



## Comparing the Effects of Inferior Turbinate Radiofrequency and Intranasal Corticosteroid on Symptoms Severity and Quality of Life in Patients with Inferior Turbinate Hypertrophy

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### ABSTRACT

**Background:** Inferior turbinate hypertrophy (ITH) is a common cause of nasal obstruction. Surgical approach is often needed if is refractory to medical treatment. Radiofrequency (RF) of inferior turbinate is known as an effective method to decrease obstruction as well as other symptoms and improving quality of life.

**Objective:** This study was designed to compare therapeutic effects of intranasal corticosteroid and RF on symptoms severity and quality of life in patients with ITH due to allergic rhinitis.

**Methods:** In this randomized clinical trial, patients with allergic rhinitis and ITH referred to BMSU Allergic Clinic were randomized to RF and intranasal corticosteroid spray (Fluticasone 125 mcg) groups. Patients were evaluated by symptoms severity measured by visual analogue scale, and Rhinitis Quality of Life Questionnaires (RQLQ) four times, before, first, third and sixth months after the intervention.

**Results:** Sixty patients with allergic rhinitis and ITH were evaluated (26 males and 34 females). The mean age was 35.5 years, and the mean BMI was 22.97 kg/m<sup>2</sup>.

Conclusion: RF technique as an outpatient procedure with local anesthesia could decrease symptoms severity and increase quality of life in patients with allergic rhinitis and ITH, but long-term effects of corticosteroid and RF could be evaluated in future studies.

## Introduction

Allergic rhinitis, involving about 10- 30% of adults, is a symptomatic chronic inflammation of the nasal mucosa and a common cause of visiting otorhinolaryngologists (1, 2). Patients usually complain of periodic, seasonal, or permanent eye and ear symptoms, cough, sleepiness, daily fatigue, and alterations in work and educational activities due to sleep disorders and nasal obstruction induced by environmental allergens (3, 4, 5, 6). According to previous studies, nasal congestion and obstruction are the most problematic symptoms in patients with lower quality of life (2, 6, 7).

Inferior turbinate hypertrophy (ITH) as a common cause of nasal obstruction caused by infection, inflammation, or other medical conditions leads to an irreversible obstruction and alters normal function of the nose (2, 7).

Most of the patients benefit oral and local antihistamines, corticosteroids, leukotriene receptor antagonists and anticholinergics, which can decrease allergy symptoms but they are not effective in treating nasal congestion or obstruction as well as ITH (8).

Therefore, it has motivated physicians to think of alternative therapies, including adjunctive therapy by saline in intranasal corticosteroids, inferior turbinate surgery, cauterization and radiofrequency which are known as effective methods in decreasing congestion, obstruction, and other symptoms and improving the quality of life (9,11,27,30).

Surgery and cauterization are less considered because of their known complications (8, 9).

Few studies have been conducted to compare radiofrequency and common medical therapies worldwide, while no studies have been yet performed in Iran. Hence, this study was done to compare corticosteroids and RF in treating ITH. Accordingly, a prospective study was designed with a follow-up of six months after treatment to compare the therapeutic effects of radiofrequency and intranasal corticosteroid spray on symptoms severity and quality of life in patients with ITH due to allergic rhinitis.

## Materials and Methods

After registering this randomized clinical trial study in Ethics Committee of Baqiyatallah University of Medical Sciences and the Iranian Registry of Clinical Trial (IRCT2014042417413N1), 66 patients with mild to moderate allergic rhinitis and inferior turbinate hypertrophy who referred to BMSU Allergy Clinic (having signed a written informed consent) were randomly divided into two groups using a computer-generalized list. The study flow chart is shown in Figure 1. Patients with allergic rhinitis (diagnosed through examination, history, and diagnostic tests) and nasal obstruction, verified by decreased nasal airflow in rhinomanometry test were enrolled in the study. Smoking, pregnancy, severe allergic rhinitis, polyps, septal deviation, chronic rhinosinusitis, and history of sinus and nasal surgeries were considered as the exclusion criteria.

Local anesthesia was performed using 10% lidocaine applied 30 minutes before the procedure in the radiofrequency (RF) group.

