pISSN 2454-5929 | eISSN 2454-5937

Original Research Article

DOI: http://dx.doi.org/10.18203/issn.2454-5929.ijohns20171194

A comparative study between nasal clips and anterior nasal packing in septoplasty/submucosal resection patients at VIMS Bellary, Karnataka

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Received: 27 January 2017 Accepted: 01 March 2017

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ABSTRACT

Background: Nasal packing is used primarily to control bleeding, for internal stabilization and to prevent postoperative complications in endonasal surgeries. Nasal septal clip is one of the alternatives, whose effectiveness in surgical practice is less studied upon. To compare the effectiveness between nasal septal clip and anterior nasal packing following septoplasty/submucous resection.

Methods: Prospective Randomised Controlled Study was conducted in Department of Otolaryngology at Vijayanagara Institution of Medical Sciences, Bellary, between November 2014 to May 2016. Study involved 100 patients fulfilling inclusion and exclusion criteria. Adopting sealed envelope technique, patients were allotted into two equal groups for anterior nasal pack and nasal septal clip following septoplasty or submucosal resection. Interventions were done following standard procedures and data was collected by using pre-tested proforma.

Results: Mean age of anterior nasal pack group and nasal septal clip group was 27.86 and 25.24 years respectively. Intra-operatively, packing with nasal septal clip was easier with significantly less trauma to mucous membrane ($X^2 = 6.353$, P = 0.011), consuming significantly less time (t = 9.329, P < 0.0001) and support provided to septum could be assessed visually when compared to anterior nasal packing. During immediate post-operative period and while pack removal, nasal septal clip had significantly less complications (P < 0.001). Follow-up complications like septal haematoma, synaechiae & septal perforations were lesser in nasal septal clip group

Conclusions: During intra-operative period, immediate post-operative period, during nasal pack removal and during follow-up period nasal septal clip provided technical superiority, smooth post-operative experience and lesser complications compared to anterior nasal packing proving nasal septal clip to be a better choice for nasal packing. Limitations of NSC are its availability and cost.

Keywords: Deviated nasal septum, Anterior nasal packing, Nasal septal clip, Septoplasty, Submucosal resection

INTRODUCTION

Septoplasty and submucosal resection (SMR) are one of the most common and earliest learned otolaryngologic operations. For many decades, nasal packing was routinely performed following submucosal resection & septoplasty. This practice was based on the assumption that packing would result in good flap apposition and minimize the risk of complications such as bleeding, septal hematoma, and adhesion formation.¹

Postoperative nasal packing after septal surgery, itself caused patient distress, pain and secondary bleeding during removal.² Nasal packing has also been reported to cause edema of the nose and peri-orbital area, excessive lacrimation, sleeplessness, dry mouth and even cardiopulmonary complications.²

Different alternatives like BIPP, gels, vaseline gauze, merocel, antibiotic guaze have been tried to minimize the effects of nasal packing³. Various absorbable materials have been marketed to obviate the need for removal of

packing. These products include modified hyaluronan, bovine gelatin mixed with thrombin, platelet-rich gels and tissue adhesives. However, biocompatibility and cost issues have been raised.⁴

Later at the end of century, to get out of this customary packing alternative techniques like through and through suturing using absorbable sutures.⁵ Absorbable stapels, septal splints with qulting sutures, septal magnets, septal clips etc have been introduced but none could be standardized because of their individual merits and demerits.

Hence, we conducted a prospective randomized controlled trial to compare the customary vaseline soaked ribbon gauze packing to that of nasal septal clip (NSC) (Figure 1) to provide functional septal support to the operated nasal septum as a means of nasal packing in post SMR and septoplasty surgeries.



Figure 1: Nasal septal clip (NSC).

Hence this study is done to test the effectiveness and comparing the anterior nasal packing and nasal septal clips following septoplasty/submucous resection.

METHODS

Study design

Prospective randomized controlled trial. The study was conducted in the Department of Otolaryngology at Vijayanagara Institution of Medical Sciences, Bellary. The study was conducted over a period of November 2014 to May 2016. Ethical clearance was obtained from the ethical committee of Vijayanagara Institution of Medical Sciences, Bellary.

