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Mary Ann Liebert
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Histological Impact of Rhinophototherapy Compared to Intranasal Corticosteroids on Inflammatory Cells and Nasal Mucosa in Allergic Rhinitis

Kuganathan Ramasamy, MBBS[1], Hardip Singh Gendeh, Dr ORL-HNS[1,2], Aneeza Khairiyah Wan Hamizan, MS[1,2], Suria Hayati Md Pauzi, MMed[3], Farah Dayana Zahedi, MS[1,2], Nur Fadhilah Megat Ismail, BMLT[1,2], Nurwardah Alfian, DMLT[3], Nur Nastasha Abdul Razak, DMLT[3], Karuthan Chinna, PhD[4], and Salina Husain, MS[1,2]

Abstract

Objective: To assess the effect of rhinophototherapy (RPT) on nasal mucosa and inflammatory cells in allergic rhinitis compared to intranasal corticosteroids (INCS).

Methods: Adult patients (≥18 years) with newly diagnosed perennial allergic rhinitis (AR) were randomly divided into 2 groups, RPT and INCS. Treatment was administered for 2 weeks. Primary outcome was evaluation of the inflammatory cells and mucosal damage via inferior turbinate biopsy, performed post-treatment. Secondary outcomes measured were visual analogue score (VAS) of clinical symptoms (overall, runny nose, sneezing, nasal block, nasal itchiness and ocular itchiness) and nasal patency using rhinomanometry and peak nasal inspiratory flow (PNIF).

Results: Thirty-five patients were included, with 18 patients randomized into RPT and 17 patients into INCS. The mean age of patients was 31.3 ± 9.6 (range: 19-57). There was no statistically significant difference observed in terms of inflammatory cells in both groups. Similarly, both groups had no differences in mucosal damage parameters. Patients in RPT group showed statistically significant improvement for overall and specific symptoms VAS score ($P < 0.05$). Comparing both groups, patients using INCS reported bigger effect size for overall VAS score and specific VAS score for runny nose, sneezing, nasal and eye itchiness. Both groups showed improvement in PNIF reading post-treatment although only RPT group showed statistical significance ($P = .015$). In terms of rhinomanometry, both groups showed significant improvement in post-treatment nasal flow rate ($P < .05$). There was decrease in total nasal resistance observed in both groups, albeit with RPT being statistically significant ($P = .004$). There were no adverse events reported in both groups.

Conclusion: There is no significant difference in inflammatory cells of inferior turbinate mucosa and mucosal damage between RPT and INCS. RPT is a safe and suitable short-term alternative (2 weeks) for AR patients who are contraindicated for or unable to tolerate INCS.

Clinical trial number: The study was registered with ClinicalTrials.gov with the ID: NCT05919316.

Keywords

corticosteroid, inflammatory cell, mucosa injury, phototherapy, red light

Introduction

Allergic rhinitis (AR) is a prevalent health conundrum affecting 10% to 40% of individuals worldwide.[1] It represents a major public health burden, contributing to substantial economic costs besides affecting quality of life and work or school performance.[2] It is driven by an immunoglobulin E (IgE)-mediated inflammatory response that occurs in the nasal mucosa upon exposure to inhaled allergens.[3,4]

Intranasal corticosteroids (INCS), such as mometasone furoate and fluticasone furoate, are well-established first-line therapy for AR by inhibiting the production of

[1]Department of Otorhinolaryngology-Head & Neck Surgery, Faculty of Medicine, Universiti Kebangsaan Malaysia, Kuala Lumpur, Malaysia
[2]Allergic Unit, Hospital Canselor tuanku Muhriz (HCTM), Univeristi Kebangsaan Malaysia, Kuala Lumpur, Malaysia
[3]Department of Pathology, Faculty of Medicine, Universiti Kebangsaan Malaysia, Kuala Lumpur, Malaysia
[4]Faculty of Business and Management, UCSI University, Kuala Lumpur, Malaysia

Corresponding Author:
Hardip Singh Gendeh, MS, Specialist Otorhinolaryngologist, Head and Neck Surgeon, Department of Otorhinolaryngology-Head & Neck Surgery, Faculty of Medicine, Universiti Kebangsaan Malaysia, Jalan Yaacob Latif, Kuala Lumpur 56000, Malaysia.
Email: hardip.gendeh@hctm.ukm.edu.my

