

Barrier Protection Measures for the Management of Allergic Rhinitis: A Systematic Review and Meta-analysis

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Abstract

Background: Pharmacotherapy for allergic rhinitis (AR) still remains unsatisfying regarding its effect and safety. Barrier protection measures may be a good choice for the patients with AR.

Objective: To assess the efficacy and safety of barrier protection measures in the treatment of AR.

Methods: We selected relevant randomized controlled trials published between January 1, 1990, and February 20, 2019, by searching Embase, PubMed, Cochrane, Web of Knowledge, and ClinicalTrials.gov. The primary outcome for this analysis was rhinitis symptom scores, overall quality of life, nasal peak inspiratory flow (NPIF), and adverse events. Differences were expressed as weighted mean difference (WMD) with 95% confidence intervals (CIs) for continuous outcomes. Statistical heterogeneity across trials was assessed with the statistic ($P < .1$) and the I^2 statistic.

Results: Fifteen RCTs (with data for 1154 participants) satisfied our inclusion criteria. The types of barrier protection measures comprised cellulose, pollen blocker cream, microemulsion, and nasal filter. To reduce the potential risk of bias and heterogeneity, we carried out subgroup analysis according to different types of barrier protection measures (cellulose: WMD = -2.18, 95% CI, -3.01 to -1.35, $P < .00001$; pollen blocker cream: WMD = -4.55, 95% CI, -6.10 to -3.00, $P < .00001$; microemulsion: WMD = -0.22, 95% CI, -0.42 to -0.03, $P = .03$). Findings from our meta-analysis show that, compared with placebo, barrier protection measures can yield improved symptomatic control for AR, with no increase in adverse events. Furthermore, barrier protection measures can improve the quality of life and NPIF.

Conclusion: Although further studies are still needed, our findings clearly lend support to barrier protection measures as a safe and efficacious option for the treatment of AR patients.

Keywords

barrier protection measures, allergic rhinitis, therapy, efficacy

Introduction

Allergic rhinitis (AR) represents a global health problem affecting 10% to 20% of the population.¹ Although AR is not a life-threatening illness, it plays an important role because of its impact on patients' social life, school performance, and work productivity. Furthermore, AR is often followed with many consequences such as asthma, sinusitis, otitis media, and obstructive sleep apnoea.²

Nowadays, the most commonly used therapeutic modality for AR is pharmacotherapy, but concerns still remain regarding its safety both among patients and doctors.³ For example, compared with older antihistamines, newer antihistamines are longer-acting and

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nonsedating but still cannot avoid adverse effect.⁴ Nasal steroid sprays are proved to have great potential anti-inflammatory capability but many patients are reluctant to take them due to fear of adverse effects.⁵ So patients still look forward to seeking nonpharmacological alternatives.

Avoidance of allergens is the most basic and important principle in the management of AR.¹ However, instructing the patients to avoid allergens does not help much in the case of ubiquitous allergens.⁶ An alternative way would be to cover the nasal mucosa with a protective layer of inert material. Such an approach is called “barrier protection measures” or “barrier-enforcing measures.”⁷ This protective barrier helps to prevent inhaled allergen from reaching the nasal mucosa and the specific Immunoglobulin E (IgE) of the mucosal immune system cells. As such, the allergic reaction will be blocked at the very beginning of the allergic cascade, in contrast to commonly used symptomatic medications such as antihistamines or corticosteroids, which act at the end of this cascade.⁸ In the last 2 decades, efficiency of barrier protection measures such as cellulose powder, pollen blocker cream, microemulsion, nasal filters, and white vaseline have been investigated. However, there are very few systematic reviews in this field and none involve meta-analysis up to now. We therefore plan to identify all randomized controlled trials (RCTs) to fully assess the efficacy and safety of barrier protection measures in the treatment of AR.

Material and Methods

Search Strategy and Selection Criteria

This systematic review and meta-analysis are reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement and was registered at International Prospective Register of Systematic Reviews (number CRD42019126185).

