

Randomized double-blind placebo-controlled crossover study of efficacy of pollen blocker cream for perennial allergic rhinitis

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ABSTRACT

Background: This study evaluates the efficacy and safety of a pollen blocker cream in treatment of perennial allergic rhinitis (PAR) in a Chinese population.

Methods: A randomized double-blind placebo-controlled, crossover trial was conducted in the Outpatient Department of the Eye, Ear, Nose, and Throat Hospital, Fudan University, Shanghai, China. Patients diagnosed with PAR were randomly assigned to receive pollen blocker cream or placebo, which was applied and evenly distributed to the lower internal nose region three times daily for a total of 30 days. The primary outcome measures for efficacy were nasal symptom scores (NSSs) and quality of life scores (QoLSs). Medication scores and adverse events were also monitored.

Results: After application of pollen blocker, the mean NSS fell from 23.1 to 12.4 points, and the QoLSs fell from 83.9 to 53.2 points ($p < 0.001$). The decrease in NSSs of pollen blocker (10.7) was highly significant compared with the placebo (3.6; $p < 0.001$). The decrease in QoLSs of pollen blocker was 30.7 compared with 7.1 in the placebo group, and the difference was also significant ($p < 0.05$). Interestingly, the mean NSS of the placebo group also decreased from 23.7 to 20.1 ($p < 0.05$). Additionally, the efficacy of pollen blocker was superior to the placebo both in adults and in children. However, there was no significant difference for individual symptoms of rhinorrhea, nasal itching, sneezing, and nasal congestion between the pollen blocker group and placebo group ($p > 0.05$). Only one mild epistaxis was reported.

Conclusion: The pollen blocker was significantly more effective than the placebo in relieving allergy symptoms and improving life quality of PAR in 30 Chinese people.

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Allergic rhinitis (AR) is a global health problem and its prevalence is increasing. Current data indicate that 40% of children and 10–30% of adults in industrialized countries suffer from the disease. It is further estimated that within the next 15 years, the prevalence of AR in the Western world will reach 50%.¹ AR has great impact on quality of life (QoL),² and leads to impairment of social life and productivity at school and work.³ It has been established that AR impairs work productivity of a greater magnitude than hypertension and diabetes mellitus type II.⁴ In addition, AR implies elevated social costs and causes enormous socioeconomic burden.⁵ Accordingly, developing new and effective treatment strategies is very important to stop its development. Although medication is associated with a low rate of side effects and conventional drugs are effective to relieve the symptoms of AR, causal treatment strategies such as allergen avoidance are necessary to achieve long-term improvement of symptoms.

The nose ointment—Dr. Theiss Alergol pollen blocker cream (referred to as “pollen blocker”; Phyt-Immun GmbH, Homburg, Germany)—has already been distributed as a medical device among European countries, owing to its efficacy and low risk of adverse effects. When applied to the lower nose region, it forms a mechanical barrier that entraps aeroallergens. This type of mechanism is similar to allergen avoidance. Postmarketing surveillance studies of the efficacy of various nasal ointments for AR started a few years ago.^{6–9} Nevertheless, few practitioners in China have used pollen blocker to treat AR, and no randomized controlled trials have been reported in recent years. The objective of the present study was to assess the efficacy and safety of this nasal ointment in the treatment of perennial AR (PAR) for Chinese people, aiming to put forward an effective, safer, and more convenient alternative remedy.

MATERIALS AND METHODS

Study Design

A prospective, randomized double-blind placebo-controlled, crossover study was conducted in the Eye, Ear, Nose, and Throat (EENT) Hospital, Fudan University, Shanghai, China, from September to December 2011. First, a 7-day preliminary assessment phase was performed to determine whether the candidates met the criteria for inclusion in the study, followed by the main phase of the study consisting of 30 days of treatment after random assignment of a patient to the pollen blocker or placebo group.

In the preliminary assessment phase, the patients were provided with the necessary information about the clinical study. All participants were required to submit a signed informed consent form before the start of treatment and they underwent eligibility screening, based on clinical history, skin-prick test, and serum-specific IgE assays (CAP-RAST; Pharmacia-Diagnostics, Freiburg, Germany) for assessment of inclusion and exclusion criteria (Table 1). The study protocol was approved by the Ethics Committees of the EENT Hospital, Fudan University.

