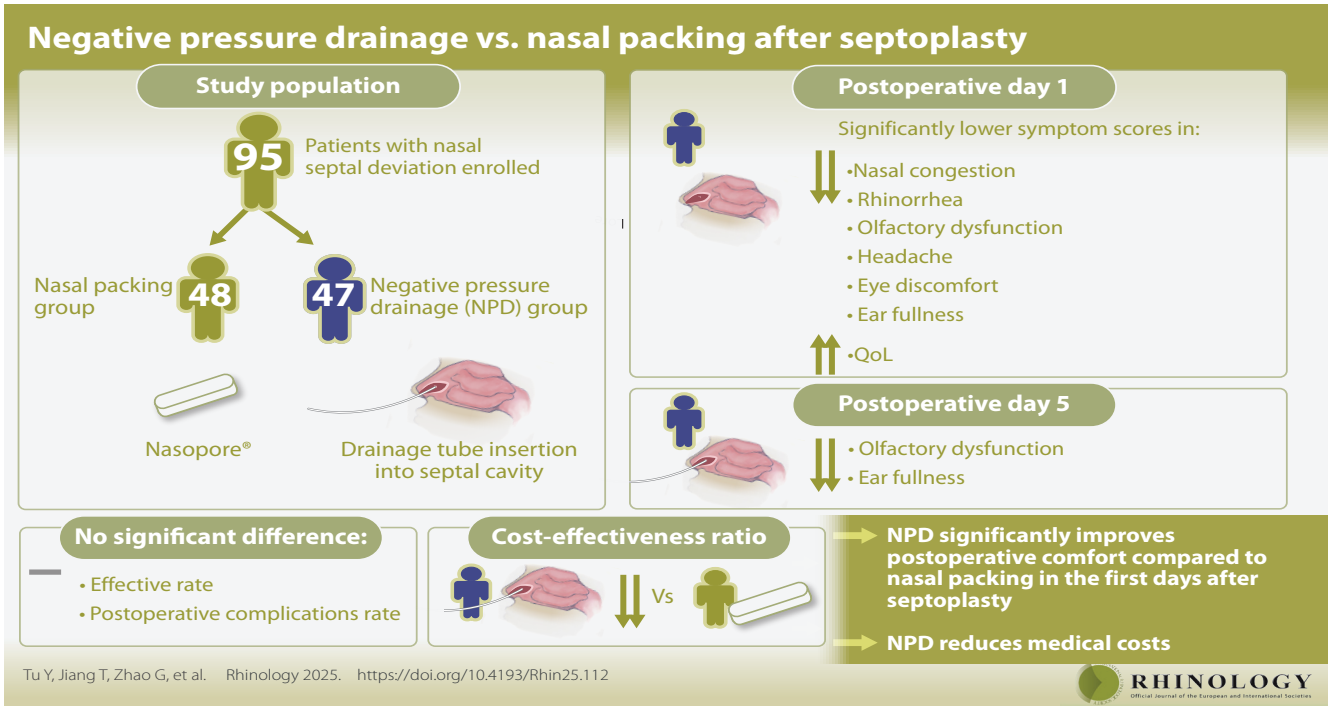

Abstract

Background: Negative pressure drainage is a commonly used method in surgery, but studies applying negative pressure drainage in septoplasty are relatively few.

Methodology: A randomized clinical trial was conducted to compare negative pressure drainage and nasal packing after septoplasty. Patients with nasal septal deviation underwent septoplasty from November 2023 to March 2024 were enrolled. Symptom scores and quality of life scores were assessed on postoperative day 1, day 5, and at 1 month to evaluate postoperative comfort.

Results: A total of 95 patients completed the study, the median (IQR) age was 29 (21, 43) years, and 73 (77%) identified as male. 48 (51%) patients were randomized to nasal packing group and 47 (49%) to negative pressure group. On postoperative day 1, the negative pressure group showed significantly lower symptom scores for nasal congestion, rhinorrhea, olfactory dysfunction, headache, eye discomfort, ear fullness, and better quality of life compared to the packing group. On postoperative day 5, the negative pressure group showed significantly lower scores for olfactory dysfunction and ear fullness compared to the packing group. There was no significant difference in effective rate and postoperative complications rate between negative pressure group and packing group. The cost-effectiveness ratio for the negative pressure group was significantly lower than the packing group.