We selected relevant studies published between January 1, 1990, and February 20, 2019, by searching Embase, PubMed, Cochrane, Web of Knowledge, and ClinicalTrials.gov. We used the following combined text and MeSH terms: “rhinitis, allergic” and “barrier protection measures.” The complete search used for PubMed was (rhinitis, allergic[MeSH Terms] OR allergic rhinitides[Text Word] OR rhinitides, allergic [Text word] OR allergic rhinitis[Text word]) AND (barrier protection measures[Text Word] OR cellulose[MeSH Terms] OR polyanhydroglucuronic acid[Text word] OR acid, polyanhydroglucuronic[Text word] OR alpha-cellulose[Text word] OR alpha cellulose[Text word] OR rayophane [Text word] OR avicel[Text word] OR sulfite cellulose [Text word] OR alphacel[Text word] OR pollen blocker[Text word] OR ointment[Text word] OR

microemulsion[Text word] OR filters[Text word] OR white vaseline[Text word]). We considered all potentially eligible studies for review. We also did a manual search, using the reference lists of key articles published in English and Chinese.

Study Selection and Data Extraction

We regarded studies as eligible for inclusion if they were RCTs done in patients with diagnosed AR with or without asthma, compared different barrier protection measures with placebo, and reported changes in rhinitis symptom scores or overall quality of life or nasal peak inspiratory flow (NPIF) and adverse events. Observational and retrospective studies were excluded.

Two independent investigators reviewed study titles and abstracts, and studies that satisfied the inclusion criteria were retrieved for full-text assessment. Trials selected for detailed analysis and data extraction were analyzed by 2 investigators; a third investigator was consulted in case of disagreement to improve accuracy.

We extracted the following data from each selected study: study design, total number of participants, age, disease diagnosis, allergen, intervention, treatment duration, change in total nasal symptom score (TNSS), change in individual nasal symptom score (including sneezing, runny nose, itchy nose, and blocked nose), change in rhinoconjunctivitis quality of life questionnaire (RQLQ), change in NPIF, and adverse events. The methodological quality of each RCT was assessed according to the Cochrane Collaboration's tool for assessing risk of bias.⁹

Outcome data, extracted from the included studies and suitable for meta-analysis, were entered into RevMan software, version 5.3.0 (The Cochrane Collaboration, Oxford, UK). Differences were expressed as weighted mean difference (WMD) with 95% confidence intervals (CIs) for continuous outcomes. Statistical heterogeneity across trials was assessed with the χ^2 statistic ($P < .1$) and the I^2 statistic.¹⁰ As a guide, I^2 values of 25%, 50%, and 75% correspond to low, medium, and high levels of heterogeneity.¹¹ If a significant heterogeneity was found, we applied a random-effects model to pool results and 95% CI. Otherwise, a fixed-effects model was used. For the χ^2 statistic, a P value of $< .1$ was considered statistically significant. Sensitivity analyses were carried out to assess the robustness of the conclusions, if sufficient studies are available. We assessed publication bias by visually inspecting funnel plots.¹²

Results

Characteristics of the Included Studies

We identified 1206 studies and included 15 trials (with data for 1154 participants) in our analysis (Figure 1).

