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Comparison of the efficacy and adverse effects of bipolar radiofrequency turbinate reduction with and without lateral outfracture in the treatment of inferior turbinate hypertrophy: A randomized controlled trial

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Comparison of the efficacy and adverse effects of bipolar radiofrequency turbinate reduction with and without lateral outfracture in the treatment of inferior turbinate hypertrophy: A randomized controlled trial

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Background : *Radiofrequency inferior turbinate reduction has been proven to reduce the volume of the inferior turbinate. The aim of lateral outfracture of the inferior turbinate is to displace the position of the inferior turbinate laterally which makes the nasal cavity wider. The efficacy of the lateral outfracture is questionable. However, some authors usually combine lateral outfracture of the inferior turbinate with other techniques of inferior turbinate reduction.*

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- Objective** : *To compare efficacy and adverse effects between bipolar radiofrequency turbinate reduction with lateral outfracture (BRTR with LO) and bipolar radiofrequency turbinate reduction alone (BRTR alone) in chronic rhinitis patients with inferior turbinate hypertrophy.*
- Setting** : *Department of Otolaryngology, King Chulalongkorn Memorial Hospital*
- Research design** : *Randomized controlled trial*
- Material and Methods** : *Fifty patients were enrolled. Intervention was randomized and performed by BRTR with LO or BRTR alone. Nasal obstruction symptom on postoperative week 8, total nasal volume on postoperative week 8 and adverse effects were compared. The outcome assessor, who was not the surgeon, and the patients were blinded to the treatment allocation.*
- Results** : *Means \pm SD of the preoperative and postoperative week 8 nasal obstruction symptom scores in BRTR with LO group were 7.13 ± 1.26 and 1.60 ± 1.40 , respectively. In BRTR alone group, there were 7.03 ± 1.55 and 1.11 ± 1.36 , respectively. Medians (IQR) of the nasal obstruction symptom on week 8 in BRTR with LO and BRTR alone groups were 1.40 (0.35 - 2.55) and 0.70 (0.05 - 1.70), respectively. The difference did not have statistical significance ($p = 0.100$). Means \pm SD of the nasal volume on postoperative week 8 in BRTR with LO and BRTR alone groups were 9.97 ± 1.84 and 10.11 ± 2.24 , respectively. The difference did not have statistical significance ($p = 0.822$), Medians (IQR) of the intraoperative pain in BRTR with LO and BRTR alone groups were 2.30 (0.50 - 4.90) and 0.90 (0.15-6.25), respectively. The difference did not have statistical significance ($p = 0.600$), Medians (IQR) of the postoperative pain day 1 in BRTR with LO and BRTR alone groups were 0.60 (0.30 - 2.95) and 0.50 (0.15 - 2.95), respectively. The difference did not have*

statistical significance ($p = 0.669$), Proportions (%) of none/mild/moderate/severe postoperative bleeding in BRTR with LO and BRTR alone groups were = 4/64/28/4 and 20/64/16/0, respectively. The difference did not have statistical significance ($p = 0.214$).

Conclusion : *No statistically significant differences of the efficacy and adverse effects were found between bipolar radiofrequency turbinate reduction with lateral outfracture and bipolar radiofrequency turbinate reduction alone in chronic rhinitis patients with inferior turbinate hypertrophy. Although no statistical significance in adverse effects, severe postoperative bleeding was observed in one patient who underwent bipolar radiofrequency turbinate reduction with lateral outfracture.*

Keywords : *Radiofrequency, turbinate reduction, turbinoplasty, outfracture, lateral outfracture, chronic rhinitis.*

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ทรงกลด เอี่ยมจตุรภัทร, พิชัย ลิ้มปรีชาตีไพบูลย์, ญานินทร จัตตวิวัฒน์, สุพินดา ชูสกุล, จันทิมา พรรณาโส, วลี ตูลวรรณนะ, สงวนศักดิ์ ธนาวิรัตนานิจ. วสันต์ ปัญญาแสง. การศึกษา ประสิทธิภาพและผลข้างเคียงของการผ่าตัดลดขนาดของเทอร์บิเนตอันล่างโดยใช้คลื่น ความถี่วิทยุร่วมกับการหักเทอร์บิเนตอันล่าง เทียบกับการใช้คลื่นความถี่วิทยุอย่างเดียว. จุฬาลงกรณ์เวชสาร 2556 มี.ค. - เม.ย.; 57(2): 131 - 44

