# Comparative Study between lateral laminectomy and conchoplasty in the surgical treatment of symptomatic middle turbinate Concha Bullosa

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# ABSTRACT

**Objective:** To evaluate and compare the short term outcomes of lateral laminectomy (partial turbinectomy) and conchoplasty (turbinoplasty) techniques in the surgical treatment of symptomatic middle turbinate concha bullosa. **Background:** Concha bullosa (pneumatized nasal turbinate) is one of the most common anatomical variants of the lateral nasal wall which occurs mainly at the middle turbinates.

The effective method to control symptomatic Concha bullosa is mainly surgical via various techniques.

**Patients and Methods:** This prospective study was carried out on 40 patients from October 2016 till April 2018. All patients who were presented with symptomatic concha bullosa, and then subjected to preoperative clinical, endoscopical, radiological assessment and by using an evaluation tests. Patients were divided equally and randomly into two groups, group A for lateral laminectomy and group B for conchoplasty, and all of them were arranged to postoperative re-evaluation follow up visits after 3 and 6 months.

**Results:** The mean age group of our studied patients was  $31.8 \pm 8.4$  years. (37.5%) of patients were male, while (62.5%) of them were female. The most recorded postoperative complications in group A were development of nasal crustations (35%) and synechia formation (20%),the postoperative minimal epistaxis was more in group A (15%) than in group B (5%).

**Conclusion:** Conchoplasty is an effective, safe and conservative procedure for the surgical treatment of symptomatic concha bullosa with anatomical and physiological preservation of the middle turbinate.

Key Words: Concha bullosa, middle turbinate, partial turbinectomy, turbinoplasty.

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## **INTRODUCTION**

Middle nasal turbinates are important anatomical landmark structures of the lateral nasal wall which projecting form the lateral masses of ethmoid bones. that have an important physiological vital functions as deflection of inspired air upwards to reach the olfactory epithelium, lamination of air flow, heating and humidification of inspired air<sup>[1]</sup>. The middle turbinate do not contain air cells, sometimes they are pneumatized as an extension of pneumatization process at its ethmoidal origin, this results in a phenomenon known as Concha Bullosa (CB) which firstly named by Zuckerkandl in 1882. CB is considered one of the most common variants of sinonasal and osteomeatal complex (OMC) regions ,which occurring in about 38% ( range 14% - 53% ) of people<sup>[2,3,4]</sup>. The exact reason of the pneumatization of the middle nasal turbinate, is still unclear, but there are some studies

suggest a possible genetic component ,trauma, intrauterine event, perinatal or postnatal developmental defects and maxillary growth abnormalities<sup>[5]</sup>. Although in vast majority of cases were asymptomatic, an extensive middle turbinate pneumatization can result in contact rhinogenic headache and narrowing of the drainage pathways of the anterior paranasal sinuses with subsequent obstructive nasal symptoms. It may also result in impairment of intraoperative endoscopic access to the osteomeatal complex area<sup>[6]</sup>. Middle Concha Bullosa (MCB) was classified into three main subtypes: vertical or lamellar type, inferior or bulbous type and mixed or extensive type<sup>[7]</sup>. Asymptomatic cases requires no treatment, but surgery is a definitive treatment for symptomatic types of concha bullosa, which may undertaken by various techniques as crushing, conchopexy, turbinectomy and turbinoplasty<sup>[6,8]</sup>.

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### PATIENTS AND METHODS

This prospective randomized controlled study was carried out on 40 patients who were presented to outpatient clinic of ENT department of Menoufia University Hospital with symptomatic concha bullosa, from October 2016 till April 2018. This study was approved from the institutional ethical committee of Menoufia University Hospital's Review Board, also written consents from all patients were taken before the beginning of this study. Patients of this study had complaining mainly of headache, nasal obstruction or both without significant improvement on various medications as analgesics and anti-migranous drugs, till the time of this study. Patients with asymptomatic CB, previous nasal surgery, chronic rhinosinusits with or without nasal polyposis, allergic rhinitis, age under 18 years and those with debilitating disease or considered unfit for surgery were excluded from this study. All patients who had complaning of headache were assessed preoperatively via topical anesthetic test by application of cotton pack containing xylocaine 2% inserted between an areated middle turbinate and the lateral nasal wall and also between the same turbinate and the adjucent portion of nasal septum, lasting for 10 minutes. This test was considered positive if persistant pain reduced by about 50% or more after 5 minutes. Patients with positive topical xylocaine test were only included in this study. All patients were subjected to preoperative full history taking, full ENT clinical examination, rigid nasoendoscopic assessment, radiological CT scanning of the nose and paranasal sinuses (Multidetector CT Scanner, GE Healthcare, USA, Light Speed Ultra 8 Slice, Thin cuts 2 mm), and by evaluation tests VAS (Visual Analogue Score) and SNOT-22(Sino-Nasal Outcome Test-22). The patients of this study then were divided equally and randomly into two groups, group A for lateral laminectomy and group B for conchoplasty, and all of them were arranged to postoperative re-evaluation clinically, endoscopically and by evaluation tests after 3 and 6 months.