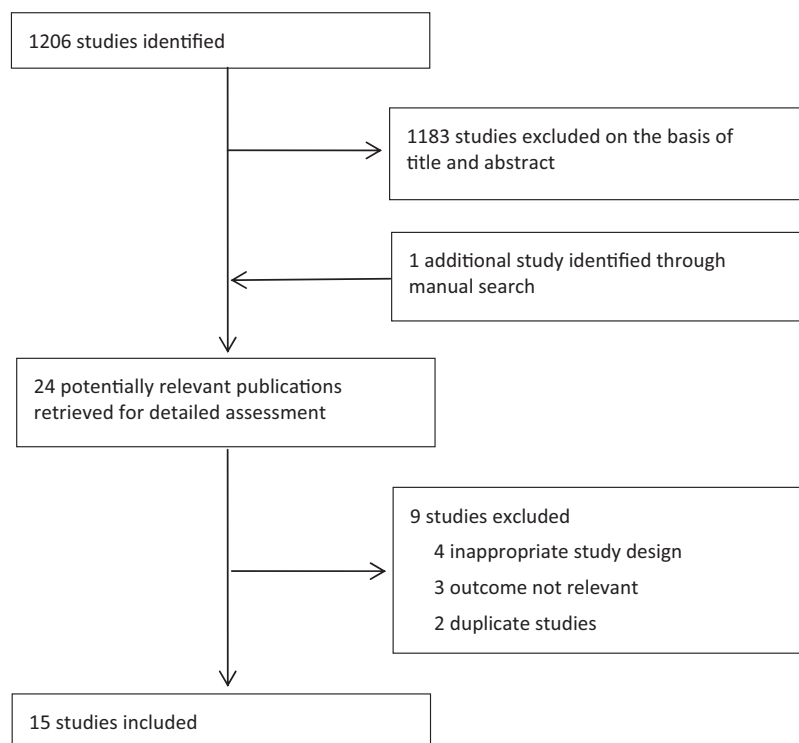


Figure 1. Flowchart of studies included.

These 15 trials were published between 2004 and 2017.^{5,8,13–25} In addition, 13 trials were published in English language and 2 were published in Chinese. The main characteristics of the included studies are listed in Table 1. Seven of the included RCTs adopted a parallel group design and 8 had a crossover design. The patients' age ranged from 7 to 69 years. Seven trials tested seasonal AR (SAR), 4 trials tested perennial AR (PAR), and 4 trials involved both types. Seven trials compared cellulose with placebo^{5,14,15,17,22–24}; 3 trials compared pollen blocker cream with placebo^{13,19,21}; 3 trials compared microemulsion with placebo^{8,16,18}; 2 trial compared nasal filter with placebo.^{20,25} The duration of treatment varied from single dose to 133 days. A wide range of outcome measures was used, with the most common nasal symptom scores, quality of life scores, nasal airflow rate, and adverse events.

Risk of Bias Assessment in Included Studies

Figure 2 shows the assessment of risk of bias in the trials. Among all the included trials, 10 of them had not described how to generate the randomized sequence, so we had to judge their selection^{5,8,13,16,18–23} bias as “unclear risk.” Allocation concealment, blinding of study subjects, investigators, and outcome assessment were almost universally maintained by the use of similar placebo preparations. None was stopped early, and the

numbers and reasons for withdrawal or dropout were reported in details in all trials.

Nasal Symptom Scores

Symptom reporting remains the most appropriate end point for the study of AR. All of the included trials reported total/individual nasal symptom scores in our present study, as a primary outcome measure.

Cellulose powder versus placebo. Five^{5,17,22–24} studies can be used for quantitative analysis. The aggregated result showed that cellulose powder led to a mean greater reduction in TNSS than the placebo ($P < .00001$), with statistically significant between-study heterogeneity (Figure 3). Further sensitivity analysis was performed by sequentially excluding individual studies, but significant heterogeneity between studies was still evident, and the test for overall effect remained significant. In the 2 trials of Emberlin et al.,^{14,15} TNSS were higher in the placebo group than in the active group, and the differences overall are significant at the $P \leq .05$ level.

In term of individual nasal symptom scores, the meta-analysis of 3 RCTs^{5,17,24} revealed that the cellulose powder was superior to placebo in improving blocked nose symptom ($n = 208$; WMD = -0.47 , 95% CI, -0.70 to -0.24 , $P < .0001$; heterogeneity: $P = .74$, $I^2 = 0\%$; Figure 4). At the same time, the combination of

Table 1. Characteristics of Included Studies.

