A randomized study of temperature-controlled versus bipolar radiofrequency for inferior turbinate reduction

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Abstract The objective of this study is to compare outcomes of temperature-controlled radiofrequency (TCRF) and bipolar radiofrequency (BRF) for inferior turbinate reduction in patients with chronic rhinitis (CR). This was a prospective, randomized non-inferiority trial. Eighty-four adult patients with CR refractory to medication were randomized into two intervention groups: TCRF(42) or BRF(42). Primary outcomes consisted of patient-orientated visual analog scale (VAS; 0–10) of nasal obstruction at 4th postoperative week. Secondary subjective outcomes included VAS of nasal discharge, sneezing, hyposmia, and postnasal drip. Objective outcomes included crusting, mucociliary transportation time, minimal cross-sectional area, total nasal volume, and nasal airway resistance performed by blind assessors before and at 4th postoperative week and 1-year follow-up. Baseline and perioperative data showed no statistically significant difference between both groups, except for longer operative time in TCRF (481.5 ± 36.2 vs. 371.1 ± 30 s, p < 0.001) and slightly more crusts in BRF group (p = 0.04). Both intention-to-treat and per-protocol analyses, TCRF(39) versus BRF(41), revealed no significant difference among subjective and objective outcomes between two groups at 4th postoperative week. The 95 % confidence intervals of mean differences of VAS scores of all subjective symptoms were within defined margin (−1.5 to 1.5), except for nasal discharge. At 1-year follow-up, there was still no significant difference in the outcomes. Minimal pain and minor bleeding without serious adverse effects from both interventions were reported. Both BRF and TCRF resulted in similar short-term outcomes, while less operative time was found in BRF group. Further studies, particularly, on cost-effectiveness should be conducted for better treatment selection.

Level of evidence 1b.

Keywords Radiofrequency · Temperature controlled · Bipolar · Inferior turbinate reduction · Chronic rhinitis · Thai

Introduction

Chronic nasal obstruction from hypertrophic inferior turbinates (ITs) is a common presentation of chronic rhinitis (CR), particularly for patients with obstructive sleep-disordered breathing [1]. When its conservative treatment, i.e., environmental control or allergen avoidance and medications, e.g., antihistamines, decongestants, and nasal steroids has failed, a surgical reduction of ITs is often helpful [2, 3]. Although there is a wide range of available modes of interventions [4–9], radiofrequency (RF) in reducing soft tissue volumes of ITs seems to be the most popular choice due to its simplicity and less invasive character [2, 3, 10–14]. RF induces limited tissue coagulation necrosis and subsequent scar formation within submucosal layer of ITs while preserving mucociliary function by control of energy released from a special probe [3, 9, 10, 15, 16]. With such technological advancement, current RF devices with spectrums ranging from 100 to 4,000 kHz are and have been available for the clinical practice [3, 14, 16].

In 1998, Li et al. first described a temperature-controlled RF (TCRF) device (Somnus Medical Technologies, Inc, Sunnyvale, CA, USA) which effectively delivered 476 kHz

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radio wave through an active monopolar electrode for the treatment of hypertrophic ITs without any adverse effects [17]. The unique mechanism is that its RF energy released can be automatically adjusted by a feedback from impedance and temperature of tissue which leads to potentially less extensive tissue damage. Several subsequent studies have also confirmed that the TCRF can effectively improve nasal obstruction [3, 8, 10, 12, 13, 15, 16], patients’ quality of life [18–20], snoring [21, 22], daytime sleepiness [21], and adherent rates of positive airway pressure therapy in patients with obstructive sleep apnea [21, 23]. Nevertheless, it has some disadvantages: high cost of generator with disposable probes and a relatively long procedural time.