#### **Operative technique:**

All surgical procedures were performed using zero degree rigid nasoendoscope under general anathesia, after an preoperative preparation by application of cotton soaked in 1:1000 adrenaline solution via packing forceps to be placed in the middle meatus between middle turbinate and lateral nasal wall and also medially between middle turbinate and adjucent part of the nasal septum , left for about 10-15 minutes , then starting the submucosal injection of 1 ml of 2% xylocaine / oxymetazoline into the antero-inferior surface of concha bullosa as shown in figure (1). For lateral laminectomy, the anterior and lateral parts of the pneumatized middle turbinate, including both the covering mucosa and underlying bone, were removed by leaving back only the inferio-medial half of the middle turbinate<sup>[3]</sup>.

According to conchoplasty technique, following a midline incision of an areated middle turbinate with a sickle knife, which was done at the inferior and anterior end of the

turbinate in the saggital plane direction. This incision was then prolonged posteriorly, as much as possible as shown in figure (2). Starting from the incision line, and by careful dissection, a plane between the bony walls of the concha bullosa and its mucoperiosteal covering was created with subsequent formation of superiorly and posteriorly based mucosal flaps medially and laterally, which then was raised untill the bony lateral lamella could be removed using Blakesley forecepes as shown in figure (3).The mucosal flaps were reposited with application of gel film, so reducing the size of the turbinate, without disturbance of its covering mucosa and retaining its original shape.

#### Statistical analysis

Statistical calculations and data analysis of this study was done using Statistical Package for the Social Sciences (SPSS V 17), IBM Corp, Armonk, NY, USA. Mean value and Standard Deviation (SD) were used for quantitative data, and Frequency and percentage for qualitative data. Paired Student *T-test* was used to compare between related samples, while Unpaired Student *T-test* was used to compare between two groups in quantitative data. Chi square test was used to compare between two independent qualitative variables.

## RESULTS

A total of 40 patients included in this study were between 18 - 48 years old, the mean age group of the patients was  $(31.8 \pm 8.4)$ . In this study, there were 15 males (37.5%) and 25 females(62.5%) of the patients who 45% of them were from rural and 55 % were from urban areas.(table 1) Our study showed that the mean VAS of preoperative headache assessment in both groups were slightly different, as the mean preoperative VAS in group A was  $(80.0 \pm 8.2)$ , while the mean VAS in group B was ( $87.8 \pm 6.8$ ). After 3 months postoperatively, headache assessment by VAS in group B showed highly significant decrease in headache intensity (from 87.8  $\pm 6.8$  to 20.8  $\pm 11.6$ ), which more than that of group A (from 80.0  $\pm$ 8.2 to 39.0  $\pm$ 20.2). (table 2,4) After 6 months, the mean VAS in group B continued to decrease significantly (the mean VAS was  $10.8 \pm 2.9$ ) with (P = 0.009), while in group A (the mean VAS was  $25.0 \pm 26.8$ ) which was not significant statically (p = 0.20). (table 3,5)