เหตุผลของการทำวิจัย : การผ่าตัดลดขนาดของเทอร์บิเนตอันล่างโดยใช้คลื่นความถี่วิทยุ ได้รับการพิสูจน์แล้วว่าได้ผลดี ส่วนการหักเทอร์บิเนตอันล่างไป ด้านข้างจะทำให้ช่องจมูกกว้างขึ้น แต่ยังคงมีข้อสงสัยเกี่ยวกับ ประสิทธิภาพอยู่ อย่างไรก็ตามแพทย์หลายท่านมักใช้การหักเทอร์บิเนต อันล่างไปด้านข้างร่วมกับการผ่าตัดลดขนาดของเทอร์บิเนตอันล่าง โดยใช้คลื่นความถี่วิทยุ โดยคาดว่าผลการรักษาจะดีขึ้นไปอีก

วัตถุประสงค์ : เพื่อศึกษาประสิทธิภาพและผลข้างเคียงของการผ่าตัดลดขนาดของ เทอร์บิเนตอันล่างโดยใช้คลื่นความถี่วิทยุร่วมกับการหักเทอร์บิเนต อันล่าง (BRTR with LO) เทียบกับการใช้คลื่นความถี่วิทยุอย่างเดียว (BRTR alone)

รูปแบบการวิจัย : การศึกษาแบบสุ่ม มีกลุ่มควบคุม (เปรียบเทียบ)

สถานที่ทำการศึกษา : แผนกโสต ศอ นาสิกวิทยา โรงพยาบาลจุฬาลงกรณ์

ตัวอย่างและวิธีการศึกษา : ผู้ป่วยจำนวน 50 คน ได้รับการสุ่มเพื่อทำการผ่าตัดลดขนาดของ เทอร์บิเนตอันล่าง โดยแบ่งเป็น 2 กลุ่ม คือกลุ่ม BRTR with LO กับกลุ่ม BRTR alone โดยเปรียบเทียบประสิทธิภาพในสัปดาห์ที่แปด หลังผ่าตัด และผลข้างเคียงของการผ่าตัดระหว่างกลุ่ม 2 กลุ่มดังกล่าว โดยผู้วัดผลซึ่งไม่มีส่วนเกี่ยวข้องกับการแปลผลการวิจัยครั้งนี้

ผลการศึกษา : ค่าเฉลี่ย \pm ส่วนเบี่ยงเบนมาตรฐานของอาการคัดจมูกก่อนและ หลังผ่าตัด 8 สัปดาห์ ในกลุ่ม BRTR with LO = 7.13 ± 1.26 และ 1.60 ± 1.40 ตามลำดับ ส่วน BRTR alone = 7.03 ± 1.55 และ 1.11 ± 1.36 ตามลำดับ ค่ามัธยฐาน (ค่าพิสัยระหว่างควอไทล์) ของอาการคัดจมูกหลังผ่าตัด 8 สัปดาห์ ในกลุ่ม BRTR with LO และ BRTR alone = $1.40 (0.35 - 2.55)$ และ $0.70 (0.05 - 1.70)$ ตามลำดับ ซึ่งไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.100$), ค่าเฉลี่ย \pm ส่วนเบี่ยงเบนมาตรฐานของ nasal volume หลังผ่าตัด 8 สัปดาห์ ในกลุ่ม BRTR with LO และ BRTR alone = 9.97 ± 1.84

และ 10.11 ± 2.24 ตามลำดับ ซึ่งไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.822$), ค่ามัธยฐาน (ค่าพิสัยระหว่างควอไทล์) ของอาการปวดในระหว่างการผ่าตัด ในกลุ่ม BRTR with LO และ BRTR alone = 2.30 (0.50 - 4.90) และ 0.90 (0.15 - 6.25) ตามลำดับ ซึ่งไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.600$), ค่ามัธยฐาน (ค่าพิสัยระหว่างควอไทล์) ของอาการปวดในวันแรกหลังผ่าตัด ในกลุ่ม BRTR with LO และ BRTR alone = 0.60 (0.30 - 2.95) และ 0.50 (0.15 - 2.95) ตามลำดับ ซึ่งไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.669$), ค่าสัดส่วน (%) ของการไม่มีเลือดออกหลังผ่าตัด/เลือดออกเล็กน้อย/เลือดออกปานกลาง/เลือดออกมากในกลุ่ม BRTR with LO และ BRTR alone = 4/64/28/4 และ 20/64/16/0 ตามลำดับ ซึ่งไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.214$)