Conclusions: Negative pressure drainage after septoplasty significantly improves postoperative comfort in the first days after surgery, without affecting surgical efficacy or safety, and helps reduce medical costs.

Key words: nasal septum deviation, septoplasty, negative pressure drainage, nasal packing

Introduction

Septal deviation is a common disease in otolaryngology and has often an impact on the patients' quality of life [1]. Septoplasty is one of the most common surgical procedures in otolaryngology [2]. Postoperatively, the traditional method involves nasal packing to stabilize the nasal structure, prevent septal hematoma formation, and avoid nasal adhesions and narrowing [3]. However, nasal packing is associated with drawbacks such as damage to the nasal mucosa, oral breathing, and facial pressure pain. As a result, many researchers have explored alternative methods to nasal packing, such as septal suturing [4], septal splints [5] and septal stapler [6]. These non-packing techniques have shown good clinical outcomes and alleviated patient discomfort, but their widespread application has been limited due to higher costs and equipment requirements.

Negative pressure drainage (NPD) is a surgical technique that utilizes an external device to create a sustained negative pressure environment within surgical cavities, thereby facilitating fluid drainage and reducing tissue edema. Its core mechanisms include: 1) Physical suction effect to drain accumulated blood and exudate, lowering postoperative hematoma risk; 2) Centripetal force generated by negative pressure to promote re-approximation of separated mucosal layers, accelerating healing; 3) Reduction of mechanical compression from traditional packing materials on nasal structures, thus alleviating mucosal injury and pain. Although NPD has been extensively applied in breast surgery [7] and trauma repair [8], its implementation in septoplasty remains relatively few [9,10]. As an innovative technique combining drainage and mucosal protection, NPD's clinical value has not been fully elucidated. Therefore, randomized controlled trials are urgently required to assess its efficacy, safety, and cost-effectiveness in septoplasty.

We hypothesize that compared to traditional nasal packing, NPD will significantly improve postoperative symptoms and quality of life by minimizing mechanical compression and mucosal injury, without increasing surgical failure rates or complication risks. Additionally, we anticipate that NPD may decrease overall healthcare costs through shortened hospital stays and reduced material consumption. This study aims to compare NPD with nasal packing in terms of both subjective and objective indicators after septoplasty, providing additional reference data for the implementation of this new technique and offering scientific evidence to help patients choose the most appropriate treatment option.

Materials and methods

Patients

This prospective randomized clinical trial (Trial registration: No. ChiCTR2400085399) was conducted at a single tertiary ENT specialty hospital, between November 2023 to March 2024. The study protocol was reviewed and approved by the institutional review board of Shandong Provincial ENT Hospital. All patients provided written informed consent at study enrollment. We followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline. Patients were considered candidates for this study if they were18 years or older, with nasal septal deviation with or without inferior turbinate hypertrophy causing nasal dysfunction or symptoms. Exclusion criteria included chronic rhinosinusitis, nasal polyps, allergic rhinitis, hypertension, diabetes, sleep apnea, and history of previous nasal surgery. The participants were randomized according to computer-generated code and assigned in a 1:1 allocation to NPD group and nasal packing group. Of the 50 patients enrolled in each group, 5 were withdrawn from the study analysis: 3 due to lost to follow-up and 2 due to alterations in the surgical procedure (Figure 1).