Recently, bipolar RF (BRF) devices which release radio wave through a reusable bipolar electrode without a need of patient earth wires have also been available [3, 16, 24]. The BRF has advantages over the TCRF including shorter procedural time and potentially better safety, especially among patients with a cardiac pacemaker because its current is limited to the direct surrounding of the tip of applicator [16]. In 2007, Cavaliere et al. conducted a randomized study between Coblator II ENT (Arthrocure Corp, Sunnyvale, CA, USA)—a type of bipolar RF device and the TCRF device in 150 patients with non-allergic rhinitis and found that both devices produced no statistically significant differences in the capacity of symptomatic improvement and maintenance of nasal function [16]. In 2008, Blumen et al. also reported a comparable efficacy among four RF generators including the TCRF, Coblator, Ellman, and Select Sutter, applying at soft palate for the treatment of snoring [24]. However, there is currently no comparative study of the TCRF with BRF other than the report of the Coblator for the treatment of hypertrophic ITs. Therefore, the objectives of this study were to compare subjective and objective outcomes of TCRF with those of another BRF device (Select Sutter, Fribourg, Germany) which is cheaper and requires less procedural time for CR treatment [14]. Since we had hypothesized that our results might occur in accordance with the aforementioned studies, this study was developed in a non-inferiority design in the hope that its results may be useful for ear-nose-throat specialists to select a proper choice of treatment for their patients.

Materials and methods

Study design

This investigation was designed as a randomized, non-inferiority study to compare the difference of outcomes between TCRF and BRF for the treatment of CR. After having obtained an approval from the Institutional Review Board (IRB), a research grant and a clinical trial registration number, the study was conducted between September 2010 and December 2013. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Subjects

Patients were recruited from a snoring clinic in a tertiary referral center, Thailand. Informed consent was obtained from all individual participants recruited in the study. Inclusion criteria were (a) subjects age ≥ 18 years old, (b) having symptoms of CR refractory to intranasal steroids and oral antihistamine within 3 weeks, and (c) positive consents. Exclusion criteria were subjects with any of the following: active rhinosinusitis, nasal polyps, severe deviated nasal septum, nasal valve collapse, sinonasal tumor(s), and/or history of either previous sinus surgery or head neck irradiation. Also excluded were subjects with the following: allergy or intolerance to lidocaine or oxymetazoline, underlying hematologic disease, unstable cardiovascular problems, and uncontrolled psychiatric problems.

Temperature-controlled radiofrequency (TCRF)

After intranasal packing with 1 % lidocaine-soaked cotton pieces and submucosal injection of 0.5 % lidocaine with 1:400,000 adrenaline along inferior turbinate, RF via TCRF probe (Sononoplasty model S2, Sunnyvale, CA, USA) was applied to five mucosal points bilaterally [three points at inferomedial parts of ITs starting from posterior to anterior and two points at the anterior aspects parts of the ITs]. The energy of TCRF generator was set at 300 J, 85 °C, and 15 Watts (W) with total energy of 1,500 J each side.

Bipolar Radiofrequency (BRF)

Subjects in BRF group underwent BRF procedure under local anesthesia similar to the TCRF group. A reusable BRF probe, Select Sutter (Fribourg, Germany), set at 2.5 W was applied for same “area” points of ITs with duration of 3–5 s for each point. However, the surgeon would immediately stop releasing this energy as soon as a change in mucosal color or a burning sound was detected.

Postoperative care

All interventions were performed by the same surgeon with similar postoperative care. After interventions, all
subjects were observed in the recovery area for 15–20 min before hospital discharges without any nasal packing. Home medications included topical decongestants (0.05% oxymetazoline), acetaminophen (to be taken if needed) and oral antibiotics during first postoperative week. Nasal saline irrigation (approximately 100 ml for each nostril) was recommended twice daily for 1 month after the operation.

Outcome measurements

Primary outcome measurements were performed by self-reported 10-cm visual analog scales (VAS) of nasal obstructive symptoms including severity, frequency, and overall obstruction (severity multiplied by frequency of obstruction/10) at 4th postoperative week. The scores may range from 0 to 10 (0 = no symptom and 10 = maximal severity of symptoms). Success rates were defined as proportions of subjects with at least 50% dropped of the VAS score of overall nasal obstruction after operation.