สรุป

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ไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติของประสิทธิศักร์และผลข้างเคียงของการผ่าตัด ระหว่างการผ่าตัดลดขนาดของเทอร์บิเนตอันล่างโดยใช้คลื่นความถี่วิทยุร่วมกับการหักเทอร์บิเนตอันล่าง กับการใช้คลื่นความถี่วิทยุอย่างเดียว ในผู้ป่วยจมูกอักเสบเรื้อรังที่มีเทอร์บิเนตอันล่างโตเกิน ถึงแม้จะไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ในกลุ่มที่หักเทอร์บิเนตอันล่างพบเลือดออกหลังผ่าตัดมาก 1 ราย

คำสำคัญ

:

คลื่นความถี่วิทยุ, การผ่าตัดลดขนาดของเทอร์บิเนต, การหักเทอร์บิเนต, จมูกอักเสบเรื้อรัง, จมูกอักเสบภูมิแพ้.

Radiofrequency inferior turbinate reduction is one of the most common techniques used for reducing the soft tissue volume of the inferior turbinate. It has been proven to reduce nasal obstruction in chronic rhinitis patients with inferior turbinate hypertrophy.⁽¹⁻²⁾ The maximum effects of radiofrequency inferior turbinate reduction are achieved around 8 weeks after treatment and sustained at least 6 months to 2 years.⁽²⁻³⁾ Measurement of the average volumes of the inferior turbinates by MRI revealed a 8.70% postoperative reduction whereas the percentage of improvement assessed by the patients was 64.76 %.⁽⁴⁾

Lateral outfracture (LO) of the inferior turbinate displace the position of the inferior turbinate laterally. It makes the nasal cavity wider without reduction of the volume of the inferior turbinate. Some authors believe that the inferior turbinate will spring back into its previous position after only a short time.⁽⁵⁾ However, others usually combine LO with inferior turbinate reduction surgery.⁽⁶⁾

There have been limited studies that investigated the efficacy and adverse effects of the LO combined with inferior turbinate reduction techniques. Passali, et al⁽⁷⁾ analyzed the long-term efficacy of 6 surgical techniques and found that the additional LO of the inferior turbinate improved the long-term results compared to submucosal resection alone. However, the difference did not reach statistical significance. They used nasal packing in their study. There is only one randomized controlled trial from searching "outfracture" in PubMed and Cochrane Center Register of Controlled Trials. In that study⁽⁸⁾,

the authors compared the effects of submucosal electrocautery ablation with or without LO of the inferior turbinate and concluded that the submucosal cauterization of inferior turbinate with outfracture is better than the procedure without outfracture. Nasal packing was also used in their study. The postoperative nasal packing may control the postoperative bleeding better but the patients feel much more uncomfortable. To date, there is no randomized controlled trial to compare the efficacy and adverse effects of radiofrequency turbinate reduction with LO and radiofrequency turbinate reduction alone. Therefore, the present prospective, randomized, controlled trial was undertaken to address some of these questions.

Research Design

This study was a prospective, randomized, controlled trial to compare the efficacy and adverse effects of bipolar radiofrequency turbinate reduction (BRTR) with and without LO for the treatment of inferior turbinate hypertrophy.

Material and Methods

The research proposal was approved by the Ethics Committee of the Faculty of Medicine, Chulalongkorn University. Fifty patients were enrolled at Department of Otolaryngology, King Chulalongkorn Memorial Hospital, Bangkok, Thailand from July 2009 to October 2010. The inclusion and exclusion criteria were shown in Figure 1. Written informed consent form was given from all patients.