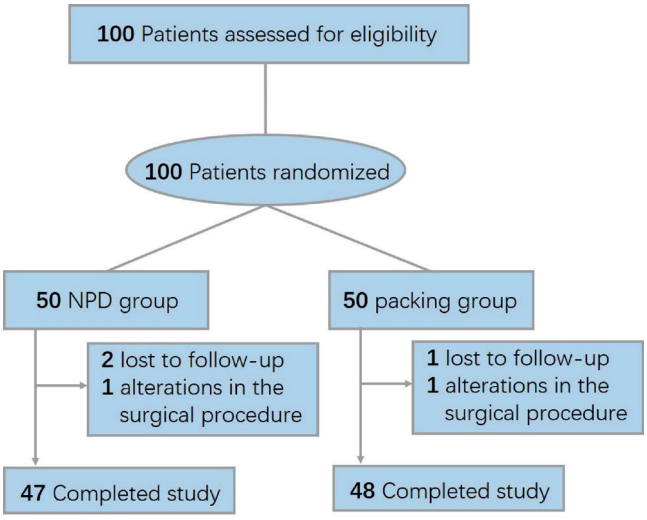

Figure 1. Participant CONSORT flow diagram

Surgery

All surgical procedures were performed by the same experienced otolaryngologist. Under general anesthesia, the patients underwent endoscopic septoplasty with three tension lines resection based on the study by Wang et al. [11]. Three high tension lines tablearound anterior, inferior and posterior attachments of the septal cartilage. It is an effective and well-tolerated procedure, which can provide a good approach that is applicable for various septal deviations. For patients with hypertrophic rhinitis, submucosal plasma ablation of the inferior turbinate was also performed. During the surgery, it was ensured that there was no active bleeding in the septal cavity, and that the septal mucosa was not perforated. The surgical cavity was thoroughly irrigated with saline. In the packing group, nasal packing with Nasopore was used, with one and a half pieces placed in each nostril. The nasal packing was removed 48 hours postoperatively.

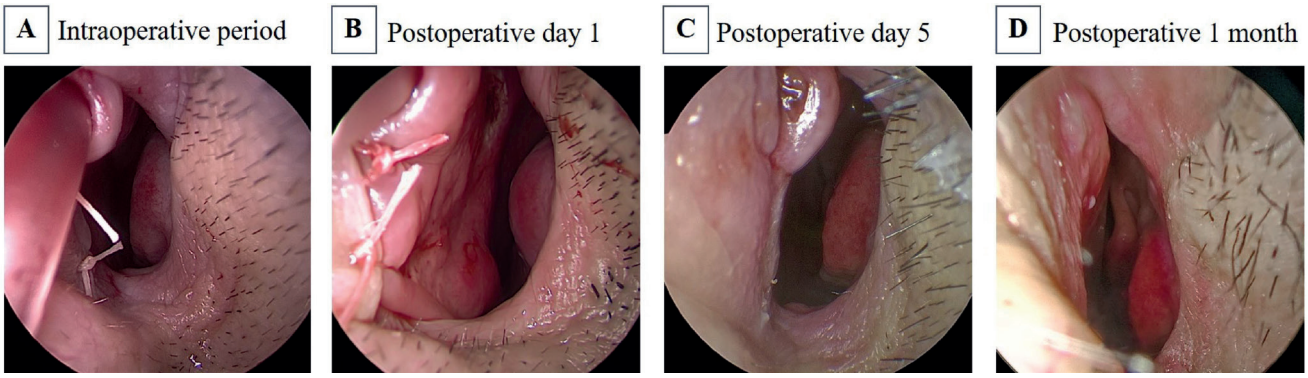

Figure 2. Representative endoscopic images of negative pressure drainage after septoplasty.

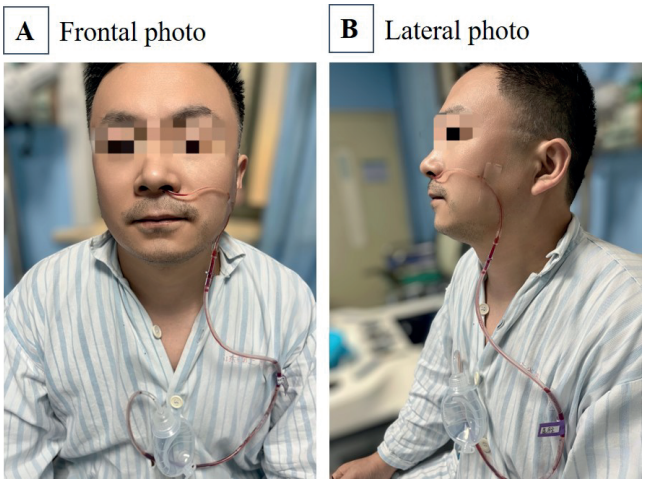

Figure 3. Postoperative full-face photographs.