Study	Study Design	Group (N)	Age Range (y)	Disease Diagnosis	Allergen	Intervention	Duration of Treatment	Outcome Measure
Schwartz et al. ¹³	Crossover	A(43) P(48)	23–36 23–36	SAR/PAR	Pollen/house dust/ animal dander	Pollen blocker cream	9 days	SS, NAR, AE
O'Meara et al. ²⁵	Parallel	A(22) P(24)	17–75	SAR/PAR	Ragweed/grass pollen	Nasal filters	1 weeks	MSC, TSC, acceptability
Emberlin et al. ¹⁴	Parallel	A(47) P(50)	18–58 18–58	SAR	Grass pollen	Cellulose powder	4 weeks	SS, AE, medication scores
Emberlin et al. ¹⁵	Crossover	A(15) P(15)	38–47 38–47	PAR	House dust mite	Cellulose powder	Single dose	SS, NAR, AE
Andersson et al. ¹⁶	Crossover	A(9) P(9)	22–28 22–28	SAR	Birch/grass pollen	Microemulsion	Single dose	SS, AE, nasal lavages analysis
Aberg et al. ¹⁷	Parallel	A(25) P(28)	8–18 8–18	SAR	Birch pollen	Cellulose powder	4 weeks	SS, AE
Andersson et al. ¹⁸	Crossover	A(20) P(20)	19–48 19–48	PAR	House dust mite	Microemulsion	6 days	SS, AE
Li et al. ¹⁹	Crossover	A(30) P(30)	7–48 7–48	PAR	Mite/animal dander/ pollen/cockroach	Nasal ointment (pollen blocker cream)	4 weeks	SS, RQLQ, AE
Ojeda et al. ⁸	Parallel	A(53) P(52)	18–57 18–69	SAR	Grass/birch/olive tree pollens	Microemulsion	Ranged from 29 to 133 days (pollen season)	SS, RQLQ, AE
Aberg et al. ⁵	Parallel	A(54) P(53)	18–40 18–40	SAR	Timothy grass pollen	Cellulose powder	4 weeks	SS, AE
Kenney et al. ²⁰	Crossover	A(76) P(76)	24.8 (M) 24.8 (M)	SAR	Grass pollen	Nasal filters	2 days	SS, AE
Li et al. ²¹	Crossover	A(115) P(115)	6–60 6–60	PAR	Mite/animal dander/pollen	Nasal ointment (pollen blocker cream)	4 weeks	SS, AE
Wan and Li ²²	Parallel	A(18) P(18)	19–40 18–49	SAR/PAR	Mite/animal dander/pollen	Cellulose powder	4 weeks	SS, AE
Paz et al. ²³	Crossover	A(20) P(20)	18–55 18–55	SAR	Grass/ragweed	Cellulose nasal spray	Single dose	Nasal airway resistance SS, NAR, AE
Li et al. ²⁴	Parallel	A(24) P(25)	18–52 19–55	SAR/PAR	Mite/animal dander/pollen	Cellulose powder	3 months	SS, RQLQ, AE

Abbreviations: A, active group; AE, Adverse event; M, mean; MSC, major symptom complex; N, number; NAR, nasal airflow rate; P, placebo group; PAR, perennial allergic rhinitis; RQLQ, rhinoconjunctivitis quality of life questionnaire; SAR, seasonal allergic rhinitis; SS, symptom score; TSC, total symptom complex.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Aberg2011	+	+	+	+	+	+	+
Aberg2014	?	+	+	+	+	+	+
Andersson2008	?	+	+	+	+	+	+
Andersson2011	?	?	+	+	+	+	+
Emberlin2006	+	+	+	+	+	?	+
Emberlin2007	+	+	+	+	+	+	+
Kenney2015	?	+	+	+	+	+	+
Li2013	?	+	?	+	+	+	+
Li2015	?	+	+	+	+	+	+
Li2017	+	+	+	?	+	+	+
Ojeda2013	?	+	+	+	+	+	+
Paz2016	?	+	+	+	+	+	+
Schwetz2004	?	+	+	?	+	+	+
T.J.o'Meara2005	+	+	+	+	+	?	+
Wan2015	?	+	+	+	+	+	+

Figure 2. The assessment of risk of bias in these trials.

2 RCTs^{15,24} suggested that the cellulose powder was superior to placebo in improving itchy nose symptom ($n=77$; WMD=-0.54, 95% CI, -0.96 to -0.11, $P=.01$; heterogeneity: $P=.06$, $I^2=73\%$; Figure 5). Data on runny nose symptom scores and sneezing scores were available for meta-analysis in 4 trials^{5,15,17,24} ($n=238$). Pooled results suggested that the cellulose powder group was significantly superior to the placebo group (Runny nose symptom scores: WMD=-0.59, 95% CI, -0.83 to -0.35, $P<.00001$; P for heterogeneity =.49, $I^2=0\%$;

Figure 6; Sneezing scores: WMD=-0.60, 95% CI, -0.82 to -0.37, $P<.00001$; P for heterogeneity =.26, $I^2=24\%$; Figure 7).