Secondary subjective outcome measurements consisted of self-reported 10-cm VAS of symptoms including anterior nasal discharge, sneezing, sense of smell reduction (hyposmia) and postnasal drip (posterior rhinorrhoea) evaluated at two time points, i.e., 4th postoperative week and 1-year follow-up which also included the VAS of nasal obstructive symptoms. Secondary objective outcomes consisted of the following; (a) means of bilateral minimal cross-sectional area (MCA) and total nasal volume (VOL) derived from acoustic rhinometry (ARM, Eccovision Acoustic Rhinometry System V 3.54, Germany) and (b) means of total nasal airway resistance (NAR) at pressure difference of 75 Pa derived from active anterior rhinomanometry (RMM, ATMOS 300, Germany) at 4th postoperative week and 1-year follow-up.

For records on side effects, assessment included: (a) VAS scores of intraoperative pain, (b) severity of intranasal crusting graded by a trained researcher—blind to treatment/procedure groups at 1st and 4th postoperative weeks, and (c) mucociliary transport time (MTT) measured by saccharine test at 4th postoperative weeks compared to baseline. The severity grading intranasal crusting range from mild (thick mucus discharge or crusts with diameter of <10 mm which could be easily removed), to moderate (crusts with diameter of 10–20 mm but could be completely removed), and to severe (crust with diameter of >20 mm which could not be completely removed, or caused bleeding from the raw surface with a need of subsequent nasal packing). On mucociliary function, MTT was measured after having applied approximately 15 mg of 2% sodium saccharin on the head of ITs while subjects were seated and instructed to avoid nasal blowing. As soon as sweetness was experienced, the MTT was recorded by a research assistant—blind to treatment/procedure groups.

Sample size calculation

To obtain an adequate sample size of this study, calculation was based on the primary outcome, e.g., a change of the VAS scores of nasal obstructive symptom between two groups at 4th postoperative week. Using a hypothesis for the equivalence of outcome, the estimated margins for 95% confidence interval (CI) of meaningful clinical difference between both interventions were set at level of −1.5 to 1.5. Along with a power of 80%, two-sided error accepted at level of 0.05, and a standard deviation (SD) of 2.5 derived from the previous study of Banhiran et al. [19], an initial estimated sample size was at least 36 subjects per treatment groups.

Randomization, allocation concealment, and blinding methods

Computerized randomized of subjects into two groups, either TCRF or BRF, at a ratio of 1:1 following sequential numbers of simple block randomization was performed by a third party with no personal interest in this particular research. The allocation sequence was concealed in opaque envelopes blinded to the subjects as subjective outcome assessors and trained research assistants as objective outcome assessors. However, the assigned interventions could not be blinded to the surgeon who performed the procedures.

Statistical analysis

Both intention-to-treat analyses and per-protocol analyses were performed for the primary outcome with reports of the two-sided 95% CI of the mean differences compared between two interventions. Continuous data were presented as mean ± SD and categorical data were presented as frequencies and percentages (%). Paired t test or Wilcoxon signed-rank test were used to compare differences of continuous data before and after treatment. Independent t test or Mann–Whitney U test was used to compare differences of continuous data between two different groups of subjects. Chi-square tests were used to compare between two groups of categorical data. Analysis of covariance (ANCOVA) with Bonferroni’s method was used to adjust unequal baseline continuous data between two groups of intervention for the comparison of outcomes. The Predictive Analytics Software (PASW) Statistics version 18.0 (New York, USA) was used for statistical analysis. Significance level was set at p < 0.05 in two-tailed tests.
Results

During September 2010 to January 2013, ninety consecutive subjects were initially assessed for eligibility criteria. However, four patients refused to be subjects of this study and two subjects were excluded due to their findings of nasal polyps with rhinosinusitis. After randomization, the remaining eighty-four subjects (55 males and 29 females) aged from 23 to 82 years were assigned into two groups: 42 in TCRF group and 42 in BRF group (CONSORT flow chart diagram, Fig. 1). On baseline and perioperative data, most values in various categories of both groups of subjects were not different ($p = 0.10-96$), except for the mean operative time which was significantly longer in the TCRF group ($p < 0.001$, Tables 1, 2).