Description of the NPD

In the NPD group, a scalp needle silicone tube was used to create a negative pressure drainage tube. The tube had a diameter of 2 mm, and four side holes were cut at the end, spaced 1 cm apart and distributed in different directions (up, down, left, and right). The drainage tube was inserted through the septal incision into the posterior septal cavity and exited from the top of the incision. The incision was then sutured, and the drainage tube was fixed in place (Figure 2). During the initial 6-hour postoperative phase when patients remain under post-anesthesia monitoring, central negative-pressure systems (pressure set at 25-30 kPa) ensure stable drainage. Subsequent transition to portable negative-pressure bulbs enables unrestricted daily activities (Figure 3). If the septal cavity was still not closed after 6 hours of continuous central negative pressure, the suction was continued for up to 12 hours. After 24 hours postoperatively, the drainage volume was monitored. If the drainage volume in the suction bulb was <4 ml, the drainage tube was removed. If the drainage volume was ≥4 ml, drainage was continued for up to 48 hours postoperatively.

Outcome assessment

The primary outcome measures were Nasal Obstruction Symptom Evaluation (NOSE) score and symptom VAS score on postoperative day 1 and day 5. We used NOSE score to assess nasal congestion symptoms, used VAS score to assess seven symptoms (rhinorrhea, olfactory dysfunction, headache, sneezing, eye discomfort, ear fullness, and sleep disturbances). Secondary outcome measures included clinical efficacy, QoL, safety, cost-effectiveness and nasal function. A 30% or greater reduction in NOSE score at1-month postoperative was considered effective. We used Sino-nasal Outcome Test-22 (SNOT-22) score to assess patient-reported QoL. The amount of bleeding of NPD group and postoperative complications (adhesion, hematoma, perforation, infection) in both groups was recorded. The total medical costs during the patients' hospital stay were recorded, comprehensively encompassed all direct and indirect costs of both groups. The average cost-effectiveness ratio (CER) was calculated, which represents the cost required to achieve one unit of effect. Nasal resistance at a pressure differential of 150 Pa and the nasal cavity volume from 0 to 7 cm were recorded to assess nasal function.

Sample size and statistical analysis

We hypothesize that the NPD group can improve postoperative comfort over packing group by a 20% reduction in VAS score based on findings from a study investigating pain degrees [12]. Given a type 1 error rate of 0.05 and a power of 80%, a sample size of 37 participants is necessary to discern a significant difference between NPD and packing groups. We allocated 50 individuals to each study group to account for 20% of dropouts and incomplete data. Data were analyzed using SPSS 22.0 software. Descriptive statistics were presented as medians and interquartile ranges for continuous variables; 95% confidence intervals were also presented. Within-group comparisons were performed using the paired Wilcoxon signed-rank test, while between-group comparisons were conducted using the Mann-Whitney U

Table 1. Clinical characteristics of patients.

	NPD group (n=47)	Packing group (n=48)	t (χ^2)	P
Age (years)			0.57	0.34
median	31.5	27		
25th-75th	22.3-44	21-40		
Gender			0.32	0.37
male/female	35/12	38/10		
Inferior turbinate plasma ablation	33	30	0.63	0.43
Effective rates	89%	92%	0.15	0.7

Abbreviations: NPD, negative pressure drainage.

test. Categorical data were analyzed using the Chi-square test or Fisher's exact probability test. A P-value of <0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 95 patients completed the study, the median (IQR) age was 29 (21, 43) years, and 73 (77%) identified as male. 48 (51%) patients were randomized to nasal packing group and 47 (49%) to NPD group. There were no significant differences between the two groups in terms of age, gender, inferior turbinate plasma ablation, or efficacy rates (Table 1).

Postoperative symptom score

On postoperative day 1, the NPD group showed significantly lower symptom scores for nasal congestion (95% CI, -29.74 to -8.149; P<.001), rhinorrhea (95% CI, -2.81 to -0.3; P=.03), olfactory dysfunction (95% CI, -3.77 to -0.7; P=.02), headache (95% CI, -2.98 to -0.48; P=.007), eye discomfort (95% CI, -3.03 to -0.92; P=.003), ear fullness (95% CI, -2.99 to -0.62; P=.004), and better quality of life (95% CI, -21.8 to -3.67; P=.01) compared to the packing group. On postoperative day 5, the NPD group showed significantly lower scores for olfactory dysfunction (95% CI, -2.07 to -0.18; P=.01) and ear fullness (95% CI, -1.86 to -0.25; P=.003) compared to the packing group (Table 2). No significant differences in symptom scores were observed between the two groups at 1 month postoperatively (data not shown).