- Inclusion criteria
 - Patient's age was between 18 and 60 years.
 - Chronic rhinitis with a history of nasal obstruction for at least 1 year.
 - All patients had inferior turbinate hypertrophy and were refractory to medical treatment (intranasal corticosteroids and oral antihistamines) for at least 3 months.
 - All patients have equal nasal obstruction on both sides before intervention and felt better after decongestion of the inferior turbinate with topical decongestants.
 - The minimum nasal obstruction symptom score from VAS was greater than or equal to 5.
- Exclusion criteria
 - Patients with previous turbinate surgery, clinically significant septal deformity, septal perforation, nasal valve collapse, nasal polyps, chronic rhinosinusitis, rhinitis medicamentosa, atrophic rhinitis, benign or malignant tumors of the nasal cavity, and nasal radiotherapy.
 - Pregnancy, smoking, oral steroid use, coagulation disorder, cardiac pacemaker
 - Evidence of clinically significant uncontrolled systemic disease (e.g., tuberculosis, psychological disorders, diabetes mellitus, hypertension)
 - Acute infection or inflammation of the nose within 2 weeks.
 - Acute infection or inflammation of the paranasal sinuses within 4 weeks.

Figure 1. Inclusion and exclusion criteria.

Sample size calculation

Sample size calculation was based on a desired ability to detect a difference in two independent means with the significance level of 0.05 and the power of 80%. The sample size determination with 10% drop out estimation in each group was 41/ group.

Randomization, allocation concealment and blinding methods

All consecutive patients who met the eligible criteria and signed informed consent were included. Patients were randomly allocated into blocks of four randomization either to BRTR with LO or BRTR

alone. The allocation was concealed in the opaque envelopes. The envelopes were opened just before the operation. All patients in both groups received the same technique of radiofrequency. In the group that was performed BRTR alone, the Freer elevator was also inserted and touched beneath the lateral aspect and above the medial aspect of the inferior turbinate to reduce the bias of the patients. The outcome assessor, who was not the surgeon, and the patients were blinded to the treatment allocation.

Preoperative and postoperative objective measurements

Acoustic rhinometry was performed before

and after decongestion with 2 puffs of 0.05% oxymetazoline hydrochloride nasal spray for 15 minutes. Each measurement was repeated 3 times to ensure reproducibility. The tests were done in the morning from 9.00 to 10.00 one day before the operation. The room temperature was maintained at 25 degrees Celsius. The patient rested up for 30 minutes before testing and was tested in a sitting position. All of the acoustic rhinometries were performed by the same outcome assessor.

Intervention/Operative techniques

All patients were performed as a day surgery under local anesthesia by one surgeon. Cotton pledgets soaked with 0.05% oxymetazoline hydrochloride and 4% lidocaine hydrochloride in the proportion of 1:1 were placed in the nasal cavity covering the entire inferior turbinate. After leaving cotton pledgets in place for 10 minutes, the inferior turbinate was infiltrated with 1 to 2 cc of 1% lidocaine with 1:100,000 epinephrine.

BRTR: Curis TM[®] Microsurgical Radiofrequency was used in this study. After 10 minutes of local infiltration, the bipolar "Binner" electrode was inserted submucosally at three different sites of each inferior turbinate (upper part of the head of the inferior turbinate, lower part of the head of the inferior turbinate, and 15 mm behind the point between the first and second punctures). The setting for the treatment was RaVoRTM mode of operation in the automatically stop function with the maximum power of 6 Watts.

LO of the inferior turbinate: Freer elevator was inserted into the inferior meatus below and lateral to the lateral margin of the inferior turbinate, then force

was applied in the medial direction until the insertion of the turbinate bone fractured. Having applied the force alternately on the medial and lateral aspects of the inferior turbinate at its insertion to a mobile and complete disconnection.⁽¹⁾ Then the force was applied on the medial aspect of the inferior turbinate to the lateral direction until the inferior turbinate was pushed laterally as much as possible.

In the group that BRTR was performed alone, Freer elevator was also inserted beneath the lateral aspect and above the medial aspect of the inferior turbinate, but not to fracture it.

No nasal packing was required with exception in the cases with severe bleeding.