Primary outcomes

Both intention-to-treat and per-protocol analyses were used for determining the primary outcomes at 4th postoperative week. The 95% CI of mean differences of all nasal obstruction VAS scores between both treatment groups adjusted by ANCOVA was within the defined margins; and, the proportions of subjects who met the criteria of success were also not statistically different ($p = 0.09-0.52$, Table 3). Since there were four non-attendees (3 in the TCRF group and 1 in the BRF group) because of flooding disaster, data of the remaining 39 subjects of TCRF group and 41 subjects of BRF group were used for the per-protocol analyses.
Table 1 Baseline demographic data

<table>
<thead>
<tr>
<th></th>
<th>TCRF (N = 42)</th>
<th>BRF (N = 42)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>27 (64.3)</td>
<td>28 (66.7)</td>
<td>0.82</td>
</tr>
<tr>
<td>Female</td>
<td>15 (35.7)</td>
<td>14 (33.3)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>48.4 ± 12.2</td>
<td>44.0 ± 11.6</td>
<td>0.10</td>
</tr>
<tr>
<td>Severity of obstruction</td>
<td>6.3 ± 1.3</td>
<td>6.1 ± 1.0</td>
<td>0.40</td>
</tr>
<tr>
<td>Frequency of obstruction</td>
<td>6.4 ± 1.6</td>
<td>5.8 ± 1.6</td>
<td>0.14</td>
</tr>
<tr>
<td>Overall obstruction</td>
<td>4.1 ± 1.7</td>
<td>3.7 ± 1.4</td>
<td>0.21</td>
</tr>
<tr>
<td>Nasal discharge</td>
<td>3.7 ± 1.9</td>
<td>4.2 ± 2.4</td>
<td>0.28</td>
</tr>
<tr>
<td>Sneezing</td>
<td>4.1 ± 2.4</td>
<td>4.2 ± 2.2</td>
<td>0.82</td>
</tr>
<tr>
<td>Sense of hyposmia</td>
<td>3.3 ± 2.7</td>
<td>3.4 ± 2.2</td>
<td>0.96</td>
</tr>
<tr>
<td>Postnasal drip</td>
<td>4.8 ± 2.4</td>
<td>5.2 ± 2.2</td>
<td>0.44</td>
</tr>
<tr>
<td>Mean MCA (cm²)</td>
<td>0.53 ± 0.16</td>
<td>0.56 ± 0.13</td>
<td>0.26</td>
</tr>
<tr>
<td>Total nasal volume (cm³)</td>
<td>13.42 ± 2.65</td>
<td>14.04 ± 2.64</td>
<td>0.29</td>
</tr>
<tr>
<td>Nasal resistance at 75 Pa</td>
<td>0.23 ± 0.14</td>
<td>0.21 ± 0.14</td>
<td>0.56</td>
</tr>
<tr>
<td>Positive skin prick test</td>
<td>38 (90.5)</td>
<td>36 (85.7)</td>
<td>0.36</td>
</tr>
</tbody>
</table>

The continuous data are presented in mean ± standard deviation. The categorical data are presented in number of patients (%)

TCRF temperature-controlled radiofrequency, BRF bipolar radiofrequency, MCA minimal cross-sectional area, Pa Parot

Table 2 Perioperative information

<table>
<thead>
<tr>
<th></th>
<th>TCRF (N = 42)</th>
<th>BRF (N = 42)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (s)</td>
<td>481.5 ± 36.2</td>
<td>371.1 ± 3.0</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Intraoperative pain</td>
<td>3.2 ± 2.7</td>
<td>3.1 ± 2.7</td>
<td>0.90</td>
</tr>
<tr>
<td>scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative crust (at first week)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>5 (11.9)</td>
<td>15 (35.7)</td>
<td>0.04**</td>
</tr>
<tr>
<td>Mild</td>
<td>36 (85.7)</td>
<td>26 (61.9)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1 (2.4)</td>
<td>1 (2.4)</td>
<td></td>
</tr>
</tbody>
</table>

The continuous data are presented in mean ± standard deviation. The categorical data are presented in number of patients (%)

TCRF temperature-controlled radiofrequency, BRF bipolar radiofrequency, MTT mucociliary transport time

* The mean difference is significant at the level of <0.001 (two-tailed)
** The mean difference is significant at the level of <0.05 (two-tailed)