Total dosage of RF was  $1500 \pm 200$  joules at three points (300-359 joules with two punctures in every point): in the front portion of the inferior turbinate and parallel to septum, parallel to palmaris, and 2 cm posterior to the other two points. All these procedures were performed by one specialist. The patients were discharged immediately after RF prescribing a three-day nasal decongestant. In intranasal steroid (INS) group, fluticasone intranasal spray was prescribed ( $125 \mu\text{g}$  twice a day, one puff in each side of the nose). Symptoms (runny nose, obstruction, itchy nose, sneezing, cough, and facial pain) were assessed by symptoms severity score (0-10 VAS score). Quality of life was assessed using the Persian version of the Rhinitis Quality of Life Questionnaires (RQLQ) (12). The patients were evaluated prior to the intervention and also in third and sixth months after it.

#### Statistical Analysis

Data were analyzed using SPSS software version 21 (SPSS Inc. Chicago, IL) for windows. Normal distribution variables (approved by one-sample Kolmogorov–Smirnov test) were compared using independent sample T-test between the groups and paired sample T-test within the groups. Mann-Whitney U test was used between the groups and Wilcoxon test within the groups in non-normal distribution variables. Chi square test was used to compare categorical variables in the two groups.

#### Results

Sixty patients with mild to moderate allergic rhinitis were analyzed (43.3% male and 56.7% female). There were no significant differences between the two groups in terms of age, gender, and BMI (Table 1).

#### Symptoms Severity

The mean runny nose severity score was  $6.43 \pm 1.04$  in the RF group and  $6.5 \pm 1.41$  in the INS group before the intervention ( $P=0.835$ ).

Runny nose VAS score decreased to  $5.43 \pm 1.16$  and  $5.7 \pm 1.14$  in the RF and INS groups within six months, respectively ( $P=0.376$ ).

The mean nasal obstruction VAS score was  $6.83 \pm 0.52$  in the RF group and  $6.35 \pm 1.19$  in the INS group prior to the intervention ( $P=0.045$ ).

Nasal obstruction VAS score decreased to  $5.28 \pm 0.798$  and  $3.6 \pm 1.21$  in the RF and INS groups within six months, respectively ( $P<0.001$ ).

The mean itchy nose severity score was  $4.36 \pm 2.04$  in the RF group and  $3.74 \pm 1.75$  in the INS group before the intervention ( $P=0.206$ ).

Itchy nose VAS score decreased to  $3.29 \pm 1.59$  and  $2.67 \pm 0.89$  in the RF and INS groups within six months, respectively ( $P=0.051$ ).

The mean sneeze severity score was  $5.36 \pm 1.53$  in the RF group and  $5.78 \pm 1.05$  in the INS group before the intervention ( $P=0.223$ ).

Itchy nose VAS score decreased to  $4.28 \pm 1.68$  and  $4.93 \pm 1.33$  in the RF and INS groups within six months, respectively ( $P=0.105$ ).

The mean cough severity score was  $6.15 \pm 0.87$  in the RF group and  $6.25 \pm 1.42$  in the INS group before the intervention ( $P=0.761$ ).

Cough VAS score was decreased to  $4.11 \pm 1.09$  and  $4.47 \pm 1.62$  in the RF and INS groups within six months, respectively ( $P=0.318$ ).

Facial pain severity score was  $5.05 \pm 1.24$  in the RF group and  $5.34 \pm 1.31$  in the INS group before the intervention ( $P=0.262$ ).

Itchy nose VAS score decreased to  $1.99 \pm 1.61$  and  $2.76 \pm 1.69$  in the RF and INS groups within six months, respectively ( $P=0.077$ ).

Changes in symptoms severity are shown in Table 2.

### Quality of Life

The mean quality of life was  $2.44 \pm 0.38$  in the RF group and  $2.32 \pm 0.36$  in the INS group ( $P=0.227$ ). The mean changes from baseline amounts in RF and INS groups were, respectively,  $0.53 \pm 2.32$  and  $0.42 \pm 0.21$  in the first month ( $P=0.01$ ),  $1.18 \pm 0.31$  and  $0.93 \pm 0.31$  in the third month ( $P=0.002$ ), and  $1.62 \pm 0.43$  and  $1.31 \pm 0.29$  in the sixth month ( $P=0.001$ ) (Table 3).