Postoperative care and medications

All patients received the same postoperative care and medications. Normal saline nasal irrigation twice a day was started the day after the operation for 2 weeks. One gram of acetaminophen was used by patients as needed for pain every 4 hours. Amoxicillin 1 gram twice a day after meal (Clindamycin 300 mg three times a day in case of penicillin allergy) was given for 7 days. Loratadine 10 mg once a day in the morning was given for 8 weeks. Triamcinolone acetonide nasal spray 2 puffs each nostril once daily in the morning was started 1 week postoperatively for 8 weeks.

Outcome measurements

The primary outcome was nasal obstruction symptom on postoperative week 8, measured by VAS (0 - 10). The secondary outcomes were total nasal volume (sum of both predecongested nasal volumes from nostril to 5 cm) on postoperative week 8,

measured by acoustic rhinometry (cm³), overall improvement, measured by worse, same, mild, moderate, and substantial, intraoperative pain, measured by VAS (0 - 10), postoperative pain on postoperative day 1, measured by VAS (0 - 10) and the number of time of acetaminophen taken, and postoperative bleeding within 1 day postoperatively, measured by none, mild (stopped spontaneously within 1 hour), moderate (stopped spontaneously

between 1 hour and 3 hours), and severe (stopped by nasal packing).

The maximum effects of radiofrequency inferior turbinate reduction are achieved around 8 weeks after treatment.⁽²⁻³⁾ Then the postoperative week 8 data of nasal obstruction symptom, total nasal volume, and overall improvement were used to compare.