Pollen blocker cream versus placebo. Data on TNSS were available in only 2 trials.^{19,21} The meta-analysis revealed that pollen blocker cream was superior to placebo in reducing total nasal symptoms ($n=290$; WMD=-4.55, 95% CI, -6.10 to -3.00, $P<.00001$; heterogeneity: $P=.18$, $I^2=45\%$; Figure 8). Data of the symptom scores in the trial of Schwetz et al.¹³ revealed that the pollen blocker cream had a more significant effect compared with placebo ($P<.001$).

In term of individual nasal symptom scores, Li et al.²¹ reported a significant difference of individual nasal symptom scores (congestion, itching, runny nose, and sneezing) in favor of the pollen blocker group ($P<.01$).

Microemulsion versus placebo. The pooled results of 2 studies^{8,16} suggested that significant difference existed in the reduction of TNSS between microemulsion group and placebo group (WMD=-0.22, 95% CI, -0.42 to -0.03, $P=.03$; Figure 9); yet, medium level of heterogeneity was present ($P=.05$, $I^2=74\%$). In the trials of Andersson et al.,¹⁸ taken the whole treatment period into account, a statistically significant difference was observed in favor of the microemulsion ($P<.01$).

In term of individual nasal symptom scores, Ojeda et al.⁸ reported efficacy results in reduction of nasal congestion were favorable for the microemulsion, because significant differences were found ($P=.017$).

Nasal filters versus placebo. Two trials^{20,25} evaluated nasal filters in reducing symptom scores of AR. We cannot perform the meta-analysis because of the lack of enough data. However, in the trials of O'Meara et al.,²⁵ subjects wearing active nasal filters had significantly reduced scores, at all time-points compared with placebo group (all P values $<.05$). Another trial²⁰ showed the daily TNSS was significantly reduced for the nasal filter when compared with placebo ($P=.03$).

Kenney et al.²⁰ showed no difference existed between nasal filters and placebo in improving nasal congestion ($P=.573$) and sneezing ($P=.032$). Both Kenney et al.²⁰ and O'Meara et al.²⁵ have shown significant difference existed between nasal filters and placebo in improving nasal itch ($P=.038$ and $P=.034$) and runny nose ($P=.01$ and $P=.035$).

Rhinoconjunctivitis Quality of Life Questionnaire

Cellulose powder versus placebo. Only 1 trial²⁴ showed RQLQ in AR was significantly improved for the cellulose powder when compared with placebo ($P<.05$). Therefore, we cannot perform meta-analysis.

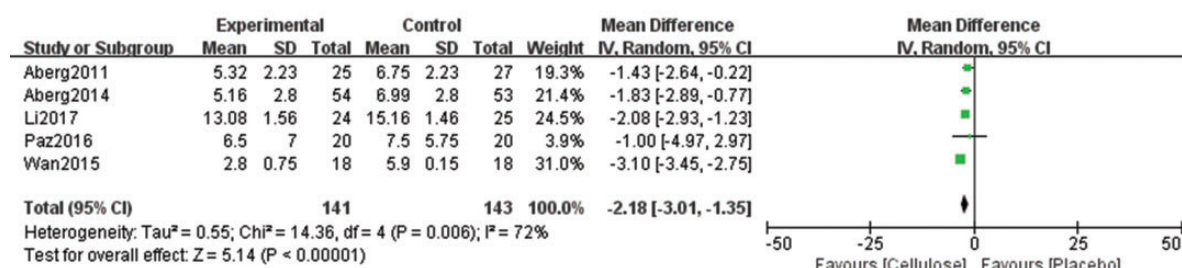


Figure 3. Meta-analysis of the RCTs comparing TNSS between cellulose powder group and placebo group. CI, confidence interval.