Secondary outcomes

At 4th postoperative week, the 95 % CI of mean differences of VAS scores of most symptoms, i.e., sneezing, sense of hyposmia and post nasal drip of both treatment groups was within the defined margins (p = 0.13–0.92) but nasal discharge slightly exceeded the margin in favor of BRF group (p = 0.13) Objective outcomes including

Table 3 Nasal obstructive symptoms at 4th week after operation

<table>
<thead>
<tr>
<th></th>
<th>TCRF</th>
<th>BRF</th>
<th>Differences (95 % CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intention-to-treat analysis</td>
<td>N = 42</td>
<td>N = 42</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity of obstruction</td>
<td></td>
<td></td>
<td>3.4 ± 1.8</td>
<td>2.7 ± 1.9</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td></td>
<td></td>
<td>2.9 ± 2.1</td>
<td>3.4 ± 1.8</td>
</tr>
<tr>
<td>Frequency of obstruction</td>
<td></td>
<td></td>
<td>3.4 ± 1.8</td>
<td>2.6 ± 2.1</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td></td>
<td></td>
<td>2.9 ± 2.1</td>
<td>3.2 ± 2.2</td>
</tr>
<tr>
<td>Overall obstruction</td>
<td></td>
<td></td>
<td>1.4 ± 1.2</td>
<td>1.0 ± 1.4</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td></td>
<td></td>
<td>2.7 ± 1.9</td>
<td>2.6 ± 1.6</td>
</tr>
<tr>
<td>Overall success rate (%)</td>
<td></td>
<td></td>
<td>28 (66.7)</td>
<td>32 (76.2)</td>
</tr>
</tbody>
</table>

The continuous data are presented in mean ± standard deviation. The categorical data are presented in number of patients (%)

The p values were derived from analyses of covariance (ANCOVA) of differences between two interventions with an adjustment for multiple comparisons by Bonferroni’s method

TCRF temperature-controlled radiofrequency, BRF bipolar radiofrequency, CI confidence interval

means of MCA, VOL, and NAR at 75 Pa also showed no statistically significant difference between two treatment groups (p = 0.3–0.78, Table 4).

At 1-year follow-up, 57 subjects (25 in TCRF and 32 in BRF) completed the follow-up for per-protocol analyses of the 1-year secondary outcomes. Nevertheless, the 95 % CI of mean differences of VAS scores of all symptoms between both treatment groups was still within the defined margin. Objective outcomes including means of MCA, VOL, and NAR at 75 Pa also showed no statistically significant difference between two treatment groups (Table 5).

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Table 4 Secondary outcomes at 4th week after operation

<table>
<thead>
<tr>
<th></th>
<th>TCRF (N = 39)</th>
<th>BRF (N = 41)</th>
<th>Differences (95 % CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal discharge</td>
<td>3.3 ± 2.5</td>
<td>2.6 ± 2.1</td>
<td>0.77 (−0.24, 1.80)</td>
<td>0.13</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>0.4 ± 3.2</td>
<td>1.5 ± 2.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sneezing</td>
<td>2.7 ± 2.2</td>
<td>2.7 ± 1.9</td>
<td>0.10 (−0.80, 1.01)</td>
<td>0.82</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>1.2 ± 3.3</td>
<td>1.6 ± 2.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sense of hypoxia</td>
<td>2.7 ± 2.6</td>
<td>2.3 ± 2.5</td>
<td>0.36 (−0.73, 1.46)</td>
<td>0.51</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>0.7 ± 3.2</td>
<td>1.1 ± 3.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postnasal drip</td>
<td>3.4 ± 2.5</td>
<td>3.6 ± 2.2</td>
<td>0.05 (−0.89, 0.99)</td>
<td>0.92</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>1.4 ± 2.8</td>
<td>1.7 ± 2.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean MCA (cm²)</td>
<td>0.55 ± 0.12</td>
<td>0.58 ± 0.11</td>
<td>−0.02 (−0.07, 0.03)</td>
<td>0.42</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>−0.02 ± 0.15</td>
<td>−0.02 ± 0.13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total nasal volume (cm³)</td>
<td>14.11 ± 2.59</td>
<td>13.94 ± 2.03</td>
<td>−0.45 (−0.41, 1.3)</td>
<td>0.30</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>−0.65 ± 2.33</td>
<td>0.13 ± 2.33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAR at 75 Pa</td>
<td>0.18 ± 0.09</td>
<td>0.17 ± 0.10</td>
<td>0.01 (−0.03, 0.04)</td>
<td>0.78</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>0.18 ± 0.09</td>
<td>0.19 ± 0.09</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The continuous data are presented in mean ± standard deviation. The categorical data are presented in number of patients (%).