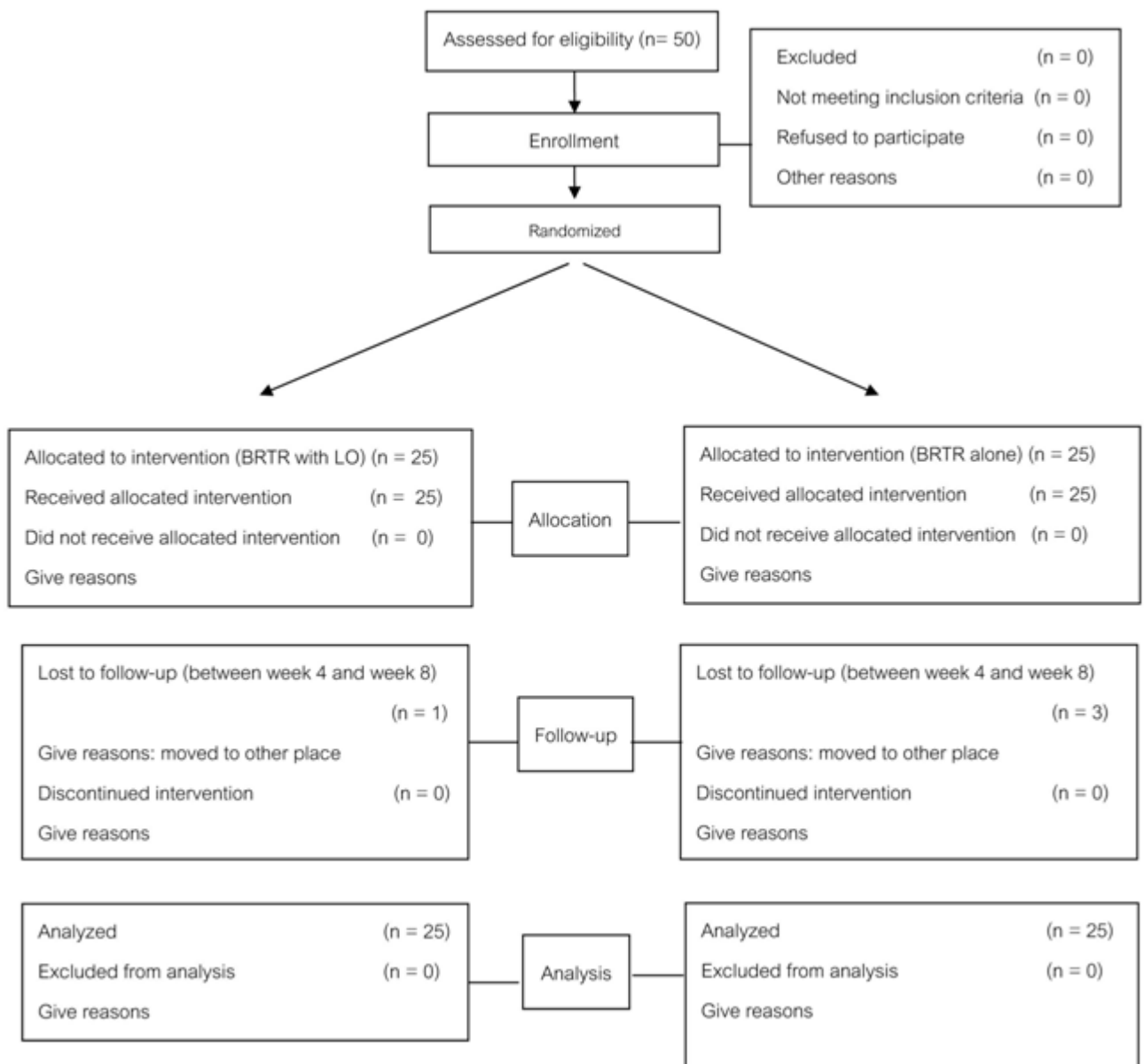


Figure 2. Flow chart of the Consort E-Flowchart.

Data analysis

Data were analyzed with SPSS version 17 software for descriptive statistics, two sample t-test, Mann-Whitney U test and Chi-square for trend. Intention-to-treat analysis was used. The worst data of the BRTR with LO group and the best data of the BRTR alone group were used in cases that were loss to follow up.

Results

Characteristics of patients and baseline data

Fifty patients who met the eligible criteria and wished to participate in the study were enrolled consecutively. Patients were randomly allocated either to undergo BRTR with LO or BRTR alone. Characteristics and baseline data of the patients are shown in Table 1.

Analysis of the primary and secondary outcomes

Data of the fifty patients were used for analysis. Results of the analysis are shown in Table 2. Two-sample t-test was used to compare the mean of the data of the acoustic rhinometry. Mann-Whitney U test was used to compare the medians of the visual analog scores of nasal obstruction symptom, intraoperative pain, postoperative pain day1, and times of acetaminophen taken. Chi-square for trend was used to analyze the ordinal data of postoperative bleeding and overall improvement. Results of the primary outcome (nasal obstruction symptom) and secondary outcomes (nasal volume, overall improvement, intraoperative pain, postoperative pain day 1, and postoperative bleeding did not show statistically significant difference between BRTR with LO and BRTR alone groups.

Table 1. Demographic data and baseline characteristics.

		Group	
		BRTR with LO	BRTR alone
Number of patients		25	25
Age (year)	Mean \pm SD	40.08 \pm 11.70	39.44 \pm 11.38
	Median (IQR)	42 (30.50 - 49.50)	39 (32 - 50)
Sex	Male (n)	5 (20%)	5 (20%)
	Female (n)	20 (80%)	20 (80%)
Duration of symptom (month)	Mean \pm SD	24.12 \pm 23.99	19.32 \pm 9.81
	Median (IQR)	18 (12 - 36)	24 (12.50 - 24)
Skin prick test	Negative	11 (44%)	13 (52%)
	Positive	14 (56%)	12 (48%)
Nasal obstruction symptom scores (VAS 0-10)		7.13 \pm 1.26	7.03 \pm 1.55
Total nasal volume: acoustic rhinometry (cm ³)		8.00 \pm 1.50	8.16 \pm 1.42

Table 2. Primary and secondary outcomes.