Clinical efficacy and nasal function

At 1 month postoperatively, both groups showed significant reductions in nasal congestion scores and quality of life scores compared to preoperative values, with statistically significant differences. Nasal resistance significantly decreased, and nasal cavity volume significantly increased compared to preoperative values, with statistically significant differences (Table 3). However, there were no significant differences between the two groups in any of these indicators at both preoperative and 1-month postoperative assessments (data not shown).

Safety and cost-effectiveness analysis

In the NPD group, the total bleeding volume within 24 hours was 9.85 (4.7, 14.7) ml. The nasal packing group experienced 1 case of adhesion and 1 case of hematoma postoperatively, while the NPD group had 2 cases of hematoma. There were no statistically significant differences in postoperative complications rate between groups (95% CI, -0.12 to 0.12; P>.99). The hospitalization costs for the NPD group were 15,260 (13,460, 17,470) yuan, significantly lower than the 17,190 (14,680, 19,170) yuan for the nasal packing group. The CER for the NPD group was 253.8 (208.8, 386.1) yuan/point, significantly lower than the CER of 313.7 (223.7, 423.9) yuan/point for the nasal packing group (95% CI, -385.5 to -52.66; P=.02), suggesting that the NPD group achieved per unit of treatment effect with a lower cost.

Discussion

Septoplasty without postoperative nasal packing has long been a goal pursued by otolaryngologists, leading to continuous exploration in this area. Nasal septal suturing has become a commonly used alternative, with multiple studies indicating that, compared to nasal packing, suturing can reduce postoperative complications and improve postoperative comfort [13-15]. However, nasal septal suturing can extend the surgery time and exacerbate nasal mucosal injury, which may limit its widespread application. NPD is a widely used surgical technique for closing surgical cavities and preventing postoperative fluid accumulation and hematomas. In septoplasty, NPD allows for the drainage of blood and fluid from the surgical cavity, reduces tissue swelling, promotes local blood circulation, and helps to press the two layers of mucosa together by closing the gaps between them using suction. A previous study [9] has shown that NPD is simple to perform, improves postoperative comfort, and yields effective results. However, challenges remain regarding the specific method, duration, and choice of drainage tubes, which we have also explored in this study. After 6 hours of continuous drainage, the nasal septum gradually formed a closed cavity, and the seepage of blood and fluid ceased. We also observed that the nasal septal tears showed varying degrees of shrinkage after NPD, possibly due to the centripetal force generated by the continuous negative pressure suction. Early literature reported that the indication for NPD of the nasal septum was the absence of mucosal tears [10]. Our study redefines this concept and broadens the indications for NPD. Regarding the duration of NPD, we found that most of the drainage occurred within the first 24 hours, with very little blood-tinged fluid expelled between 24 and 48 hours. Most patients achieved drain removal and discharge within 24 hours, fulfilling the "same-day or next-

Table 2. Comparison of symptom scores between two groups on postoperative days 1 and day 5.