The mean VAS of preoperative nasal obstruction assessment in group A was (51.0  $\pm$ 7.4), while in group B was (47.5  $\pm$ 7.1). After 3 months postoperatively, nasal obstruction assessment by VAS in group B showing significant improvement (87.8  $\pm$ 11.3) which more than that of group A (67.0  $\pm$  6.7). (table 6,8) Postoperative 6 months, the assessment of nasal obstruction by VAS in both groups showed non significant improvement as the mean VAS in group A was (71.0  $\pm$ 8.8) which was not significant (P = 1.15), and in group B the mean VAS was (85.0  $\pm$ 7.6) with (p= 0.21). (table7,9). According to the assessment of nasal obstruction 3 months postoperatively by SNOT-22 was (2.6  $\pm$  0.8) in group A while in group B was (1.9  $\pm$  0.6) which showed significant improvement (p=0.0001) slightly more in group B than goup A. (table 10,12) After 6 months postoperatively, the mean SNOT-22 results of both groups showed non significant impovement  $(2.0 \pm 0.7)$  in group A and  $(1.4 \pm 0.5)$  in group B with (P<0.05) which was non significant.(table 11,13). According to duration of operation, there was a statically significant difference between both groups as the mean time by minutes of group A was  $(21.3\pm5.1)$ , while was  $(45.3\pm12.0)$ in group B with (p=000.1) which was highly significant. (table 14) The main postoperative recorded complications in group A were development of nasal crustations (35%), and synechia formation (20%), while postoperative minimal epistaxis was developed in (15%) in group A ,but was only (5%) in group B. No synechia formation was recorded in patients of group B but (15%) of patients of this group had developed nasal crustations. (table 15) No other significant complications detected at this short term postoperative follow up visits .The overall outcome results in this comparative study showing significant improvement of the symptoms (P<0.05) in the patients of group B than in group A.



**Fig. 1:** showing endoscopic view of submucosal injection of 1ml of 2% xylocaine with oxymetazoline into the antero-inferior surface of the right side middle turbinate concha bullosa. MT(middle turbinate), S(septum),LW(lateral wall)



**Fig. 2:** showing endoscopic view of midline vertical incision of antero-inferior surface of the right side middle turbinate concha bullosa by sickle knife (K).



**Fig. 3:** showing (A) endoscopic view of the dissector (D) creating a plane between the lateral bony walls and the mucosal coverings of right middle turbinate concha bullosa and (B) showing subsequent formation of mucoperiosteal flabs till exposing the lateral lamella (L.L) of middle turbinate then removed by Blakeley forceps (B) with reposition of flaps on remained middle turbinate.

 Table 1: Epidemiological study of symptomatic concha bullosa cases

Variables		Total No. of cases $= 40$		
Age (Years)		18 – 48 years old		
$Mean \pm SD$		31.8±8.4		
		No.	%	
Gender	Female	15	37.5 %	
	Male	25	62.5 %	
Residence	Urban	18	45 %	
	Rural	22	55 %	

 Table 2: Preoperative and 3 months postoperative headache

 assessment by VAS in group A

VAS	Patients with headache =10 t-tes		p-value
	Group A Mean ± SD		
Preoperative	80.0 ±8.2	(2(1	0.0001.110
After 3 months	$39.0 \pm 20.2$	0.301	0.0001 HS

P value: NS= Non-significant (P-value > 0.05), S = significant (P -value  $\leq$  0.05 HS= highly significant (P-value  $\leq$  0.001).

**Table 3:** Postoperative headache assessment by VAS after 3 and6 months in group A

VAS	Patients with headache =10	t-test	p-value
	Group A Mean ± SD		
After 3 months	39.0 ±20.2	1 220	0.204 NS
After 6 months	25.0 ±26.8	1.329	0.204 NS

P value: NS= Non-significant (P-value > 0.05), S = significant (P-value  $\leq$  0.05 HS= highly significant (P-value  $\leq$  0.001).

 Table 4: Preoperative and 3 months postoperative headache

 assessment by VAS in group B

VAS	Patients with headache =12	t-test	p-value
	Group A		
	Mean $\pm$ SD		
Preoperative	$87.8\pm 6.8$	22 402	0.0001 HS
After 3 months	$20.8 \pm 11.6$	22.492	

P value: NS= Non-significant (P-value > 0.05), S = significant (P -value  $\leq$  0.05 HS= highly significant (P-value  $\leq$  0.001).

**Table 5:** Postoperative headache assessment by VAS after 3 and6 months in group B

VAS	Patients with headache =12	t-test	p-value
	Group A Mean + SD		
	Mean ± SD		
After 3 months	$20.8 \pm 11.6$	3 020	0.000 \$
After 6 months	$10.8 \pm 2.9$	3.029	0.009 3

P value: NS= Non-significant (P-value > 0.05), S = significant (P -value  $\leq 0.05$  HS= highly significant (P-value  $\leq 0.001$ ).