The p values were derived from analyses of covariance (ANCOVA) of differences between two interventions with an adjustment for multiple comparisons by Bonferroni's method.

TCRF temperature-controlled radiofrequency, BRF bipolar radiofrequency, MCA minimal cross-sectional area, NAR nasal airway resistance, Pa Pascal, CI confidence interval.

Table 5 Secondary outcomes at 1 year after operation

<table>
<thead>
<tr>
<th></th>
<th>TCRF (N = 25)</th>
<th>BRF (N = 32)</th>
<th>Differences (95 % CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of obstruction</td>
<td>3.3 ± 2.0</td>
<td>2.9 ± 1.7</td>
<td>0.15 (−0.79, 1.08)</td>
<td>0.76</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>3.0 ± 2.5</td>
<td>3.2 ± 1.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of obstruction</td>
<td>3.2 ± 2.2</td>
<td>3.1 ± 2.1</td>
<td>−0.21 (−1.38, 0.96)</td>
<td>0.72</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>3.4 ± 2.6</td>
<td>2.7 ± 2.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall obstruction</td>
<td>1.4 ± 1.4</td>
<td>1.2 ± 1.2</td>
<td>0.13 (−0.54, 0.80)</td>
<td>0.70</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>2.9 ± 2.2</td>
<td>2.5 ± 1.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasal discharge</td>
<td>2.7 ± 2.4</td>
<td>2.6 ± 2.1</td>
<td>−0.17 (−1.29, 0.96)</td>
<td>0.77</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>1.5 ± 3.0</td>
<td>1.7 ± 2.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sneezing</td>
<td>2.8 ± 2.4</td>
<td>2.7 ± 1.9</td>
<td>0.13 (−0.88, 1.14)</td>
<td>0.79</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>1.9 ± 2.5</td>
<td>1.7 ± 2.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sense of hypoxia</td>
<td>2.4 ± 2.4</td>
<td>2.2 ± 2.6</td>
<td>0.14 (−1.22, 1.49)</td>
<td>0.84</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>1.6 ± 3.1</td>
<td>1.2 ± 3.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postnasal drip</td>
<td>3.2 ± 2.4</td>
<td>3.2 ± 2.5</td>
<td>0.09 (−1.00, 1.18)</td>
<td>0.87</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>1.7 ± 2.5</td>
<td>2.0 ± 2.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean MCA (cm²)</td>
<td>0.56 ± 0.13</td>
<td>0.57 ± 0.13</td>
<td>0.01 (−0.02, 0.03)</td>
<td>0.66</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>−0.00 ± 0.15</td>
<td>−0.02 ± 0.12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total nasal volume (cm³)</td>
<td>14.10 ± 2.66</td>
<td>13.83 ± 2.09</td>
<td>0.27 (−0.18, 0.36)</td>
<td>0.30</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>−0.24 ± 2.09</td>
<td>0.14 ± 1.71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAR at 75 Pa</td>
<td>0.18 ± 0.07</td>
<td>0.18 ± 0.10</td>
<td>−0.01 (−0.03, 0.01)</td>
<td>0.45</td>
</tr>
<tr>
<td>Change (pre/post)</td>
<td>0.04 ± 0.11</td>
<td>0.03 ± 0.12</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The continuous data are presented in mean ± standard deviation. The categorical data are presented in number of patients (%).

The p values were derived from analyses of covariance (ANCOVA) of differences between two interventions with an adjustment for multiple comparisons by Bonferroni’s method.