	NPD	Packing	95% CI	P
Postoperative day 1				
NOSE score, median (IQR)	52.5(30, 75)	80(57.5, 95)	-29.74 to -8.149	<.001
VAS, median (IQR)				
Rhinorrhea	2(1, 5)	4(1, 8)	-2.81 to -0.3	.03
Olfactory dysfunction	2(0, 4.5)	5(0, 10)	-3.77 to -0.7	.02
Headache	0(0, 3)	2(0, 6.5)	-2.98 to -0.48	.007
Sneezing	1(0, 3)	1(0, 3)	-0.95 to 0.92	.78
Eye discomfort	0(0, 2)	3(0, 6)	-3.03 to -0.92	.003
Ear fullness	0(0, 2)	2(0, 6)	-2.99 to -0.62	.004
Sleep disturbances	2(0, 6)	4(2, 8)	-2.85 to 0.19	.08
SNOT-22, median (IQR)	22(11.5, 37)	40(19.5, 50.3)	-21.8 to -3.67	.01
LKS, median (IQR)	NA	NA	NA	NA
Postoperative day 5				
NOSE score, median (IQR)	20(10, 35)	25(10, 30)	-7.06 to 7.35	.95
VAS, median (IQR)				
Rhinorrhea	2(1, 5)	1(1, 3)	-0.42 to 1.66	.13
Olfactory dysfunction	0(0, 2)	2(0, 4.3)	-2.07 to -0.18	.01
Headache	0(0, 1)	0(0, 1)	-0.95 to 0.13	.16
Sneezing	1(0, 2)	0(0, 1)	-0.37 to 0.7	.31
Eye discomfort	0(0, 1)	0(0, 1)	-0.47 to 0.48	.93
Ear fullness	0(0, 0)	2(0, 2)	-1.86 to -0.25	.003
Sleep disturbances	0(0, 2)	0(0, 2)	-0.52 to 1.13	.53
SNOT-22, median (IQR)	10(5, 19)	13(4.5, 18.5)	-8.07 to 2.57	.7
LKS, median (IQR)	2(2, 3)	3(2, 4)	-0.74 to 0.15	.32

Abbreviations: NPD, negative pressure drainage; NOSE, nasal obstruction symptom evaluation; LKS, Lund-Kennedy score.

day discharge" criteria for outpatient surgery. Thus, NPD did not prolong hospitalization duration, but rather streamlined clinical workflows by reducing post-packing removal follow-up demands. In selecting the drainage tube, we chose a 2mm diameter scalp needle silicone tube, which proved to be simple, effective, and associated with a low hematoma occurrence rate. Without the mechanical pressure from nasal packing, there is less mucosal damage, and tissue repair is faster. This allows for earlier use of nasal spray medications postoperatively. NPD effectively alleviates subjective discomfort on postoperative days 1 and 5 and improves quality of life. For patients with nasal septum deviation who also have obstructive sleep apnea-hypoventilation syndrome or serous otitis media, postoperative packing may exacerbate hypoxemia [16] or impair Eustachian tube function [17,18]. In such cases, NPD helps mitigate adverse effects on other physiological systems, reducing postoperative risks. However, the absence of nasal packing could potentially lead to increased bleeding or hematoma, making the safety of negative pressure drainage a key concern in clinical practice.

The median bleeding volume at 24 hours postoperative was 9.85 ml in NPD, which is like the average 10.1 ml of bleeding observed with nasal packing at 48 hours, as reported in the literature [15]. The incidence of hematoma observed in this study was comparable to that reported by Awan et al. [19]. In the NPD group, two cases of hematoma occurred, with no adhesions or perforations, suggesting that NPD has a safety profile like nasal packing. We reviewed and analyzed the two hematoma cases in the negative pressure group. Both patients were male, aged 58 and 34, diagnosed with nasal septal deviation and underwent septoplasty. During surgery, no active bleeding was noted in the septal cavity. After returning to the ward, continuous central negative pressure suction was applied, and 6 hours later, negative pressure bulbs were connected. Upon removal of the drainage tube at 24 hours post-operation, nasal septal hematomas were observed. The mucosa at the septal incision site was separated, and accumulated blood in the surgical cavity was thoroughly cleared. Expansive sponges were used to pack both nasal cavities, and compression was applied for 3 days. After remo-

Table 3. Comparison of clinical efficacy in both groups.