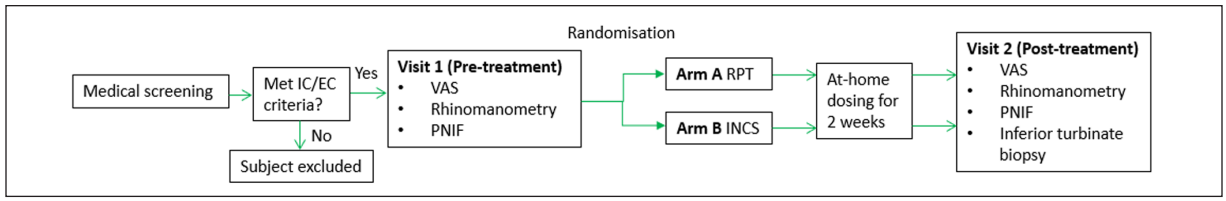

Figure 1. Study flow chart.
Abbreviations: EC, exclusion criteria; IC, inclusion criteria; INCS, intranasal corticosteroid; PNIF, peak nasal inspiratory flow; RPT, rhinophototherapy; VAS, visual analogue scale.

pro-inflammatory mediators, such as interleukins-4 and -5.[5,6] Despite possessing excellent safety profile over long-term usage, INCS may not be suitable for all patients, such as pregnant or breastfeeding women, individuals with glaucoma and those who cannot tolerate INCS due to side effects or contraindications.[7-9]

Rhinophototherapy (RPT) has emerged as an effective alternative, exerting a strong immunosuppressive effect by inducing apoptosis in inflammatory cells, such as eosinophils, mast cells and T cells, thereby inhibiting the effector phase of allergic reactions.[10] Besides ultraviolet light treatment, low-level narrow band red-light phototherapy has shown clinical benefit with minimal side effects.[11]

To our knowledge, there has not been any study on a direct comparison between RPT and INCS in AR treatment with respect to histological analysis from inferior turbinate biopsies. The study aims to assess the effects of RPT on inflammatory cells in the nasal mucosa compared to INCS. Secondary objectives include evaluating clinical efficacy using objective (rhinomanometry and peak nasal inspiratory flow [PNIF]) and subjective (Visual Analogue Scale [VAS]) measures.

Methods

A prospective randomized pilot trial was conducted at the Department of Otorhinolaryngology-Head and Neck Surgery, Hospital Canselor Tuanku Muhriz, Universiti Kebangsaan Malaysia (UKM), involving adults (≥18 years) newly diagnosed with perennial AR, confirmed by either a positive skin prick test or serum IgE (≥0.35 kU/L).[12] Exclusion criteria included history of anaphylaxis, poorly controlled asthma, nasal pathologies (eg, malignancy, chronic rhinosinusitis, polyposis, severe septal deviation), bleeding disorders, anticoagulant/antiplatelet use, pregnancy and recent upper respiratry tract infection. Participants discontinued antihistamines, leukotriene receptor antagonists, steroids (oral/intranasal) for at least 30 days prior. Subjects were randomized into 2 groups: (1) intranasal RPT using Bionette® (630 nm red light, 4.5 minutes, thrice daily) and (2) mometasone furoate nasal spray (Nasonex®, 50 mcg/dose, 2 sprays per nostril once daily). The investigators were blinded to the type of intervention given.

The study comprised a pre-treatment visit, a 2-week treatment period and a post-treatment visit on the following day (Figure 1). A 2-week period was chosen as this is the minimum duration required to optimize the therapeutic effect of INCS. Post-treatment, inferior turbinate biopsy was performed for histological analysis. The biopsy was performed at the anterior portion of the inferior turbinate under local anaesthesia. Co-phenylcaine spray was applied, followed by packing with ribbon gauze soaked in 0.2% lignocaine for 5 minutes. The biopsy was taken using through-cut straight forceps to minimize tissue crushing. Eosinophils and neutrophils were quantified on H&E-stained slides, and mast cells on CD117-stained slides. Ten high-power fields (hpf; magnification 400×) were selected randomly, and positively stained cells were enumerated. Average of 3 readings were taken. Mucosal damage was evaluated based on ulceration, squamous metaplasia and fibrosis. Pre- and post-treatment changes in PNIF, rhinomanometry and VAS scores were assessed. Statistical analysis was conducted using SPSS v25.0, with paired *t*-test for within-group pre- and post-treatment comparisons, independent *t*-test for between-group inflammatory cell count comparison and Chi-square tests for mucosal damage. A P-value $< .05$ was considered statistically significant.

Results

A total of 35 patients completed the study—18 (51.4%) in the RPT group and 17 (48.6%) in the INCS group. Baseline characteristics were comparable between groups, except for PNIF values (Supplemental Table 1).