In the 30-day treatment period, the active nasal ointment (5-g tube of ointment, a petrolatum-based ointment containing highly refined long-chain hydrocarbons; Dr. Theiss Naturwaren GmbH, Homburg, Germany) or placebo (gel containing 5% carboxymethylcellulose, 93.5% water, 0.5% citric acid, and 1% potassium sorbate) was applied. Each patient used a finger or a cotton swab to apply a cylinder, ~1 cm long, of the ointment to each nostril and to spread it evenly in the anterior region of the nose. As directed by the investigator, the ointment was applied three times daily, and each patient was requested to keep a record of application frequency in his/her diary.

During days 1 through 14, the patients applied pollen blocker or placebo. On day 14, a hospital visit was scheduled and the patients returned their test product and did not use it after the visit. After 2 days of washout, day 17 marked the beginning of the second phase of treatment. The patients checked in and were issued the test product that they had not used in the first phase in accordance with the crossover design schedule. The patients used the issued product on days 17 through 30 in the same manner as they had applied the

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Table 1 Inclusion and exclusion criteria

Inclusion criteria

- Male or female subject at least 6 yr of age
- Submission of signed consent form after being informed of the relevant study details by the investigator
- Diagnosis with at least 1 yr of PAR (confirmed by clinical history and positive skin-prick tests, and serum specific-IgE of >0.7 kU/L)
- Average NSS of at least 20 during the week before randomization

Exclusion criteria

- Known hypersensitivity to ingredients in the product under investigation
- Bronchial asthma treated with oral or inhaled cortisone regularly
- Severe septum deviation
- Nasal polyps
- Severe acute or chronic concomitant disease that seriously affects the patient's general health
- Concomitant disease that, according to current information, could affect the variables assessed in this study to such an extent that an objective judgement would not be possible
- Reasonable doubts about patient cooperation or compliance
- Dementia or any other serious intellectual impairment that would preclude correct history recording or impair the patient's judgment
- Participation in another clinical study <30 days before this study or during this study
- Participation in this study at an earlier date
- Women of childbearing age who were not using sufficient contraception

NSS = nasal symptom score; PAR = perennial allergic rhinitis.

former product on days 1 through 14. On day 30, the patients received a final examination.

Each patient was requested to keep separate diaries during the whole study period, logging the severity of nasal symptoms: sneezing, nasal itching, rhinorrhea, and nasal congestion in a diary each day. The severity of each symptom was scored on a scale of 0 to 10 (visual analog scale), which grades the severity of symptoms from "no symptoms" (0 cm) to "the highest level of symptoms" (10 cm). In addition, each patient recorded a Rhinoconjunctivitis Quality of Life Questionnaire¹⁰ in the preliminary phase (day 0) and on days 14, 17, and 30. Each patient was requested to make a note of all concomitant medications in his/her diaries. The patients' integral evaluation was obtained on completion of treatment.

Statistical Analysis

Continuous variables were expressed as mean $\pm$ SD. The comparison between pretreatment and posttreatment values was performed using paired *t*-test or Wilcoxon signed-rank test for normally and nonnormally distributed data, respectively. Difference between groups was analyzed using Student's *t*-test (for those with normal distribution) or Mann-Whitney *U* test (for those with nonnormal distribution). Categorical data were compared using chi-squared test. Mixed model analysis of variance for 2 $\times$ 2 crossover studies was fitted when assumption for normality was met. All analyses were performed with the Statistical Analysis Software (SAS, Version 9.1; SAS Institute, Inc., Cary, NC). A two-sided value of *p* < 0.05 was considered statistically significant.

RESULTS

Patient Population

A total of 41 patients diagnosed with PAR were screened for enrollment in this trial from September to December of 2011. Eleven of the patients did not fulfill inclusion requirements and were excluded; therefore, 30 subjects were included and randomized to treatment with pollen blocker or placebo.