	Pre-op	Post-op 1 month	95% CI	P
NOSE score, median (IQR)				
NPD	57.5 (35, 75)	10 (5, 15)	-55.73 to -34.15	<.001
Packing	65 (45, 80)	10 (5, 20)	-57.5 to -34.7	<.001
SNOT-22, median (IQR)				
NPD	33 (14.5, 43.5)	5 (1, 16)	-32.31 to -14.75	<.001
Packing	34 (18, 50)	5 (0.5, 18)	-34.5 to -14.54	<.001
Nasal resistance, Pa/($cm^3 \cdot s$)				
Left side				
NPD	1.25 (0.93, 1.55)	0.74 (0.6, 1.0)	-0.62 to -0.26	<.001
Packing	1.15 (0.68, 1.6)	0.72 (0.56, 0.88)	-0.59 to -0.1	.003
Right side				
NPD	0.73 (0.52, 0.95)	0.53 (0.46, 0.71)	-0.36 to -0.07	.04
Packing	0.7 (0.48, 1.1)	0.61 (0.43, 0.68)	-0.44 to -0.1	.06
Nasal cavity volume, cm^3				
Left side				
NPD	6.42 (5.31, 8.09)	9.92 (7.74, 11.94)	0.86 to 3.52	<.001
Packing	6.88 (4.84, 10.5)	10.14 (8.15, 12.37)	1.69 to 5.37	.003
Right side				
NPD	8.02 (6.03, 10.29)	10.67 (9.0, 14.72)	1.6 to 4.55	<.001
Packing	7.44 (5.35, 10.01)	10.31 (7.33, 11.44)	0.19 to 3.46	.05

Abbreviations: NPD, negative pressure drainage; NOSE, nasal obstruction symptom evaluation; Pre-op, pre-operation; Post-op, post-operation.

ving the packing, the nasal septum was found to be symmetric with no abnormal protrusions. No hematomas were observed at postoperative day 5 or at 1 month. A statistical analysis of coagulation indicators revealed that the platelet counts in the two hematoma patients were 263×10^9/L and 303×10^9/L, both higher than the median platelet counts of 215×10^9/L in the non-hematoma cases. In subsequent investigations with expanded sample sizes, we plan to incorporate comprehensive coagulation profiling to systematically evaluate the association between hypercoagulable states and hematoma formation. Additionally, the use of NPD post-septoplasty reduced patients' hospitalization costs. The cost per unit of therapeutic effect in the NPD group was lower than that of nasal packing, which is beneficial for both patient health outcomes and the optimized utilization of healthcare resources.

Our study has several limitations. First, the use of plasma ablation for the inferior turbinate causes varying degrees of damage to the submucosal tissue of the inferior turbinate. Therefore, isolated septoplasty without concurrent inferior turbinate treatment is ideal. However, there remains controversy about whether septoplasty should be performed alongside inferior turbinate treatment. In this study, 66% of the patients required simultaneous plasma ablation of the inferior turbinate. Although our results showed no significant difference in the proportion of patients who underwent plasma ablation between the two groups, the short follow-up period warrants further long-term studies to observe the impact of plasma ablation on nasal function. Second, NPD has limited shaping ability, particularly for stabilizing the nasal septum after septoplasty. This is especially problematic for cases of caudal septal deviation, which require balancing with nasal packing. As caudal deviations were not separately categorized for subgroup analysis, we cannot compare therapeutic outcomes between patients with caudal septal deviations and other subjects within the NPD group. Future investigations should further explore NPD's applicability in such complex cases through stratified randomization or expanded sample sizes to enhance generalizability. Furthermore, the postoperative continuous central negative pressure limits patient mobility to some extent. To minimize this restriction, we applied central negative pressure for the first 6 hours after septoplasty under general anesthesia, followed by negative pressure bulbs from 6 hours onwards, in order to reduce mobility restrictions for patients. Additionally, the drainage tube may have some effect on incision healing. After removing the drainage tube, gelatin sponges were applied for localized hemostasis at the incision site. Using Nasopore as the control group better facilitates

direct comparison with existing literature and reflects real-world clinical practice across diverse healthcare tiers. However, nasal silicone splints or septal suturing could have been a more demanding choice. Future investigations may incorporate a three-arm trial design with a silicone splint or septal suturing group, to systematically evaluate therapeutic merits and limitations of different approaches. Finally, we acknowledged the potential performance bias that may affect results because of the lack of blinding.

Conclusion

This prospective randomized clinical trial found that application of NPD after septoplasty can reduce postoperative nasal obstruction and discomfort symptoms. NPD is effective, safe, and can reduce medical costs. Further investigation is needed to further validate our outcomes and elucidate which patients are the best candidates for NPD.

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Authorship contribution

FZ and AC had full access to all data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: FZ, AC. Acquisition, analysis, or interpretation of data: YT, TJ, GZ, LX. Drafting of the manuscript: YT, TJ. Critical review of the manuscript for important intellectual content: LS.

Conflict of interest

No conflict of interest exists.

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