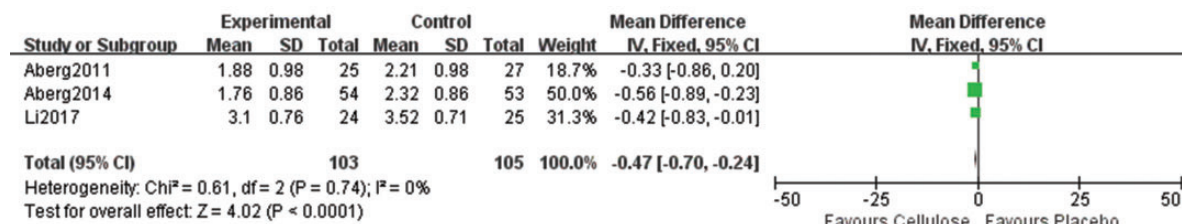


Figure 4. Meta-analysis of the RCTs comparing blocked nose symptom scores between cellulose powder group and placebo group. CI, confidence interval.

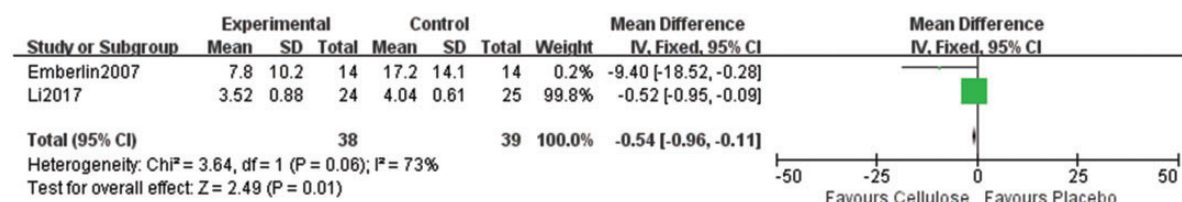


Figure 5. Meta-analysis of the RCTs comparing itchy nose symptom scores between cellulose powder group and placebo group. CI, confidence interval.

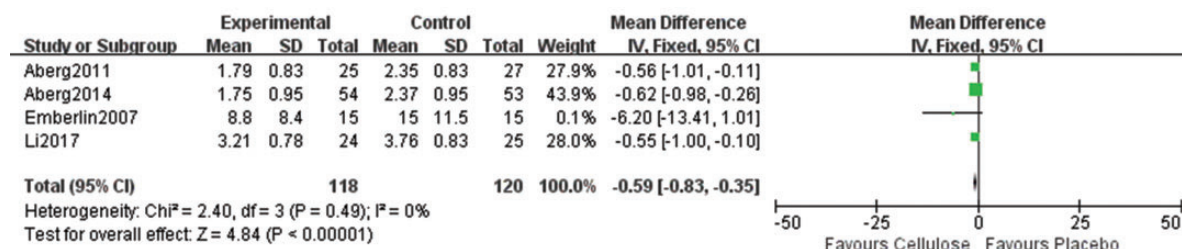


Figure 6. Meta-analysis of the RCTs comparing runny nose symptom scores between cellulose powder group and placebo group. CI, confidence interval.

Pollen blocker cream versus placebo. Li et al.¹⁹ reported the decreases in RQLQ in pollen blocker group was 30.7 compared with 7.1 in the placebo group, and the difference was significant ($P < .05$).

Microemulsion versus placebo. Ojeda et al.⁸ showed lower global scores in the mini-RQLQ were observed in the

group of patients treated with the microemulsion, indicating a better overall quality of life.

Nasal Peak Inspiratory Flow

Cellulose powder versus placebo. The meta-analysis of 2 RCTs^{15,23} suggested that the cellulose powder was superior to placebo in improving NPIF ($n = 70$; $WMD =$

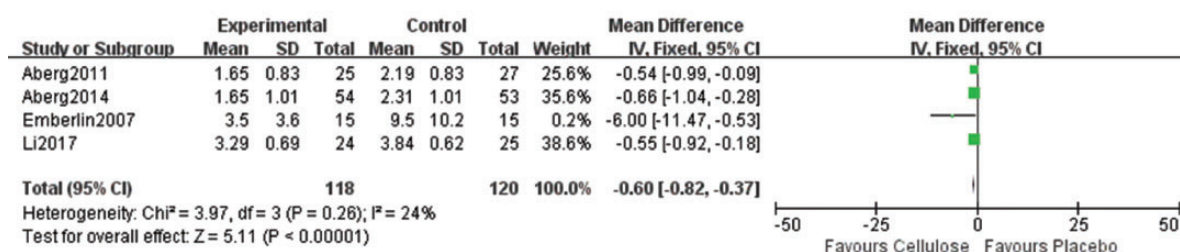


Figure 7. Meta-analysis of the RCTs comparing sneezing symptom scores between cellulose powder group and placebo group. CI, confidence interval.