The sample was composed of 19 male and 11 female subjects, 12 children (<18 years of age) and 18 adults ($\geq$ 18 years of age). Regarding their allergies, the most frequent causative allergens were mite allergens, followed by animal dander, pollen, and cockroach. The composition of patients is summarized in Tables 2 and 3. There was no significant difference between sequence 1 (first pollen blocker and

Table 2 Comparison of population composition between sequence 1 and 2

	Sequence 1 (n = 15)	Sequence 2 (n = 15)	χ^2	<i>p</i> Value*
Sex				
Male	10 (66.7%)	9 (60.0%)	0.14	0.70
Female	5 (33.3%)	6 (40.0%)		
Age, yr				
<18	5 (33.3%)	7 (46.7%)	0.56	0.46
$\geq$ 18	10 (66.7%)	8 (53.3%)		

Sequence 1, including 15 subjects who received pollen blocker and then placebo; sequence 2, including the other 15 subjects who received placebo and then pollen blocker.

**p* > 0.05.

then placebo) and sequence 2 (first placebo and then pollen blocker) for demographics, nasal symptom score (NSS), quality of life score (QoLS), and individual symptom score before treatment (*p* > 0.05). In addition, the subjects were not allowed to use any antiallergy medications or drugs that could reduce AR during the entire study period.

Effect of Pollen Blocker on NSSs and QoLS

Drug efficacy was assessed by means of NSSs and QoLSs, use of rescue medication, and integral evaluation.

Efficacy Based on Crossover Design

Pollen blocker was the product used by sequence 1 from days 1 to 14, which was used by sequence 2 from days 17 to 30. The mean and SD values of NSS and QoLS for the two identical treatment phases are illustrated in Figs. 1 and 2. Overall, the scores tended to decrease during the study period. On day 0 (before treatment), there was no significant difference of NSSs between the two sequences, and on day 14, the NSS of sequence 1 was significantly lower than sequence 2 (*p* < 0.05). After 2 days of washout, the difference between the two sequences was still statistically significant (*p* < 0.05). However, on day 30, *i.e.*, after the second stage of treatment, the NSS of sequence 2 was equal to sequence 1, and there was no significant difference between the two sequences (*p* > 0.05). As far as QoLS was concerned, although the mean values of sequence 1 were lower than that of sequence 2, there was no significant difference between the sequences

Table 3 Comparison between sequence 1 and 2 before treatment

Characteristic	Sequence 1 (n = 15)		Sequence 2 (n = 15)		p Values*
	Mean $\pm$ SD	Minimum, Maximum	Mean $\pm$ SD	Minimum, Maximum	
Age, yr	25.3 $\pm$ 12.9	7, 48	21.5 $\pm$ 12.7	7, 48	0.42
Duration, yr	9.5 $\pm$ 7.7	2, 26	8.6 $\pm$ 7.1	1.5, 31	0.76
NSS	23.1 $\pm$ 2.3	20, 27	23.7 $\pm$ 4.5	20, 32	0.61
QoLS	83.9 $\pm$ 22.5	53, 125	79.6 $\pm$ 23.4	47, 134	0.61
Rhinorrhea	6.4 $\pm$ 2.2	3, 10	5.4 $\pm$ 2.5	2, 9	0.25
Congestion	4.4 $\pm$ 1.5	2, 7	6.1 $\pm$ 2.9	1, 10	0.05
Itching	6.3 $\pm$ 1.8	4, 10	5.9 $\pm$ 2.6	2, 10	0.63
Sneezing	6.0 $\pm$ 2.3	1, 9	6.4 $\pm$ 2.0	1, 9	0.62

Duration: duration of PAR.

* $p > 0.05$.

NSS = nasal symptom score; QoLS = quality-of-life-score; PAR = perennial allergic rhinitis.

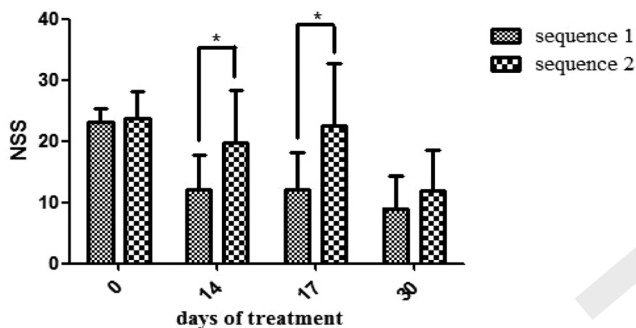


Figure 1. Mean values and SD of nasal symptom scores (NSSs) for the two sequences. Bars indicate the mean values of NSS; brackets represent SDs. Independent t-test, * $p < 0.05$.