 Table 6: Preoperative and 3 months postoperative nasal obstruction assessment by VAS in group A

VAS	Patients with nasal obstruction =10	t-test	p-value
	Group A Mean ± SD	-	
Preoperative	51.0 ±7.4	5 246	0.0001
After 2 months	$67.0 \pm 6.7$	5.540	HS

P value: NS= Non-significant (P-value > 0.05), S = significant (P -value  $\leq 0.05$  HS= highly significant (P-value  $\leq 0.001$ ).

 Table 7: Postoperative nasal obstruction assessment by VAS after

 3 and 6 months in group A

VAS	Patients with nasal obstruction =10	t-test	p-value
-	Group A Mean ± SD		
After 3 months	$67.0 \pm 6.7$	1 1 5 2	0.269 Mg
After 6 months	$71.0 \pm 8.8$	1.152	0.208 NS

P value: NS= Non-significant (P-value > 0.05), S = significant (P -value  $\leq 0.05$  HS= highly significant (P-value  $\leq 0.001$ ).

**Table 8:** Preoperative and 3 months postoperative nasalobstruction assessment by VAS in group B

VAS	Patients with nasal obstruction =8	t-test	p-value
-	Group A Mean ± SD		
Preoperative	47.5 ±7.1	( 117	0.0001.110
After 3 months	87.8 ±11.3	0.44/	0.0001 HS

P value: NS= Non-significant (P-value > 0.05), S = significant (P-value  $\leq$  0.05 HS= highly significant (P-value  $\leq$  0.001).

 Table 9: Postoperative nasal obstruction assessment by VAS after

 3 and 6 months in group B

VAS	Patients with nasal obstruction =8	t-test	p-value
	Group A		
	Mean $\pm$ SD		
After 3 months	87.8 ±11.3	1 200	0.213
After 6 months	85.0 ±7.6	1.299	NS

P value: NS= Non-significant (P-value > 0.05), S = significant (P -value  $\leq$  0.05 HS= highly significant (P-value  $\leq$  0.001).

 Table 10: Preoperative and 3 months postoperative nasal obstruction assessment by SNOT-22 in group A

VAS	Patients with nasal obstruction =10	t-test	p-value
	Group A Mean ± SD		
Preoperative	4.2 ±0.8	4.590	0.0001.115
After 3 months	2.6 ±0.8	4.382	0.0001 HS

P value: NS= Non-significant (P-value > 0.05), S = significant (P -value  $\leq$  0.05 HS= highly significant (P-value  $\leq$  0.001).

**Table 11:** Postoperative nasal obstruction assessment by SNOT-22 after 3 and 6 months in group A

VAS	Patients with nasal obstruction =10	t-test	p-value
	Group A Mean ± SD		
After 3 months	2.6 ±0.8	1 795	0.005 NG
After 6 months	2.0 ±0.7	1./85	0.095 NS

P value: NS= Non-significant (P-value > 0.05), S = significant (P-value  $\leq$  0.05 HS= highly significant (P-value  $\leq$  0.001).

**Table 12:** Preoperative and 3 months postoperative nasalobstruction assessment by SNOT-22 in group B

VAS	VAS Patients with nasal obstruction =8		p-value
	Group A Mean ± SD		
Preoperative	4.0 ±0.9	5 215	0.0001.115
After 3 months	1.9 ±0.6	5.215	0.0001 HS

P value: NS= Non-significant (P-value > 0.05), S = significant (P-value  $\leq 0.05$  HS= highly significant (P-value  $\leq 0.001$ ).

**Table 13:** Postoperative nasal obstruction assessment by SNOT-22after 3 and 6 months in group B

VAS	Patients with nasal obstruction =8	t-test	p-value	
-	Group A Mean ± SD	_		
After 3 months	1.9 ±0.6	1 700	1 700 0 109 NG	
After 6 months	1.4 ±0.5	1.709	0.108 INS	

P value: NS= Non-significant (P-value > 0.05), S = significant (P-value  $\leq$  0.05 HS= highly significant (P-value  $\leq$  0.001).