Effects on Nasal Mucosal Inflammatory Cells

There were no significant differences in inflammatory cell counts (neutrophils, eosinophils and mast cells) or mucosal damage parameters between the groups ($P > .05$; Tables 1 and 2 and Figure 2).

Clinical Responses Between Patients Using RPT and INCS

Both groups showed absolute improvements in PNIF, flow rate and total nasal resistance (TNR). Significant improvements in PNIF and TNR were observed only in the RPT group ($P < .05$). Flow rate improved significantly in both groups, with a greater

Table 1. Comparison of Inflammatory Cells (Neutrophils, Eosinophils and Mast Cells) Counts Per High Power Field (hpf; 400×) Between RPT and INCS from Inferior Turbinate Mucosal Biopsy.

Inflammatory cells	Treatment group	Cell count, mean (SD)	*P*-value
Neutrophil	RPT	0.05 (0.11)	.782
	INCS	0.07 (0.19)	
Eosinophil	RPT	1.61 (3.45)	.361
	INCS	0.79 (1.20)	
Mast cell	RPT	8.31 (6.28)	.543
	INCS	7.09 (5.32)	

Abbreviations: INCS, intranasal corticosteroid; RPT, rhinophototherapy. $P < .05$ is considered significant.

Table 2. Comparison of Mucosal Damage (Presence of ulceration, squamous metaplasia and fibrosis) Between RPT and INCS from inferior turbinate mucosal biopsy.

Mucosal damage	Treatment group	Present, n (%)	*P*-value
Ulceration	RPT	2 (11.1)	.581
	INCS	1 (5.9)	
Squamous metaplasia	RPT	5 (27.8)	.086
	INCS	1 (5.9)	
Fibrosis	RPT	14 (77.8)	.412
	INCS	15 (88.2)	

Abbreviations: RPT, rhinophototherapy; INCS, intranasal corticosteroid. $P < .05$ is considered significant.

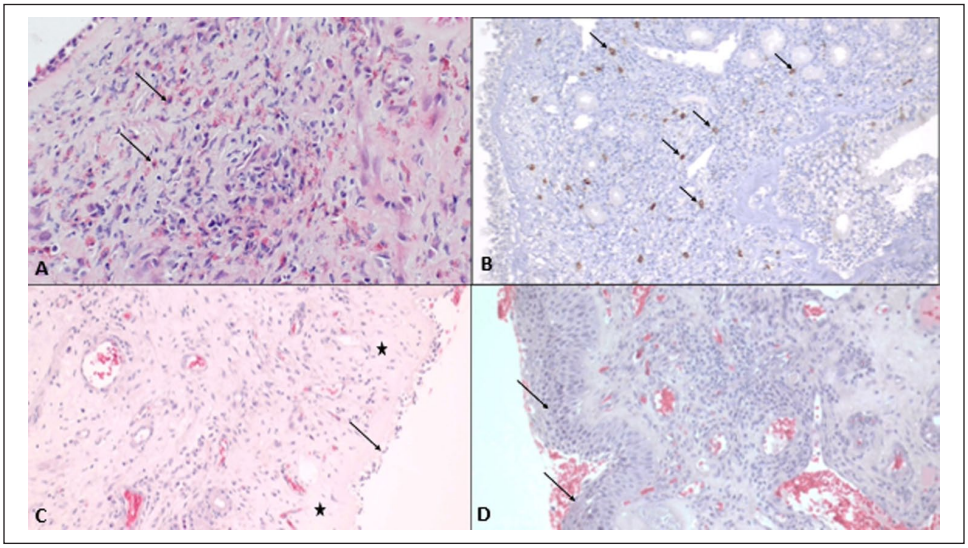

Figure 2. Histological findings in nasal mucosa. (A) Numerous eosinophils (black arrow) infiltration within the stroma, many of which show degranulation (H&E, 40×). (B) Scattered mast cells highlighted by CD117 immunostain (black arrow; 20×). (C) Focal surface ulceration (black arrow) and stromal fibrosis (black star; H&E, 20×). (D) Surface squamous metaplasia (black arrow; H&E, 20×).

increase in the RPT group (Table 3). VAS scores improved significantly across all symptoms in the INCS group ($P < .05$). The RPT group also showed significant improvement except for eye itchiness. Effect size analysis indicated greater symptom improvement in the INCS group, particularly for runny nose, sneezing and nasal itchiness (Table 3).

Safety Outcomes

Both treatments were well tolerated, with mild, self-limiting side effects such as rhinorrhoea, post-nasal drip, otalgia, epistaxis and fatigue. The overall side effect incidence was 31.4%, with rhinorrhoea being the most common (Table 4). No adverse effects were reported.