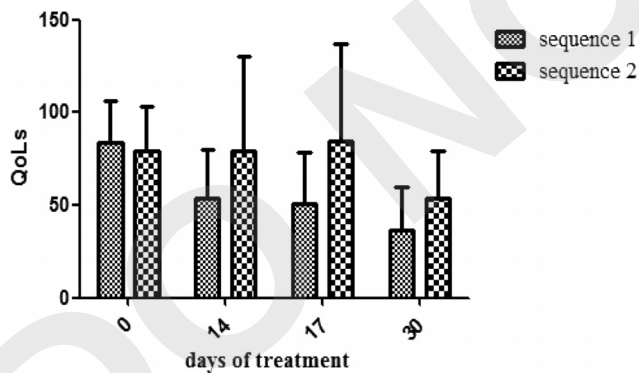


Figure 2. Mean values and SD of quality-of-life scores (QoLSs) for the two sequences. Bars indicate the mean values of QoLS; brackets represent SDs.

on every visit time ($p > 0.05$). Consequently, study results based on crossover design implied remarkable efficacy on NSS of pollen blocker.

Efficacy of Pollen Blocker and Placebo

The results were obtained by group method data handling: pollen blocker group and placebo group, irrespective of sequence.

First, the pollen blocker was significantly more effective than the placebo. After application of pollen blocker, the mean NSS fell from 23.1 to 12.4 points, the QoLS fell from 83.9 to 53.2 points. The decrease in NSS of pollen blocker (10.7) was highly significant compared with the placebo (3.6; $p < 0.001$). The decreases in QoLS of pollen blocker

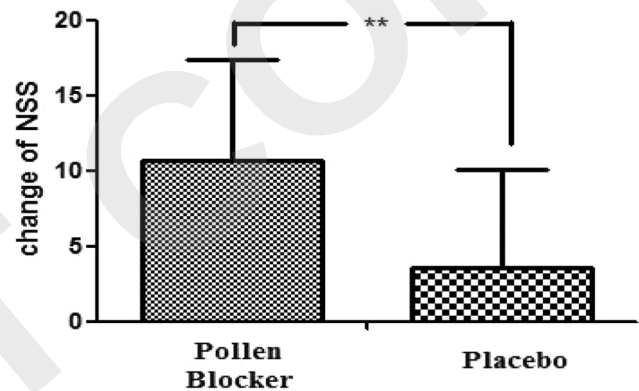


Figure 3. Change of nasal symptom scores (NSSs) between pollen blocker group and placebo group. Bars indicate the mean values of NSS; brackets represent SDs. Independent t-test, ** $p < 0.001$.

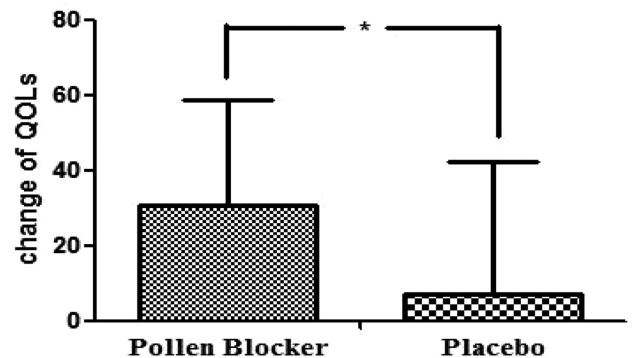


Figure 4. Change of quality-of-life scores (QoLSs) between pollen blocker group and placebo group. Bars indicate the mean values of QoLS; brackets represent SDs. Independent t-test, * $p < 0.05$.

was 30.7 compared with 7.1 in the placebo group, and the difference was also significant ($p < 0.05$), as shown in Figs. 3 and 4.

Interestingly, the mean NSS of the placebo group also decreased from 23.7 to 20.1 ($p < 0.05$). Consequently, not only pollen blocker but also the placebo led to a significant decrease in NSS in comparison with the start value on day 0 (paired t-test; $p < 0.05$).