The patients who presented to Otolaryngology OPD with history of nasal obstruction and who fulfilled our inclusion and exclusion criteria were enrolled in the study. All the patients were thoroughly evaluated clinically (ENT and systemic examination) and relevant hematological, serological and radiological investigations were done. The patients were explained about the study

in their understandable language and a written consent was obtained. A total of 100 patients who gave consent were enrolled in the study. By adopting sealed envelope technique, the patients were randomly allotted into two groups of 50 patients each for either anterior nasal pack (ANP Group) or nasal septal clip (NSC Group) as a mode of nasal packing following SMR or septoplasty surgery. After completion of SMR or septoplasty surgery, while the patient was still under anaesthesia, nasal packing on operated septum was done after achieving complete haemostasis between nasal septal flaps and nasal cavity. Further, both sides of the nose were packed with either by Nasal Septal Clip (for NSC group Figure 2) or with vaseline soaked ribbon guaze (for ANP group Figure 3). The interventions were done following standard procedures and data was collected by using a pre-tested and edited proforma.^{6,7,8}



Figure 2: Nasal septal Clip (NSC Group).



Figure 3: Nasal packing vaseline gauze (ANP Group).

Inclusion criteria

Patients aged 18 years and above irrespective of gender, patients presenting with history of nasal obstruction due to deviated nasal septum (DNS) and qualifying to

undergo SMR or septoplasty, patients who gave written consent to participate in the study.

Exclusion criteria

Patients undergoing septoplasty or SMR surgery with Endoscopic sinus surgeries, trans-septal procedures or septorhinoplasty.

Description and insertion techniques of nasal packs

In the nasal septal clip (NSC) group, after completion of surgery the flap was given a horizontal incision at lower border of mucoperiosteal flap on one side to drain any residual blood if any collection occurs between septal flaps. A cut was given along the dotted line in the middle of the soft rubber splint; the splint was lubricated with a Neosporin ointment. Using a dressing forceps the splint was gently inserted by crimping the split splint through the nostrils and then along the floor of the nasal cavity and manipulated to pass medial to middle and inferior turbinate to approximate both the flaps on both the sides. A thread is passed into the holes in the splint and tied loosely in front of columella, then holding the thread loop, the septal clip is held open by the nasal speculum and is introduced over the splint to make sure that metallic septal clip does not touch the mucosa and to maintain equal pressure on both sides of nasal septal flaps and to maintain the septum in corrected position .Finally post nasal bleeding was checked to confirm haemostasis before the patient was shifted to recovery.

In anterior nasal packing (ANP) group, after completion of surgery nasal packing was done using vaseline soaked ribbon guaze pack was inserted to fill the nasal cavity stacked layer by layer from floor to roof gently without traumatising the nasal mucosa to approximate and support the nasal septal flaps on both the sides .Post nasal bleeding was checked for haemostasis before the patient was shifted to recovery.

During nasal packing the technical aspects such as availability, time required and the ease of insertion was noted. Post operatively, all patients were given systemic antibiotics and analgesics and monitored in post-op ward for next 24 hrs and data collected as per pre-tested and edited proforma. During the postoperative period, subjective signs and symptoms like headache, epiphora, dysphagia, disturbance of sleep, bleeding etc suffered in immediate postoperative period to 1st 24 hours were noted and tabulated. Two days later, all patients had both types of packing removed in the minor OT without prior anaesthesia or analgesia and data collected as per proforma for subjective signs symptoms suffered during pack removal. Then the patients were followed up for a period of 1 month and complications noted and data collected as per the proforma .Patients were given a reminder about follow-up before date by telephonic conversation.

Data analysis

The data collected was tabulated and analysed using descriptive statistics, Student-t test and chi- square test.

Ethical clearance was obtained from the "Ethical clearance committee" of Vijayangara Institution of Medical Sciences, Bellary.

RESULTS

Out of 100 patients, 39 (39%) were females and 61 (61%) were males. The mean age of the female patients was 26.7 years and the mean age of male patients was 26.4 years. On comparison of age among males and females t = 0.156, P = 0.8762 (P > 0.05) hence there is no statistical significant difference of age among males and females as shown in Table 1.

Table 1: Distribution of cases according to age and sex.