Table 3. Comparison of the Changes in Nasal Patency, Total Nasal Resistance and VAS Between RPT and INCS Group.

Treatment group	Outcome measures	Pre-treatment, mean (SD)	Post-treatment, mean (SD)	Change, mean (SD)	% change	*P*-value	Effect size
RPT	PNIF (L/min)	95.83 (25.57)	111.67 (31.15)	15.83 (24.69)	16.5	.015	0.64
	Flow rate (cm^3/s)	233.06 (130.44)	304.17 (146.47)	71.11 (66.02)	30.5	<.001	1.08
	TNR ($Pa/cm^3/s$)	0.98 (0.86)	0.71 (0.65)	−0.27 (0.35)	27.6	.004	0.78
	Overall symptom (mm)	51.50 (23.94)	36.78 (25.66)	−14.72 (20.99)	28.6	.008	0.70
	Runny nose (mm)	49.22 (21.83)	33.72 (27.70)	−15.50 (24.98)	31.5	.017	0.62
	Sneezing (mm)	45.83 (27.73)	29.17 (27.29)	−16.67 (22.02)	36.4	.005	0.76
	Nasal blockage(mm)	58.39 (27.38)	32.83 (26.91)	−25.56 (22.86)	43.8	<.001	1.12
	Nasal itching (mm)	41.06 (29.67)	28.39 (27.79)	−12.67 (22.75)	30.9	.030	0.56
	Eye itching (mm)	35.06 (29.39)	27.83 (28.67)	−7.22 (16.74)	20.6	.085	0.43
INCS	PNIF (L/min)	123.24 (40.12)	132.06 (41.16)	8.82 (28.48)	7.2	.220	0.31
	Flow rate (cm^3/s)	266.18 (120.86)	367.29 (152.61)	101.11 (141.12)	38.0	.009	0.72
	TNR ($Pa/cm^3/s$)	0.70 (0.37)	0.52 (0.33)	−0.18 (0.42)	25.7	.095	0.43
	Overall symptoms (mm)	51.12 (22.56)	23.00 (15.35)	−28.12 (23.18)	55.0	<.001	1.21
	Runny nose (mm)	49.71 (22.94)	20.47 (19.70)	−29.24 (23.61)	58.8	<.001	1.24
	Sneezing (mm)	55.76 (24.65)	19.88 (17.29)	−35.88 (28.11)	64.3	<.001	1.28
	Nasal blockage (mm)	55.82 (24.44)	21.41 (18.09)	−34.41 (31.16)	61.6	<.001	1.10
	Nasal itching (mm)	41.88 (27.80)	14.47 (14.05)	−27.41 (25.76)	65.4	<.001	1.06
	Eye itching (mm)	34.12 (25.13)	13.47 (12.82)	−20.65 (18.59)	60.5	<.001	1.11

Abbreviations: INCS, intranasal corticosteroid; PNIF, peak nasal inspiratory flow; RPT, rhinophototherapy; TNR, total nasal resistance. $P < .05$ is considered significant.

Table 4. Side Effects Profile Among Patients Receiving RPT and INCS.

	Treatment group		
Side effects	RPT, n (%)	INCS, n (%)	Total, n (%)
Rhinorrhoea	3 (16.7)	3 (17.6)	6 (17.1)
Post-nasal drip	1 (5.6)	1 (5.9)	2 (5.7)
Otalgia	1 (5.6)	0	1 (2.9)
Epistaxis (anterior)	1 (5.6)	0	1 (2.9)
Fatigue	0	1 (5.9)	1 (2.9)
Total	6 (33.3)	5 (29.4)	11 (31.4)

Abbreviations: INCS, intranasal corticosteroid; RPT, rhinophototherapy.

Discussion

Our study demonstrates that RPT, as a standalone treatment, is comparable to INCS in both objective and subjective assessments over a 2-week period. This duration was chosen based on evidence suggesting it is the minimum required for optimizing INCS efficacy in treating AR.[13]

No significant differences were observed in inflammatory cell counts or mucosal damage between RPT and INCS groups, suggesting both are equally effective in reducing early and late phase inflammation over the short term. Although pre-treatment histology was not performed—limiting our ability to compare changes directly—this provides a potential avenue for future research. There is paucity of data on nasal mucosal inflammatory cell quantification in AR based on biopsy, with most relying on nasal smears.[14,15] For instance, Usha et al[14] identified ≥ 0.2 eosinophils/hpf on nasal smear as diagnostic for AR. While mast cell studies exist, variations in tissue processing limit standardization.[16]

Previous studies have established the safety of INCS usage on nasal mucosa.[17] In our cohort, both groups showed minimal mucosal damage, with ulceration and squamous metaplasia being rare. RPT group showed no significant differences in mucosal damage outcomes as compared to INCS group. Squamous metaplasia, a precursor to atrophy, was largely absent, supporting mucosal safety of both treatments. However, fibrosis was common across both groups, likely reflecting chronic inflammation and tissue remodelling. The pathophysiology of fibrosis in AR appears to be multifactorial with complex interplay between genetic predisposition and environmental factors.[18] The impact of INCS on reversing remodelling remains uncertain despite its anti-inflammatory effect.