Efficacy of Pollen Blocker in Adults and Children

The sample was composed of 18 adults (≥ 18 years old) and 12 children (< 18 years old). In adults, pollen blocker led to significant decreases both in NSS (10.5) and QoLS (30.0) compared with the

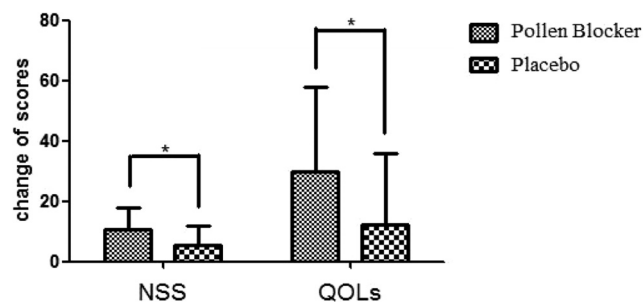


Figure 5. Change of nasal symptom scores (NSSs) and quality-of-life scores (QoLSs) in adults. Bars indicate the mean values; brackets represent SDs. Independent *t*-test, **p* < 0.05.

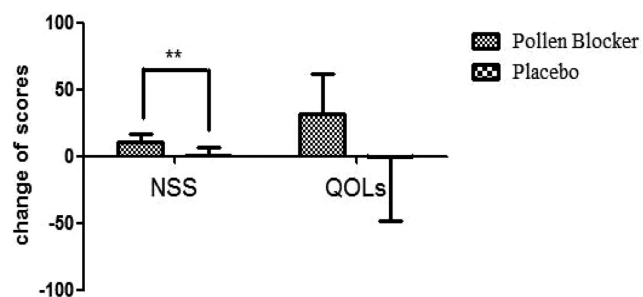


Figure 6. Change of nasal symptom scores (NSSs) and quality-of-life scores (QoLSs) in children. Bars indicate the mean values; brackets represent SDs. Independent *t*-test, ***p* < 0.001.

placebo (NSS, 5.3; QoLS, 12.4; *p* < 0.05); in children, the decrease in NSS of pollen blocker (11.1) was remarkably higher than the placebo (1.0; *p* < 0.001), while the decrease of pollen blocker in QoLS was not significant compared with the placebo (*p* > 0.05), as shown in Figs. 5 and 6.

In terms of the individual NSS of rhinorrhea, nasal itching, sneezing, and nasal congestion, there was no significant difference between the treatment groups (*p* > 0.05).

It is worth mentioning that the study was designed as a crossover trial, which can eliminate effects of nontrial factors as many as possible. Just as manifested in Tables 4 and 5, after controlling the sequence, period and nested effect of subjects, the efficacy of pollen blocker was significant (*p* < 0.05).

Overall Evaluation

There were eight patients (26.7%) reporting that the placebo was more comfortable than pollen blocker, and the former seldom irritated allergy symptoms when applied.

Adverse Events

The only reported adverse effect of pollen blocker was epistaxis (*n* = 1), which happened on the 1st and 2nd day of application and did not occur any more after that.

DISCUSSION

AR represents a major and growing medical, QoL, and socioeconomic problem in more and more parts of the world today. Besides being a debilitating disease on an individual and social level, it has a major negative impact on national and global health economics because of direct and indirect costs.^{11–17} Because 20% of people with rhinitis are not helped by guideline-directed pharmacotherapy,¹⁷ new and more effective treatments should be sought.

The treatment of AR includes patient education, allergen avoidance, pharmacotherapy, and allergen-specific immunotherapy. It is

Table 4 Decrease of NSS

Source	F Value	Pr > F
Seq	0.02	0.88
Pr	0.15	0.70
Ptid (seq)	0.99	0.51
Trtmt	16.84	0.00*

**p* < 0.001.

NSS = nasal symptom score; Seq = sequence; Ptid (seq) = nest effect; Trtmt = treatment (pollen blocker); Pr = period.

Table 5 Decrease of QoLS

Source	F Value	Pr > F
Seq	0.50	0.48
Pr	0.56	0.46
Ptid (seq)	0.50	0.96
Trtmt	6.12	0.02*

**p* < 0.05.

QoLS = quality-of life-score; Seq = sequence; Ptid (seq) = nest effect; Trtmt = treatment (pollen blocker); Pr = period.

well known that every method has its own defects. Today, with the improvement of life quality, more attention is focused on seeking safer, more convenient alternative remedies for the disease.