At the end of the study, activity score decreased to  $2.13 \pm 0.59$  in the RF and  $1.47 \pm 0.97$  in the INS group ( $P=0.002$ ). In addition, sleep score decreased to  $2.27 \pm 0.83$  in the RF and  $1.4 \pm 0.086$  in the INS group ( $P=0.000$ ). Eye symptoms score decreased to  $1.49 \pm 0.83$  in the RF group and  $1.89 \pm 0.53$  in the INS group ( $P=0.031$ ). Nasal symptoms score decreased to  $1.8 \pm 0.88$  in the RF and  $1.39 \pm 0.61$  in the INS group ( $P=0.047$ ). Non-eye/nose symptoms score decreased to  $1.67 \pm 0.74$  in the RF group and  $1.38 \pm 0.61$  in the INS group ( $P=0.112$ ). Practical score decreased to  $1.56 \pm 0.69$  in the RF and  $1.39 \pm 0.64$  in the INS group ( $P=0.314$ ). Emotional score decreased to  $1.6 \pm 0.67$  in the RF and  $1.23 \pm 0.56$  in the INS group ( $P=0.023$ ). Figure 2 shows the comparison of mean quality of life items.

### Discussion

Based on the results of this study, radiofrequency (RF) is a more effective treatment than intranasal corticosteroids (INS) in controlling the symptoms of patients, especially nasal obstruction with inferior turbinate hypertrophy due to allergic rhinitis. Demographic information (age, sex, and BMI) were not significantly different between the two groups.

Recorded changes for runny nose, itchy nose, sneezing, cough, and facial pain presented no significant differences between the two groups in contrast to obstruction severity and quality of life which supported RF in the first post-treatment month.

Three months after the treatment, changes in runny nose, obstruction, itchy nose and sneezing in patients indicated no significant differences between the two groups.

While some symptoms had significant differences between the two groups, cough severity and quality of life supported RF and facial pain supported INS.

Changes in runny nose, sneezing, cough, and facial pain showed no significant differences between RF and INS groups six months after the treatment. However, rate of changes for nasal obstruction, itchy nose, and quality of life showed a significant difference between the two groups supporting RF.

The present study generally supports the findings of the study done by Gunhan et al. on quality of life and reduction of symptoms' severity,

considering these differences: they had a twelve-month follow-up and no repeated visits after the first intervention (2). Attenuation of symptoms' severity in the third month in our study was in agreement with the findings of Sözen et al. who assessed patients only in the third month without considering their quality of life (13). Lin et al. analyzed patients with medication-resistant allergic rhinitis over a six-month period regardless of changes in their quality of life via a single visit in the sixth months.

The results corresponded to those in our study in decreasing symptoms score.

They also assessed patients in the fifth year and recorded a minor increase in symptoms (7). The results of the present study are in accord with those of Celiker et al. in decreasing sneezing and nasal congestion. They evaluated patients more repeatedly and with more variables (14).

Kayamakci et al. in their four-week follow-up study mentioned the positive effects of radiofrequency on allergic rhinitis symptoms indicating the preference of lateral displacement radiofrequency (15).

A retrospective study with a two-year follow-up by Kojima et al. showed similar findings to those in the present study in decreasing symptoms, such as runny nose, sneezing, itchy nose, and quality of life score. They did not compare radiofrequency with other treatment methods, however (16).

The results of the present study are also supported by Parida et al. in decreasing indices of nasal symptoms and a descending trend in symptoms' severity up to sixth months.

They did not consider quality of life and other treatment methods to compare with radiofrequency (17).

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Huang et al. mentioned microdebrider assisted turbinoplasty as an effective method in decreasing nasal congestion and improving the quality of life (18).

Microdebrider assisted turbinoplasty was compared with radiofrequency by Kumar et al. in a study with a six-month follow-up study. They concluded that radiofrequency is as effective as microdebrider in decreasing patients' symptoms in the first and sixth post-treatment months. Three cases recurred in the sixth month in the radiofrequency group, which shows a preference for microdebrider (19).

.In an similar study, microdebrider was shown to be more effective than radiofrequency in reducing the symptoms of 268 patients with ITH and nasal congestion during three months (20). The results of the present study are in line with Banhira et al. in reducing the symptoms severity and improving patients' quality of life. They evaluated patients with chronic rhinitis resistant to medical therapy in eight weeks using RCQ-36 questionnaire (21).

Likewise, in a retrospective study, Safiruddin et al. assessed patients four years after radiofrequency, but they reported a recurrence rate of 30% for symptoms at the end of the study (22). Regarding the long-term effects of turbinoplasty by radiofrequency, a significant decrease in symptoms was reported compared to the baseline while a minimal increase was found compared to the first month (23). On the other hand, Deenadayal et al. reported a descending trend in symptoms (obstruction, runny nose, and sneezing) compared to the baseline and prior visits without any recurrences in 200 patients with allergic and non-allergic rhinitis during two years (24).