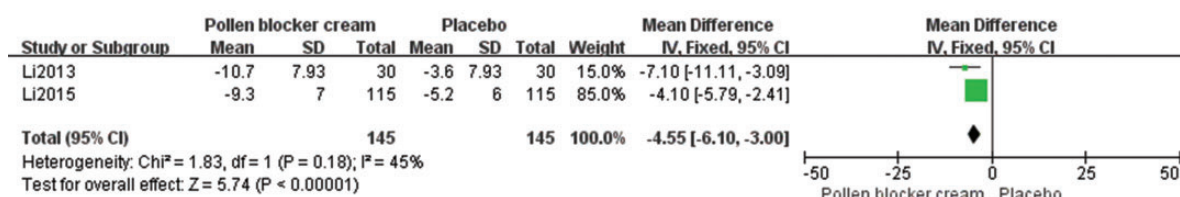


Figure 8. Meta-analysis of the RCTs comparing TNSS between pollen blocker cream group and placebo group. CI, confidence interval.

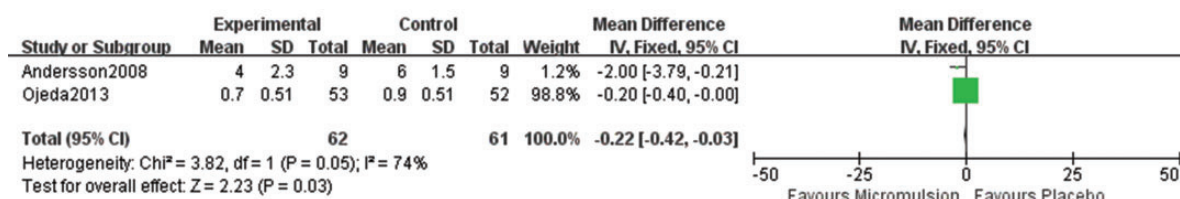


Figure 9. Meta-analysis of the RCTs comparing TNSS between microemulsion group and placebo group. CI, confidence interval.

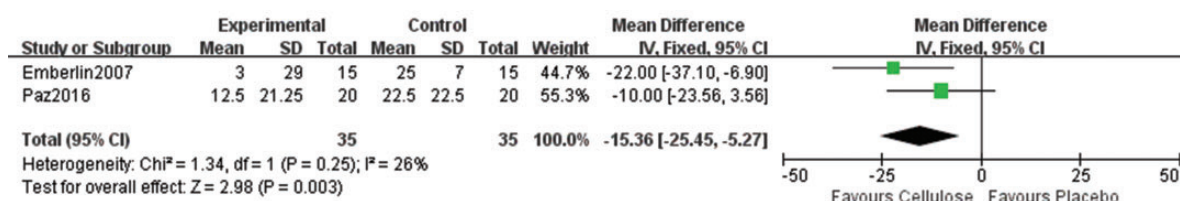


Figure 10. Meta-analysis of the RCTs comparing nasal peak inspiratory flow between cellulose powder group and placebo group. CI, confidence interval.

-15.36, 95% CI, -25.45 to -5.27, $P = .003$; heterogeneity: $P = .25$, $I^2 = 26\%$; Figure 10).

Pollen blocker cream versus placebo. Schwetz et al.¹³ reported both pollen blocker cream and the placebo led to a significant increase in the nasal airflow rate ($P < .001$). However, the investigational product was significantly more effective than the placebo.

Adverse Events

Ten of our included RCTs reported no adverse events during their study period, and the remaining 4^{5,19–21} reported mild adverse effects such as nasal irritation and nasal itch. The occurrence of adverse events in the barrier protection measures group was not significantly different compared with the placebo group. No serious

systemic reaction, which needed any medication or treatment in the hospital, was related to the therapy.

Publication Bias

We found no publication bias by visually inspecting funnel plots.