Age	Fema	Female			Total	
(Years)	No.	%	No.	%	No.	
18-20	15	38.5	21	34.4	36	
21-30	14	35.9	27	44.3	41	
31-40	6	15.4	5	8.2	11	
41-50	3	7.7	7	11.5	10	
>50	1	2.5	1	1.6	2	
Total	39	100	61	100	100	

Student t test: t = 0.156, P = 0.8762 (P > 0.05), Not Significant

Mean age of ANP group patients was 27.86 years and mean age of NSC group was 25.24 years. Comparing age in the groups of ANP & NSC by student-t test shows t=1.333~&~P=8.1855~(P>0.05). Hence the age wise distribution of nasal packing was not statistically significant as shown in Table 2.

Table 2: Distribution of cases according to the age and nasal packing.

Age	Age ANP		NSC		Total
in years	No.	%	No.	%	No.
18-20	18	36	18	36	36
21-30	16	32	25	50	41
31-40	8	16	3	6	11
41-50	7	14	3	6	10
>50	1	2	1	2	2
Total	50	100	50	100	100

Student-t test: t=1.333 & P=8.1855 (P>0.05). Not Significant

64 (64%) had anterior deviation of nasal septum and underwent septoplasty, while 36 (36%) had posterior deviation and underwent SMR as shown in Table 3.

Table 3: Distribution of cases according to type of septal deviation.

	Male		Female		Total
Type of deviation	No.	%	No.	%	No.
Anterior deviation	45	73.8	19	48.7	64
(Septoplasty)					
Posterior deviation	16	26.2	20	51.3	36
(SMR)					
Total	61	100	39	100	100

Intraoperatively vaseline soaked ribbon gauze packs were available in operation theatre, whereas nasal septal clips were made available from the manufacturer. As insertion of pack was concerned it was easy to introduce NSC in 94% of cases compared to 90% in case of ANP which was not a significant difference. Lesser trauma to mucous membrane was observed NSC group than ANP group which was statistically significant. NSC consumed significantly less time than ANP as shown in Table 4.

Table 4: Intra operative nasal packing technique and findings.

Intra operatively	ANP	NSC	Statistical test
Ease of insertion (Yes, easy)	45 (90%)	47 (94%)	Chi Square Test $X^2 = 0.543$ P = 0.461 Not Significant
Trauma to mucous membrane (Yes)	12 (24%)	3 (6%)	Chi Square Test $X^2 = 6.353$ $P = 0.011$ Significant
Time required (minutes)	Mean & SD 4.26 <u>+</u> 1.16	Mean & SD 2.12 <u>+</u> 1.14	Student t test t = 9.329 P < 0.0001 Highly significant

Visual assessment of B/L pressure was possible with the NSC as the pressure is constant and predetermined as per the make whereas with ANP this was not so because the volume of gauze could fill any of the croner of nasal cavity.

The analysis of post-operative symptoms showed that the post-operative symptoms like headache, epiphora, dysphagia, sleep disturbances, bleeding and sense of discomfort were lesser in NSC group & the observations were statistically significant as shown in Table 5.

Table 5: Postoperative subjective signs & symptoms.

Post-	ANP)	NSC		Chi Square	
operative symptoms	No.	%	No.	%	test (X ²)	
Headache	45	90	9	18	$X^2 = 52.17,$ P < 0.001, HS*	
Epiphora	50	100	7	14	$X^2 = 75.44,$ P < 0.001, HS*	
Dysphagia	38	76	5	10	$X^2 = 44.43,$ P < 0.001, HS*	
Sleep disturbance	38	76	9	18	$X^2 = 33.76,$ P < 0.001, HS*	
Nasal Bleeding	25	50	7	14	$X^2 = 14.89,$ P < 0.001, HS*	
Sense of discomfort	46	92	11	22	$X^2 = 49.98,$ P < 0.001, HS*	

*HS = Highly Significant

Analysis of signs & symptoms at nasal pack removal showed that pain and bleeding were lesser in NSC group compared to ANP group and this difference was statistically highly significant as shown in Table 6.

Table 6: Signs & Symptoms at nasal pack removal.

Findings at nasal	pack	ANP		NSC		Chi Square test (X²)
removal		No.	%	No.	%	
Pain		50	100	5	10	$X^2 = 19.048, P < 0.001, HS^*$
Bleeding		15	30	5	10	$X^2 = 6.25, P < 0.0124, HS^*$

*HS = Highly Significant.

Table 7: Follow-up findings.