Objective evaluation using rhinomanometry showed significant flow rate improvement and TNR reduction in the RPT group. In contrast, TNR reduction in the INCS group was not statistically significant, possibly due to anatomical factors like mild septal deviation and bony hypertrophy of turbinates or suboptimal spray distribution.[19] The broader surface area exposed to red light in RPT may also account for its superior results in nasal resistance improvement. Studies by Karali et al[20] and Tatar et al[21] have shown that combining RPT with INCS improves symptom control and quality of life compared to INCS alone. RPT has also been well-proven to relieve symptoms such as nasal congestion, itchiness, sneezing and rhinorrhoea. A meta-analysis by Costa et al[22] supports its efficacy across different protocols and light wavelengths. Similarly, our findings align, with RPT showing significant symptom improvement, although INCS produced greater effect sizes for overall symptoms, runny nose, nasal itch, and sneezing.

Both treatments were safe and well tolerated, with mild, transient side effects in tandem with the existing literature evidence.[22] In our study, nasal dryness—a common complaint in UV-based RPT devices— was not encountered.[11] The most frequent side effect was transient rhinorrhoea within the first 3 days of RPT treatment, which subsequently resolved within 1 or 2 days.

A major strength of this pilot study lies in combining subjective symptom scoring with objective and histological assessment, including the novel use of inferior turbinate biopsy to quantify inflammatory cells in comparing RPT and INCS. Nonetheless, several limitations exist. The small sample size reflects its status as a pilot study. Lack of baseline inferior turbinate biopsy limited our ability to directly compare the pre- and post-treatment effect of both modalities. The higher cost and potential participant dropout deterred pre-treatment biopsy. Additionally, the short study duration limited long-term outcome assessment. Future research should address these limitations by recruiting a larger cohort of subjects, including pre-treatment biopsy, extending the study duration and evaluating cost-effectiveness and long-term outcomes of RPT compared to INCS.

Conclusion

RPT is a safe and effective short-term treatment for AR, demonstrating comparable efficacy to INCS in terms of inflammatory cell reduction, mucosal damage profile and symptomatic control. RPT is a promising alternative, particularly for patients who are intolerant to or contraindicated for INCS.

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ORCID iDs

Kuganathan Ramasamy https://orcid.org/0000-0003-0394-6611
Hardip Singh Gendeh https://orcid.org/0000-0001-9679-3495
Aneeza Khairiyah Wan Hamizan https://orcid.org/0000-0001-9287-3236

Ethical Considerations

This study was granted approval by the Research Ethics Committee of Universiti Kebangsaan Malaysia (UKM; UKM PPI/111/8/JEP-2023-251).

Consent to Participate

Written informed consent was obtained from all individual participants included in the study.

Author Contributions

Study conception and design: Kuganathan Ramasamy, Hardip Singh Gendeh, Aneeza Khairiyah Wan Hamizan, Farah Dayana Zahedi, Salina Husain. Acquisition of data: Kuganathan Ramasamy, Hardip Singh Gendeh, Aneeza Khairiyah Wan Hamizan, Farah Dayana Zahedi, Nur Fadhilah Megat Ismail, Nurwardah Alfian, Nur Natasha Abd Razak. Analysis and interpretation of data: Kuganathan Ramasamy, Hardip Singh Gendeh, Suria Hayati Md Pauzi, Nurwardah Alfian, Nur Nastasha Abdul Razak, Karuthan Chinna. Drafting of manuscript: Kuganathan Ramasamy, Hardip Singh Gendeh, Suria Hayati Md Pauzi, Karuthan Chinna. Critical revisions: Kuganathan Ramasamy, Hardip Singh Gendeh, Aneeza Khairiyah Wan Hamizan, Salina Husain. All authors have read and approved the final manuscript.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Data Availability Statement

The datasets used and/or analysed during the current study are available from the corresponding author upon request.

Supplemental Material

Supplemental material for this article is available online.

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