In addition, Garzaro et al. reported not only no recurrences but also an improvement in nasal airflow and olfactory in the second year after radiofrequency compared to the second month (25).

Assanasen et al. showed that radiofrequency decreases symptoms in patients with chronic rhinitis associated with ITH 10 weeks after intervention. They reported a significant improvement in rhinomanometry score and olfactory sense and a decrease in ITH(26).

Uz et al. and Duran et al., evaluating negative effect of radiofrequency on nasal mucociliary activity in two separate study, not only reported no adverse effect for this method, but also mentioned it to be effective in relieving nasal obstruction due to ITH (28, 29).

In a prospective study, Yilmaz et al. mentioned that radiofrequency significantly decreases pre and post-decongestant visual analogue scale (VAS) score, although they demonstrated that patients benefit from RF cannot be estimated subjectively by rhinomanometry (31). Effectiveness of RF on treatment of ITH was confirmed by computed tomography (CT) and VAS score in Duran et al. study (32).

The results of the present study confirm radiofrequency (RF) as a more effective method than intranasal corticosteroids (INS) in controlling symptoms in patients with allergic rhinitis associated with inferior turbinate hypertrophy (ITH).

This is in agreement with the results of previous studies. Therefore, radiofrequency is suggested as an alternative therapeutic method for intranasal corticosteroids in patients with slight to severe permanent or seasonal allergic rhinitis. It can also be concluded that intranasal corticosteroids can have convenient outcomes in patients who do not undergo radiofrequency. However, determining long-term effects and recurrence rate in these two therapeutic methods necessitates investigations with longer follow-up periods.

.Therefore, further studies are suggested to investigate the possible associated

complications and recurrence rate of INS and RF and to compare RF with surgical methods, prospectively, randomly, and with longer follow-ups (two or four years with repeated visits). Moreover, single-blind studies can be conducted using a spray (corticosteroid or placebo) and a procedure (radiofrequency or pseudo-radiofrequency) in each group to eliminate the destructive effects of pre-existing mentalities in patients and researchers on the results. This has not been considered in any previous studies.

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Table 1. Comparing Demographic Data between Radiofrequency (RF) and Intranasal Steroid (INS) Groups

|                        | RF (N=30)    | INS (N=30)   | Total (N=60) | P Value |
|------------------------|--------------|--------------|--------------|---------|
| Age, y                 | 35.5 ± 8.56  | 37.53 ± 9.18 | 36.52 ± 8.86 | 0.379   |
| Male, No. (%)          | 12 (40%)     | 14 (46.7%)   | 26 (43.3%)   | 0.397   |
| BMI, kg/m <sup>2</sup> | 22.53 ± 3.11 | 23.42 ± 3.12 | 22.97 ± 3.12 | 0.276   |

Table 2: Comparing Mean Decrease of Symptoms Severity Score Between RF and INS Groups.

| Symptoms Severity | RF (N=30)    | INS (N=30)  | Total (N=60) | P Value |
|-------------------|--------------|-------------|--------------|---------|
| Runny Nose        |              |             |              |         |
| First month       | 0.8 ± 0.48   | 0.7 ± 0.65  | 0.75 ± 0.57  | 0.502   |
| Third month       | 3.13 ± 1.5   | 3.4 ± 1.24  | 3.26 ± 1.37  | 0.458   |
| Sixth month       | 5.43 ± 1.16  | 5.7 ± 1.14  | 5.56 ± 1.15  | 0.376   |
| Nasal Obstruction |              |             |              |         |
| First month       | 1.72 ± 0.81  | 1.17 ± 0.77 | 1.45 ± 0.83  | 0.009   |
| Third month       | 2.62 ± 0.66  | 2.33 ± 0.75 | 2.47 ± 0.71  | 0.127   |
| Sixth month       | 5.28 ± 0.798 | 3.6 ± 1.21  | 4.44 ± 1.32  | <0.001  |
| Itchy Nose        |              |             |              |         |
| First month       | 0.77 ± 0.81  | 1.01 ± 0.47 | 0.89 ± 0.67  | 0.162   |
| Third month       | 2.29 ± 1.31  | 1.84 ± 0.66 | 2.06 ± 1.05  | 0.103   |
| Sixth month       | 3.32 ± 1.59  | 2.67 ± 0.89 | 2.99 ± 1.32  | 0.051   |
| Sneezing          |              |             |              |         |
| First month       | 2.86 ± 1.15  | 2.52 ± 1.53 | 2.69 ± 1.35  | 0.233   |
| Third month       | 3.5 ± 1.52   | 4.22 ± 1.34 | 3.86 ± 1.47  | 0.056   |
| Sixth Month       | 4.28 ± 1.68  | 4.93 ± 1.33 | 4.61 ± 1.54  | 0.105   |
| Cough             |              |             |              |         |
| First month       | 2.15 ± 1.47  | 2.61 ± 2.29 | 2.39 ± 1.92  | 0.359   |
| Third month       | 3.32 ± 0.84  | 4.24 ± 1.82 | 3.78 ± 1.48  | 0.015   |
| Sixth month       | 4.11 ± 1.09  | 4.47 ± 1.62 | 4.29 ± 1.38  | 0.318   |
| Facial Pain       |              |             |              |         |
| First month       | 1.25 ± 0.77  | 1.41 ± 0.9  | 1.33 ± 0.83  | 0.444   |
| Third month       | 1.45 ± 1.09  | 2.12 ± 1.45 | 1.78 ± 1.32  | 0.049   |
| Sixth month       | 1.99 ± 1.61  | 2.76 ± 1.69 | 2.38 ± 1.68  | 0.077   |