E-11 6' 1'	ANP	ANP			— Eishaula Easad Tard	
Follow-up findings	No	%	No	%	Fisher's Exact Test	
Synaechiae	7	14	0	0	P = 0.012	
Septal haematoma	4	8	1	2	P > 0.05	
Septal perforation	2	4	1	2	P > 0.05	
Necrosis of mucous membrane	1	2	0	0	P > 0.05	

After the follow-up of the patients at 1 week, 2 week and one month interval it was observed that complications like septal haematoma, synaechiae & septal perforations were lesser in NSC group when compared to ANP group. Synaechiae was statistically significantly lesser with NCS than ANP as shown in Table 7.

DISCUSSION

Age and sex distribution

In our study 61% of our study population were males & 39% were females, with mean age of males and females being 26.4 & 26.7 years respectively. In a study conducted by Udgir et al 52% were males & 48% were females, with mean age of males and females being 27.8 & 25.1 years respectively. 969% were males and 31% were females in a study done by Veluswamy et al. 10 The observed mean age in study conducted by Ardehali et al was 24.6 years. 11

As far as age is concerned DNS might affect any age group according to "Trauma and Birth Molding" theory. SMR is done above 16 years as not to interfere with natural growth of the facial bony skeleton and septoplasty is done in any age group but with extra precaution.

In our study we selected the age group 18 years and above, as patients this age group forms a better compliance in terms of giving accurate subjective signs and symptoms suffered in the immediate postoperative period and in follow up period. The other reason would be that the nasal septal clips are available in sizes to fit this age group. As far as ANP is considered it can be done in any age group.

Intra-operative Nasal Packing Technique

The vaseline soaked ribbon guaze packs were freely available in operation theater (OT) and nasal septal clips was made available from the manufacturer hence increasing the cost.

As insertion of pack was concerned it was easy to introduce NSC in 94% of cases compared to 90% in case

of ANP which was not a significant difference. Similar observations were made in the study conducted by Udgir et al.⁹

Mean time consumed for ANP and NSC were was 4.26 ± 1.16 and 2.12 ± 1.14 minutes respectively. The time consumed for NSC was significantly lesser compared to ANP (P < 0.0001). Similarly significantly lesser time consumption for NSC was observed by study done by Udgir et al (P < 0.001).

In ANP group, the vaseline soaked ribbon guaze pack filled the uneven contours of the nasal cavity and hence B/L equality of pressure could not be assessed visually. In the NSC group, the nasal septal clip gives enough room to visualize the nasal cavity to assess B/L equality of pressure on the corrected septum. Hence NSC is better compared to ANP in giving visual access to nasal septal support and pressure.

Statistically significant less trauma to mucous membrane was observed in NSC compared to ANP (P = 0.011) but in a study done by Udgir et al no much difference in the trauma was observed between the groups.⁹

In comparison NSC is found to be technically superior over ANP because of the above advantages except the cost.

Observed immediate postoperative signs and symptoms in ANP group

In our study in ANP group, we noted Headache in 90%, Epiphora in 100%, Dysphagia in 76%, Sleep disturbance in 76%, bleeding in 50%, Sense of discomfort in 92% of patients. Similar observations were made in study done by Udgir et al and Veluswamy et al. 9,10 The postoperative complaints can be attributed to the effect of complete block of nasal cavity and pressure of the ANP on Lateral wall of the nose. Dysphagia attributed to Toynbee phenomenon, was significantly high in packed patients. If patient swallows when nasal passages are blocked, air cannot pass anteriorly and it is insufflated to middle ear. This unpleasant feeling results in poor oral intake while packs are in place as shown in Table 8.

Table 8: Studies related to postoperative signs and symptoms.

Postoperative	Anterior Nasa	al Packing		Nasal Septal	Nasal Septal Clip			
findings	Our study	Udgir et al ⁹	Veluswamy et al ¹⁰	Our study	Udgir et al ⁹	Veluswamy et al ¹⁰		
Headache	90 %	92%	72.5%	18 %	20%	15%		
Epiphora	100 %	100%	100%	14 %	12%	7.5%		
Dysphagia	76%	80%	95%	10 %	0%	5%		
Sleep disturbance	76%	80%		18 %	16%			
Bleeding	50%	0%	7.5%	14 %	20%	0%		
Sense of discomfort	92%	92%		22 %	4%			

Table 9: Studies related to signs and symptoms at pack removal.