TCRF temperature-controlled radiofrequency, BRF bipolar radiofrequency, MCA minimal cross-sectional area, NAR nasal airway resistance, Pa Pascal, CI confidence interval.

On a statistically significant difference, there was less postoperative crust in TCRF group at 1st postoperative week (p = 0.04, Table 2). However, at 4th postoperative week, almost all subjects either did not have crust or had only mild crust without statistically significant difference between both groups (p = 0.43). Also, insignificant differences were found for values of MCT between TCRF and BRF groups which were 721.2 ± 333.7 vs.

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710.7 ± 368.9 s before treatment and 775.0 ± 441.0 vs. 678.9 ± 320.3 s at 4th postoperative week, respectively (p = 0.21). The intraoperative pain and bleeding of both interventions were considered minimal without any statistically significance. No subject required nasal packing and none reported of any other serious adverse effect from the treatments.

Discussion

The TCRF for ITs reduction in CR seems to be a gold standard treatment [2-4, 8, 10-13, 15-19, 23]; but its high cost, availability, and longer procedural time might have influenced its widespread use. Although other RF devices with different output frequencies, prices, and procedural times are widely available, few publications exist to compare TCRF and other RF devices [3, 16, 24]. To gather information to help surgeons on their selective decisions on RF devices, we conducted this randomized, non-inferiority study comparing outcomes between TCRF and BRF for the treatment of CR.

On results, there was almost no statistically significant difference between the BRF and TCRF in both subjective and objective outcomes in the treatment of CR, at least in short-term follow-up. Such results of this are in accordance with two other studies (Cavaliere et al. [16] and Blumen et al. [24]). However, there were slightly more crusts and nasal discharge in BRF group at 1st and 4th postoperative week, respectively. It is not yet clear whether these findings were related to more extensive mucosal tissue injuries caused by BRF (its bigger energy probes and its relative imprecision in power control of surgeon's audiovisual feedback), unlike TCRF (computerized control by automatic feedback from tissue temperatures of ITs). Thus, our findings differ from those of Cavaliere et al. [16] which have demonstrated complete disappearance of crusts at the end of 1st postoperative week, and no statistically significant difference in nasal discharge of subjects of both TCRF and Coblator group after treatment. Regarding intraoperative pain and serious adverse events in this study, there was no significant difference between TCRF and BRF group. Therefore, our data confirm the effectiveness and safety of both procedures.

On limitations of this study, various issues were included. First, our primary outcomes were subjective symptoms from VAS scores at short-term follow-up. Nevertheless, one should bear in mind that symptoms are most important concerns of patients regardless of objective nasal investigations in which their clinical importance is still unclear [3, 10, 12, 13, 16, 18, 19]. Second, only 57 out of 82 subjects (25 in TCRF and 32 BRF) completed the 1-year follow-up protocols and their major explanations for non-attenders were troubles with transportation due to catastrophic flooding disaster and political crisis during study periods. Third, contaminated factors such as an intermittent use of intransal steroids, oral antihistamine, antibiotics, and saline irrigation were poorly controlled during 1-year follow-up. Whether this issue was related to natural fluctuating courses of CR or a diminishing effect of RF treatment overtime could not be simply explained. Thus, it is possible that all limiting factors had led to a diminished power, potential bias from multiplicity of analyses, and inconclusive findings of the secondary outcomes at 1-year follow-up.

In conclusion, both BRF and TCRF resulted in similar subjective and objective outcomes at least in short-term. The TCRF may be advantageous in that it is an automatically controlled device with potentially greater precision on extent of mucosal tissue damage, while the BRF has other advantages such as lower costs, shorter procedural time, absence of earth wiring on subjects which might be more suitable for patients with cardiac pacemaker. Therefore, the BRF might be considered another alternative for the treatment of CR, especially in an era of economic constraints. However, it may require more attention and training because the outcomes of BRF treatment largely depend on surgeon’s feedbacks and reactions which can lead to under- or over-treatment. For the future, it is suggested that more comparative studies among different treatment modalities, particularly on long-term cost-effectiveness in various populations with CR should be conducted.

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Conflict of Interest The authors declare that they have no conflict of interest.

References


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