**Table 3.** Comparing Quality of Life Between RF and INS Groups

| RQLQ                   | Before      | 1st Month  | 3 <sup>rd</sup> Month | 6 <sup>th</sup> Month | Within Groups P Value |
|------------------------|-------------|------------|-----------------------|-----------------------|-----------------------|
| RF                     | 2.44 ± 0.38 | 1.9 ± 0.35 | 1.25 ± 0.18           | 0.796 ± 0.13          | < 0.001               |
| INS                    | 2.32 ± 0.36 | 1.9 ± 0.24 | 1.39 ± 0.25           | 1.012 ± 0.19          | < 0.001               |
| Between Groups P Value | 0.227       | 0.976      | 0.015                 | < 0.001               |                       |

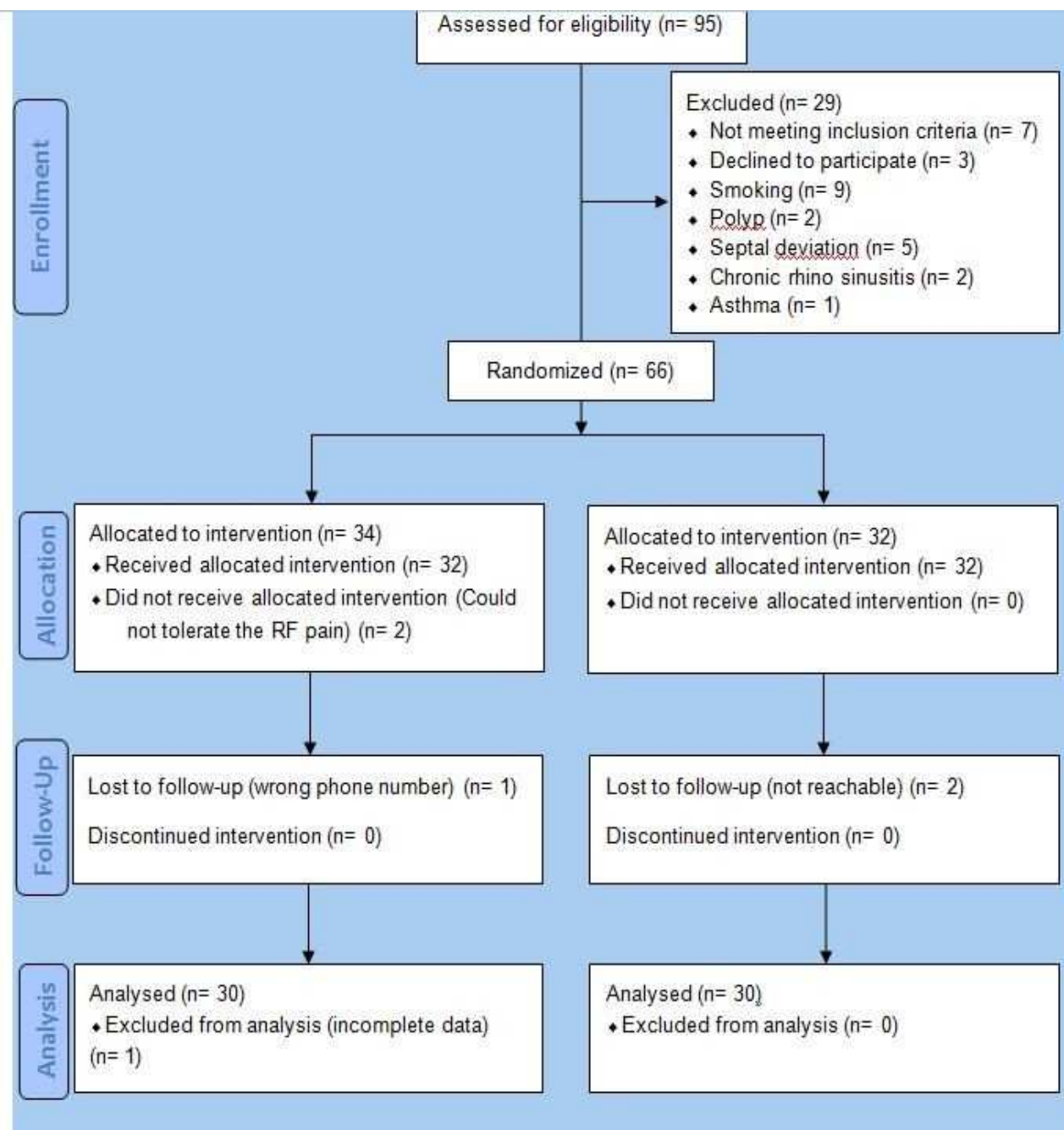


Figure 1. Study Flow Chart

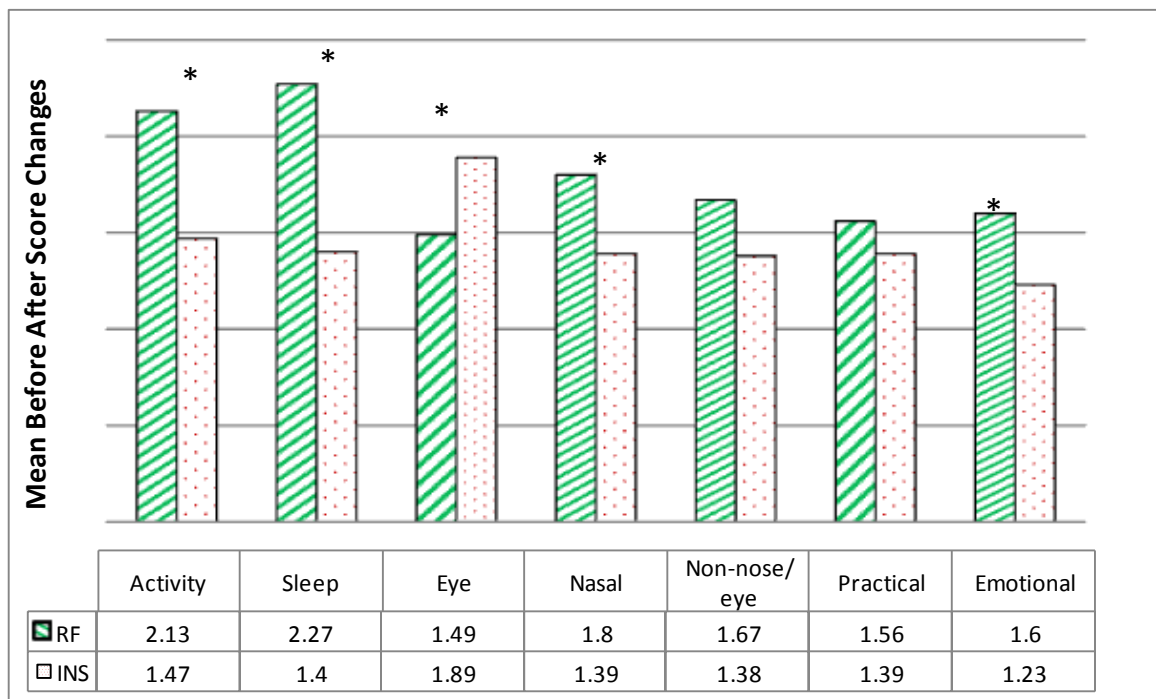


Figure 2. Comparison of Rhinitis Quality of Life Questionnaires (RQLQ) details in RF and INS Groups

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