At pack	Anterior Nas	sal Packing		Nasal Septal Clip			
removal	Our study	Udgir et al ⁹	Awan et.al ¹²	Our study	Udgir et al ⁹	Veluswamy et al ¹⁰	
Pain	100%	100%	97.80%	10 %	8%	Reported lesser pain	
Bleeding	30%	16%		10%	8 %	(VAS scale) and bleeding in NSC than ANP	

Table 10: Studies related to follow up complications.

Follow up for 1wk,	Anterior Na	asal Packing		Nasal Septal		
2wk and 1 month	Our study	Udgir et al ⁹	Awan et.al ¹²	Our study	Udgir et al ⁹	Veluswamy et al ¹⁰
Necrosis of mucous membrane	2 %	4%	57%	0 %	0%	Reported to have encountered lesser
Septal haematoma	8 %	4%	7%	2 %	4%	late complications
Synaechiae	14 %	8%	18%	0 %	4%	in NSP group than
Septal perforation	4 %	0%		2 %	0%	ANP

Observed immediate postoperative signs and symptoms in NSC group

In our study in NSC group we noted Headache in 18%, Epiphora in 14%, Dysphagia in 10%, Sleep disturbance in 18%, bleeding in 14%, Sense of discomfort in 22%. Similar observations were made in study done by Udgir et al and Veluswamy et al. 9,10

In the above mentioned studies, a lesser and statistically significant post-operative signs and symptoms were experienced by the patients with Nasal Septal Clip when compared to Anterior Nasal Packing. This shows that NSC provides better and smooth post-operative experience than ANP which is an added advantage of NSC as shown in Table 8.

In our study, pain and bleeding during pack removal was observed in 100% and 30% of patients respectively in ANP group while only 10% of patients experienced pain and bleeding in NSC group. This observed difference was statistically significant as shown in Table 9.

In similar study done by Udgir et al pain and bleeding was observed in 100% and 16% of patients respectively in ANP group while only 8% of patients experienced pain and bleeding in NSC group. Awan et al observed pain in 97.8% in ANP. Similarly Veluswamy et al observed less pain perception in NSC group compared to ANP group in VAS Scale as shown in Table 9. 10

This statistically significant and lesser pain and bleeding during pack removal with NSC compared to ANP proves it to be a better packing method.

The proportions of follow-up complications as observed in our study and the studies done by Udgir et al, Awan et al in both ANP and NSC group. 9,12 Similarly Veluswamy et al has reported to have encountered lesser late complications in NSP group than ANP. 10 The above data

shows that nasal septal clip has lesser complications compared to anterior nasal packing. Synaechiae was statistically significantly lesser in NCS when compared to ANP as shown in Table 10.

Similar to other studies, in our study we have noted lesser complications in NSC group than ANP group (though may not be statistically significant). This could be because the packs exert pressure on both the septum and lateral wall of nose when compared to NSC which exerts pressure on the septum only and the pressure induced is less than the capillary pressure as per the make. So NSC has lesser follow up complications than ANP.

CONCLUSIONS

- Intra-operatively: NSC was easy to insert, causes less trauma to mucous membrane and less time consuming than ANP.
- Immediate postoperative complaints were significantly lesser with NSC when compared to ANP which gave smooth post-operative experience.
- Lesser pain and bleeding was experienced with NSC compared to ANP during pack removal
- NSC had lesser complications during follow-up period than ANP.

So during intra-operative period, immediate postoperative period, during nasal pack removal and during follow-up period nasal septal clip provided technical superiority, smooth post-operative experience and lesser complications compared to anterior nasal packing proving nasal septal clip to be a better choice for nasal packing over ANP. Limitations of NSC are its availability and cost as compared to ANP

ACKNOWLEDGMENTS

We acknowledge the support of VIMS, Bellary, all the staff of Department of ENT, VIMS Bellary & all the

patients who agreed to participate in the study with their full co-operation.

Funding: No funding sources Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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Cite this article as: Kurle G, Patil SV, Manjunath N. A comparative study between nasal clips and anterior nasal packing in septoplasty/submucosal resection patients at VIMS Bellary, Karnataka. Int J Otorhinolaryngol Head Neck Surg 2017;3:364-70.