	Group		p-value
	BTR with LO (n = 25)	BTR alone(n = 25)	
Nasal obstruction symptom post-op week 8 (VAS 0 - 10)			
Mean \pm SD	1.60 \pm 1.40	1.11 \pm 1.36	
Median (IQR)	1.40 (0.35 - 2.55)	0.70 (0.05 - 1.70)	0.100*
Intra-op pain (VAS 0 - 10)			
Mean \pm SD	2.92 \pm 2.50	2.84 \pm 3.23	
Median (IQR)	2.30 (0.50 - 4.90)	0.90 (0.15 - 6.25)	0.600*
Post-op pain day 1(VAS 0 - 10)			
Mean \pm SD	1.75 \pm 1.98	1.71 \pm 2.10	
Median (IQR)	0.60 (0.30 - 2.95)	0.50 (0.15 - 2.95)	0.669*
Times of acetaminophen taken			
Mean \pm SD	2.04 \pm 1.99	1.72 \pm 1.90	
Median (IQR)	1 (1 - 3.50)	1 (0 - 2)	0.61*
Total nasal volume: acoustic rhinometry post-op week 8 (cm ³)			
Mean \pm SD	9.97 \pm 1.84	10.11 \pm 2.24	0.822**
Median (IQR)	9.92 (8.57 - 11.12)	9.24 (8.57 - 11.74)	
Postoperative bleeding			
None	Count (%)	1 (4%)	5 (20%)
Mild	Count (%)	16 (64%)	16 (64%)
Moderate	Count (%)	7 (28%)	4 (16%)
Severe	Count (%)	1 (4%)	0 (0%)
Overall improvement			
Worse	Count (%)	0 (0%)	0 (0%)
Same	Count (%)	0 (0%)	1 (4%)
Mild	Count (%)	2 (8%)	0 (0%)
Moderate	Count (%)	9 (36%)	7 (28%)
Substantial	Count (%)	14 (56%)	17 (68%)

* Mann-Whitney U test

** Two sample t-test

*** Chi-square for trend

Discussion

In this prospective randomized controlled study, the efficacy and adverse effects of BRTR with LO were compared to BRTR alone. Randomization and blinding methods could not guarantee equality of bias between the two groups. Baseline characteristics might not be equal in each group, such as age, duration of symptom, severity of nasal obstruction symptom from visual analog scores, degree of nasal volume from acoustic rhinometry, mucosal or bony hypertrophy of the inferior turbinate, results of skin prick test for inhalant allergens, and concomitant medication before the intervention. In the group that received BRTR alone, Freer elevator was also inserted and touched beneath the lateral aspect and above the medial aspect of the inferior turbinate to reduce the bias of the patients. In this study, the subjective nasal obstruction symptom score was used as the primary outcome and the objective nasal volume measured by acoustic rhinometry was used as the secondary outcome to evaluate the nasal patency because the subjective measurement should be more important to the clinical result of the surgery than the objective measurement. Comparison between the patients may be better and more reliable than between among each side of the nose because many normal people have nasal cycle which can interfere to the outcome variables. The nasal obstruction symptom scores on postoperative week 8 between each group, not the difference between preoperative and postoperative scores, were used for calculation to compare the real sensation of nasal obstruction symptom after the operation in each group.

Four patients were loss to follow up between postoperative week 4 and week 8, one patient was in BRTR with LO group and three patients were in BRTR-alone group. The worst data of the BRTR with LO group and the best data of the BRTR alone group were used to analyze the data in these group.

The standard deviations of the means obtained from the subjective measurement such as nasal obstruction symptom on postoperative week 8, intraoperative pain, postoperative pain and times of acetaminophen taken were very high whereas the objective measurement of nasal obstruction measured from the acoustic rhinometry was not high. Then Mann-Whitney U test was used instead of two sample t-test to compare the obtained data of nasal obstruction symptom, intraoperative pain, postoperative pain and times of acetaminophen taken. Passali, et al⁽⁹⁾ found that nasal obstruction scores as rated by patients on the visual analog scale frequently did not correlate with objective measures, as patients often overestimated the severity of their obstruction.

The efficacy of the LO of the inferior turbinate is questionable. Even in the intraoperative period the inferior turbinate was adequately displaced laterally, the inferior turbinate could spring back to its previous position after a short period of time.⁽⁵⁾ To date, there is no randomized controlled trial to compare the efficacy and adverse effects of BRTR with and without LO. However, some surgeons have performed LO of the inferior turbinate with radiofrequency inferior turbinate reduction surgery to maximize the nasal airway patency and found this technique to be both efficacious and safe.⁽⁶⁾