VAS	Duration of the operation By minutes	t-test	p-value
	Group A Mean ± SD		
-Group A ( lateral laminectomy )	21.3 ±5.1	12.02	0.0001 HS
-Group B (conchoplasty)	45.3 ±12.0	13.92	

Table 14: Duration of the operation

P value: NS = Non-significant (P-value > 0.05), S = significant (P -value  $\leq 0.05$  HS = highly significant (P-value  $\leq 0.001$ ).

Table 15: Postoperative complications in each studied groups

Complications	Group A	Group B	Chi- test	P-value
Synechia	4	0		
Crustations	7	3	2.989	0.560 NS
Bleeding	3	1		

P value: NS = Non-significant (*P*-value > 0.05), S = significant (P -value  $\leq 0.05$  HS = highly significant (P-value  $\leq 0.001$ ).

#### DISCUSSION

Concha bullosa, which is a pneumatization of the turbinate, this phenomenon was known to affect mainly the middle turbinate . The incidence of concha bullosa has been reported to be between 8 and 53%9,10. Bolger et al.1991, have classified the pneumatization of the middle concha according to the degree and localization of pneumatization into three groups: lamellar type (pneumatization limited to vertical lamella of the concha); bulbous type (the pneumatization of the bulbous (inferior portion of the turbinate) the third type is the pneumatization of both the lamellar and bulbous parts is called extensive Concha bullosa<sup>[7]</sup>. Lloyd 1990, in his study had shown that concha bullosa was associated with presence of increased infection in the paranasal sinuses<sup>[11]</sup>. Calhoun et al.1991, had found that population with symptoms of sinus disease have significantly greater incidence of concha bullosa<sup>[12]</sup>. So it is important to treat concha bullosa simultaneously during functional endoscopic sinus surgery, not only because it contributes to osteomeatal and sinus disease but also because obstruction of its own drainage can lead to mucocoele formation<sup>[13]</sup>. Many surgical treatments techniques had been explored for the treatment of concha bullosa, especially of the middle turbinate. These include crushing, partial turbinectomy, and conchoplasty. Each of these procedures has its own advantages and disadvantages. Two of the commonly done endoscopic procedures for concha bullosa are lateral partial turbinectomy and conchoplasty<sup>[14]</sup>. In our study, all the patients were with symptomatic middle turbinate concha bullosa, the differences between conchoplasty and lateral laminectomy are studied according to the outcome of surgery. According to distribution of age, Ankit et al.2013, as well as in our study showed that the majority of the patients in both the groups were in the third decade of life<sup>[14]</sup>. This is

comparative to the age distribution reported by Hatipoglu et al.2005<sup>[15]</sup>. Among 72 patients underwent laminectomy for managment of the aerated middle turbinate then studied by Kumral et al.2015, the mean age the patients was  $31.03 \pm 9$  with a range of 17 to 54 years8 .Another Fortytwo patients came with conchae bullosae were included in a study conducted by Eren et al. 2014. All of them underwent septoplasty and they were divided into 2 groups: Group one for crushing technique and Group two for crushing with intrinsic stripping. Mean age of the patients were 52.7 ranging from 18 to 41 years in Group one, and 24.2 ranging from 18 to 33 years in Group two16. In our studied cases. There was female predominance among patients with concha bullosa as what mentioned by Hatipoglu et al.2005. He reported in his study that female were about 57.3% of total cases. This is contrary to other studies wherein a male preponderance has been reported as with study of Mehta 2013, that comprised of 36 patients in his study. Out of which 20 (55.6%) were male and 16 (44.4%) female<sup>[13]</sup>. Among 72 cases studied by Kumral et al.2015, forty of them (55.6%) were men and 32 (44.4%) were women. Ankit et al.2013, showed that there were 22 (35%) female and 41 (65%) males. This discrepancy could be due to small sample size or could also be due to the fact that only patients who came for a minimum 6 months of postoperative follow up were included in the study. We studied headache and nasal obstruction as the main presenting symptoms in patients with concha bullosa. In this study, using preoperative and postoperative subjective evaluation tests that had been validated by many studies, VAS as a test for headache assessment, while VAS and SNOT22 tests for nasal obstruction. Our study showed that there was no major difference between both studied groups in the mean preoperative headache by VAS, while the postoperative headache assessment by VAS after 3 months showed statistically significant improvement which was more in conchoplasty group than lateral laminectomy group .After 6 months, the postoperative headache assessment shows continuous significant improvement only in conchoplasty group, while in the other group this improvement was statistically non significant . As well as Osama AA.et al.2012, had studied 60 patients who underwent partial lamellectomy and conchoplasty for management of contact-point rhinogenic chronic headache resulting from middle turbinate concha bullosa over three years, had concluded that there was no statistically significant difference in the results of the preoperative pain intensity on comparing the surgical groups. However, the difference in the follow-up results was statistically significant with p-value =0.03, both at 6and 12-months postoperatively using VAS test. In the conchoplasty group, pain intensity decreased significantly from a preoperative level of  $82 \pm 6$  to  $28 \pm 5$  at 6 months postoperatively with p-value = 0.001 and decreased slightly, but not significantly, to  $26\pm7$  at the 12-month. Likewise, in the lamellectomy group, pain intensity decreased significantly from 84  $\pm 2$  preoperatively to 34  $\pm 8$  at the 6-months, but was  $31 \pm 4$  at the end of the first year which