Discussion

In the management of AR, patients and doctors will continue to seek nonpharmacological alternative remedies. Nasal barrier protection measures have initially gained popularity, and a number of related RCTs have been carried out. However, up till now, only one previous systematic review⁷ in 2014 included several studies and drew a conclusion that barrier-enforcing measures had symptom-reducing effects in AR. While considering half of their included studies was not RCTs and meta-analysis was not performed, their conclusion is not so convincing. In our present study, we have collected all the RCTs about nasal barrier protection measures to obtain more data for novel meta-analysis and consistent conclusion. To the best of our knowledge, this is the first meta-analysis to explore the role of barrier protection measures in AR patients.

We found 15 RCTs that satisfied our inclusion criteria. The types of barrier protection measures comprised cellulose, pollen blocker cream, microemulsion, and nasal filter. Findings from our meta-analysis show that, compared with placebo, barrier protection measures can yield improved symptomatic control for AR, with no increase in adverse events. No matter concerning TNSS or individual nasal symptom scores, all above types of barrier protection measures have achieved satisfying control effect. Furthermore, barrier protection measures can improve RQLQ and NPIF. These data thus lend support to barrier protection measures as therapeutic strategy for AR. A relief of ocular symptoms may be secondary to the nasal effects in line with the concept of “united airways.” The data in most of our included RCTs, however, did not allow for meta-analysis.

In this systematic review, we carried out subgroup analysis according to different types of barrier protection measures in order to reduce the potential risk of bias and heterogeneity. However, some caution still should be taken into interpreting the findings of the present meta-analysis. The various populations (eg, age, sex, disease diagnosis and severity, ethnicity, and geographical background), the diverse study design, scoring systems, and different treatment duration adopted may account for the potential heterogeneity, although it is in part compensated for by use of the WMD in the meta-analyses. Another point to note is that, the numbers of cases and participants in most of the included RCTs are small. On the other hand, treatment duration in the studies is not

enough to indicate the tolerability in the long term, especially for PAR. So future long-term, large-scale, and well-designed RCTs on this topic are still required.

Barrier protection measures work as a facial mask to prevent inhaled allergens being deposited onto the nasal mucosa and reaching the specific IgE of the mucosal immune system cells.⁸ The absence of side effects makes these treatments particularly attractive in children, pregnant, and lactating women.²⁶ Nevertheless, we found there were none of RCTs conducted exclusively in children, pregnant, or lactating women in this systematic review, raising the question whether barrier protection measures are efficacious and safe to patients younger than 18 years of age, pregnant, or breast-feeding. More investigations are required to perform to answer this question.

An Allergic Rhinitis and its Impact on Asthma (ARIA) update from 2016 provides an in-depth analysis of the treatments available for subjects with AR. It suggests that the ultimate goal for the management of AR patients is achieving improvement of their quality of life.²⁷ Most patients with mild AR in their daily life would rather resort to self-treatment and prefer to seek available natural products to relieve their symptoms to an acceptable level. Based on the conclusion of our present study, barrier protection measures are very good choices for them. Concerning the moderate-to-severe cases of AR, the role of the doctors emerges as a more important determinant of the treatment choices. These patients are instructed to try to avoid allergens, to be put on pharmacological treatment in a step-wise manner. Current guideline-based pharmacological therapy includes oral antihistamines, intranasal antihistamines, intranasal corticosteroids, and oral leukotriene receptor antagonists. In this context, barrier protection measures may be regarded as a method to achieve allergen avoidance, and every patient should use such products. Therefore, direct and properly designed combination of barrier protection measures and pharmacological treatment are needed, especially topical treatments. For example, hydroxypropyl methylcellulose has been proved to enhance the efficacy of nasally applied drugs and seal together combinations of 2 or more nasal preparations.^{6,28} We are looking forward to more studies in this field.

Conclusion

Although further studies are still needed, our findings clearly lend support to barrier protection measures as a safe and efficacious option for the treatment of AR patients.

Declaration of Conflicting Interests

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

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study is supported by Guangdong Province Natural Science Grant (2018A030310325), Guangdong Province Medical Science Research Grant (A2017049), and Zhuhai City Science and Technology Project (20171009E030016).

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