In this study, nasal obstruction symptom scores on postoperative week 8 of both BRTR with LO and BRTR alone groups were less than before the operation, 7.13 ± 1.26 to 1.60 ± 1.40 and 7.03 ± 1.55 to 1.11 ± 1.36 , respectively. Nasal volumes were increased from 8.00 ± 1.50 to 9.97 ± 1.84 and 8.16 ± 1.42 to 10.11 ± 2.24 , respectively. No patients in both groups felt worse after the operation and most of them felt moderate to substantial improvement. Intraoperative pain, postoperative pain day 1 and postoperative bleeding in both groups were not much. However, one patient in BRTR with LO group had severe degree of postoperative bleeding which needed nasal packing. Comparison of the primary outcome (nasal obstruction symptom) and secondary outcomes (nasal volume, overall improvements intraoperative pain, postoperative pain day 1, and postoperative bleeding showed no statistically significant difference between BRTR with LO and BRTR alone. From this study, BRTR with LO could not decrease nasal obstruction more than BRTR alone. There were no adverse effects from LO. Although one patient in LO group had severe postoperative bleeding which needed nasal packing, but the number of sample was too small for definite conclusion.

The number of sample in this study was less than the sample size determination due to time constraint. Other factors that may contribute to the outcomes which were not controlled in this study were the hardness of the inferior turbinate bone and thickness of the soft tissue of the inferior turbinate.

In the intraoperative period after performing the LO, the surgeon certainly saw the space of the nasal cavities widened. However, the displaced

inferior turbinate could spring back to its previous position after a period of time. The widened space of the nasal cavities would turn to previous space. If nasal packing was left until the inferior turbinate bone was healed, it might prevent the spring back of the inferior turbinate. The procedures that remove part of the bone of the inferior turbinate such as submucous turbinate bone resection and powered turbinoplasty are used in combination with LO may also prevent the spring back of the inferior turbinate.

Conclusion

No statistically significant differences of the efficacy and adverse effects were found between bipolar radiofrequency turbinate reduction with lateral outfracture and bipolar radiofrequency turbinate reduction alone in chronic rhinitis patients with inferior turbinate hypertrophy. Although no statistical significance in adverse effects, severe postoperative bleeding was observed in one patient who underwent bipolar radiofrequency turbinate reduction with lateral outfracture.

Conflict of Interest Statement

The authors declare that there is no conflict of interest.

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References

1. Cavaliere M, Mottola G, Iemma M. Monopolar and bipolar radiofrequency thermal ablation of inferior turbinates: 20-month follow-up. *Otolaryngol Head Neck Surg* 2007 Aug; 137(2): 256-63
2. Nease CJ, Krempf GA. Radiofrequency treatment of turbinate hypertrophy: a randomized, blinded, placebo-controlled clinical trial. *Otolaryngol Head Neck Surg* 2004 Mar; 130(3): 291-9
3. Porter MW, Hales NW, Nease CJ, Krempf GA. Long-term results of inferior turbinate hypertrophy with radiofrequency treatment: a new standard of care? *Laryngoscope* 2006 Apr; 116(4): 554-7
4. Sapci T, Usta C, Evcimik MF, Bozkurt Z, Aygun E, Karavus A, Peker M. Evaluation of radiofrequency thermal ablation results in inferior turbinate hypertrophies by magnetic resonance imaging. *Laryngoscope* 2007 Apr; 117(4): 623-7
5. King HC, Mabry RL. Surgical approaches to correcting nasal obstruction. In: King HC, Mabry RL, eds. *A Practical Guide to the Management of Nasal and Sinus Disorders*. New York: Thieme Medical Publishers, 1993: 94 -118
6. Passali D, Passali FM, Damiani V, Passali GC, Bellussi L. Treatment of inferior turbinate hypertrophy: a randomized clinical trial. *Ann Otol Rhinol Laryngol* 2003 Aug; 112(8): 683-8
7. Nassif Filho AC, Ballin CR, Maeda CA, Nogueira GF, Moschetta M, de Campos DS. Comparative study of the effects of submucosal cauterization of the inferior turbinate with or without outfracture. *Braz J Otorhinolaryngol* 2006 Jan; 72(1): 89-95
8. Passali D, Mezzedimi C, Passali GC, Nuti D, Bellussi L. The role of rhinomanometry, acoustic rhinometry, and mucociliary transport time in the assessment of nasal patency. *Ear Nose Throat J* 2000 May; 79(5): 397-400
9. Wolfswinkel EM, Koshy JC, Kaufman Y, Sharabi SE, Hollier LH Jr, Edmonds JL. A modified technique for inferior turbinate reduction: the integration of coblation technology. *Plast Reconstr Surg* 2010 Aug; 126(2):489-91