was not significant<sup>[17]</sup>. According to nasal obstruction, Ankit et al. 2013, had studied the outcome of 63 patients who complaining mainly from nasal obstruction, and then underwent lateral partial turbinectomy and conchoplasty, there was complete cure or significant reduction in severity of complaints in 29 out of the 38 patients who underwent lateral partial turbinectomy, but in the conchoplasty group 21 out of the 25 patients were significantly symptom free at the end of follow up period of 3 month postoperative. We found out that there were no major differences between both groups at the mean preoperative assessment of the nasal obstruction either by VAS or by SNOT22 test. The 3 months postoperative assessment of nasal obstruction by both VAS and SNOT-22 showed significant improvement in patients of lateral laminectomy group less than those of conchoplasty group, while the postoperative 6 months assessment of both groups by VAS and SNOT-22 showed statically non significant improvement. According to the same study by Ankit et al. 2013, even the post operative symptom improvement profile is more or less same between the two groups, the main difference shows up in terms of incidence of postoperative complications; where there were no complications in the conchoplasty group. In our study, however all the patients of the conchoplasty group had not developed any postoperative adhesions or synechia, but the operative time for conchoplasty was longer than time for lateral laminectomy ,which was statically significant. Also the postoperative development of nasal crustaions and minimal bleeding had been noticed in this group even these complications were still less than those of the lateral laminectomy group. The rate of postoperative synechia development in lateral laminectomy group was 20% according to our results. Har-El and Slavit.1996, had described a turbinoplasty technique and reported a minimal synechia rate of 6.9% (3 of 43cases) which significantly decreased the need for postoperative cleaning compared with partial lateral turbinectomy18. Dog ru et al. 2001, in their study, had reported that there was minimal synechia detected in three of 31 cases (9.7%) , which was significantly less than lateral turbinectomy<sup>[19]</sup>. Havas and Lowinger.2000, had shown slight smell outcome benefit in their middle turbinate resection group and no iatrogenic hyposmia<sup>[20]</sup>. Osama AA et al. 2012 in their study had recorded that Postoperatively, 2 patients in the lamellectomy group had been reported with reduced olfactory capacity . In our study, we cannot comment on about any concern of the smell since we did not measure smell quantitatively but none of our cases had anosmia or hyposmia postoperatively. Our outcome results were concomitant with that of Osama AA et al. 2012, and Sigston et al.2004, who tried a modification to partial lateral turbinectomy after extracting the bony lamina of concha using the lateral posteriorly pedicled mucosal flap of the concha covering the raw surface area of the medial lamella, as they hypothesized that maintaining the mucosa with its secretory elements decreases the risk of postoperative adhesions , atrophic symptoms and avoids smell disorders<sup>[21]</sup>.

#### CONCLUSION

We concluded that CB surgery is simply aiming to reduce the size of the pneumatized turbinate with minimal surgical morbidity, so according to this and to our postoperative outcome results, most of comparative parameters were guided us to ensure that conchoplasty was more advantageous than lateral laminectomy because it had minimal mucosal injury and also provide an effective ,safe and conservative alternative procedure not only for controlling the main symptoms of symptomatic concha bullosa, but also to provide a good preservation of anatomical and physiological functions of the middle turbinate which considered one of the most important landmark structures of the lateral nasal wall.

# **CONFLICT OF INTEREST**

There are no conflict of Interest.

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