The investigational product pollen blocker is a new petrolatum-based ointment containing highly refined long-chain hydrocarbons. When applied to the lower nose region, it forms a mechanical barrier that entraps aeroallergens and reduces the number of allergens entering the nose thereby relieving allergy symptoms induced by aeroallergen. Some studies conducted in Europe have confirmed the efficacy of pollen blocker for treatment of AR: Buff,⁶ who tested only pollen in his study, observed that intranasal application of petrolatum-based ointment effectively relieved the symptoms of AR in 15 patients during pollen season. He speculated lipids might be able to prevent the release of allergens from pollen *in vivo*. In another study,⁷ a highly purified, highly viscous nose ointment with a petrolatum base achieved a significant decrease in allergic symptom score without causing adverse events. In 2004, Schwetz and coworkers⁸ used a nasal provocation test to show the ointment that was the same as our product was significantly more effective than placebo (carboxymethylcellulose) in reducing allergy symptoms, and found that the use of a placebo also led to a significant improvement of symptoms. A recently published study in 2005⁹ observed the lipid-based nose ointment tested here led to a significant improvement in sneezing and nasal itching (17 patients); meanwhile, all scores remained unchanged in the untreated control group (16 patients). These findings provide further evidence in favor of the efficacy of nose ointment-containing lipids.

As mentioned previously, the efficacy of pollen blocker was encouraging. It has already been distributed as a medical device for prevention against and treatment with AR among European countries. However, few ear, nose, and throat doctors in China have used the ointment and no randomized controlled trial assessing the efficacy of this product has been reported. In the present randomized double-blind placebo-controlled, crossover study conducted in the outpatients of EENT hospital, Fudan University, we observed the efficacy of pollen blocker ointment was significantly more effective than placebo, manifesting both in NSS and QoLS (*p* < 0.05). Furthermore, statistical analysis based on the crossover study also verified the findings: pollen blocker had a significant effect on relieving allergy symptoms and improving QoL. Additionally, the study results suggested the efficacy of pollen blocker was superior to the placebo both in adults and in children. Because the sample size was small,

more research needs to be conducted to confirm the case. As for the development of individual nasal symptoms, there was no significant difference in nasal itching, sneezing, nasal congestion, and rhinorrhea between the pollen blocker group and the placebo group.

It is well known that a strong placebo effect has been observed in allergic diseases. In our study, we also observed the similar placebo effect as presented by Schwetz⁸: the placebo group also had a decrease in NSS and 26.7% patients reported the placebo was more comfortable than pollen blocker. Today, the placebo effect is viewed as a psychobiological event resulting from the interaction between individual patient factors and factors relating to the physician and the therapeutic environment.¹⁸ Because treatment efficacy in our study is mainly evaluated by physical or subjective parameters, it is necessary for future investigators to conduct more research studies, by using objective or biochemical parameters to determine the efficacy of pollen blocker or placebo.

As for the safety of pollen blocker, it is a mixture of high-purity, long-chain hydrocarbons in a high-viscosity mineral oil base, which is not metabolized, toxicologically safe, and hypoallergenic. Health hazards due to the use of petrolatum arise only as a result of its physical effects on the gastrointestinal tract or airways when accidentally swallowed or aspirated.⁸ Only one case reported that petrolatum-induced pneumonia has been documented worldwide in a patient.¹⁹ Isolated occurrences of paraffinomas have also been reported.^{20,21} In our study, the ointment did not produce any AEs except for a mild epistaxis ($n = 1$), which occurred twice and did not last long. So, the pollen blocker was well tolerated.

Although AR is not a serious illness, it is clinically relevant and affects QoL and productivity at work or school.¹⁷ In this article, the first randomized placebo-controlled, crossover study of evaluating the efficacy and safety of pollen blocker in China has shown the petrolatum-based ointment is significantly more effective than the placebo in relieving allergy symptoms and improving life quality in 30 Chinese patients with PAR. However, because of the limitation of sample size and time in this trial, more clinical research is expected to be conducted to confirm the efficacy of pollen blocker. In general, the nasal ointment has the potential to be an alternative remedy for treatment or prevention of AR. Meanwhile, additional studies are required to investigate its mechanism.

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