

## Original Article

# Study on the effects of desloratadine citrate disodium on the postoperative complications and inflammatory response in patients with chronic sinusitis undergoing endoscopic sinus surgery

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Received September 30, 2020; Accepted December 8, 2020; Epub March 15, 2021; Published March 30, 2021

**Abstract:** Objective: To explore the effects of desloratadine citrate disodium on the postoperative complications and inflammatory markers in patients with chronic sinusitis undergoing endoscopic sinus surgery. Methods: From June 2019 to December 2020, the patients with chronic sinusitis who received treatment in our hospital were selected and divided into the control group (CG) and experimental group (EG). In both groups, patients were given endoscopic sinus surgery. On this basis, patients were treated with desloratadine citrate disodium in the EG. The total effective rate of the operation and the incidence of complications were compared between the two groups, and the VAS scores of clinical symptoms were compared between the two groups after treatment. Meanwhile, the changes of serum TlgE, ECP and inflammatory factors were compared between the two groups, and the nasal mucociliary clearing function was compared between the two groups before and after treatment. Results: After treatment, the total effective rate was 94.9% in the EG, which was significantly higher than that in the CG (82.2%). The levels of serum interleukin-6 (IL-6), interleukin-8 (IL-8), high-sensitivity C-reactive protein (hs-CRP) and tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ) in the EG were significantly lower than those in the CG, and the levels of serum TlgE and ECP were also significantly lower than those in the CG. After treatment for 3 months, the mucociliary clearance rate and mucociliary clearance rate in the EG were significantly higher than those in the CG, while the saccharin clearance time was significantly shorter than that in the CG. The incidence of complications in the EG was significantly lower than that in the CG (all  $P < 0.05$ ). Conclusion: Desloratadine citrate disodium combined with endoscopic sinus surgery can improve the clinical efficacy, reduce the level of inflammatory factors and effectively reduce the incidence of complications in patients with chronic sinusitis.

**Keywords:** Desloratadine citrate disodium, endoscopic sinus surgery, chronic sinusitis, efficacy, inflammatory factors, complication

## Introduction

Chronic sinusitis is a category of chronic diseases with inflammatory pathological changes in the nasal cavity and sinus mucosa, and characterized by recurrent attacks with a course of more than 12 weeks. It is a common nasal disease in otolaryngology [1]. The main clinical symptoms are nasal congestion, purulent discharge, hyposphraesia and/or headache. If the patient does not receive standardized treatment in a timely manner, he/she may even lose sense of smell, causing otitis media and may

also lose their vision [2]. Long-term poor ventilation and drainage caused by continuous nasal congestion will gradually lead to systemic chronic diseases such as hypertension and diabetes due to chronic hypoxia, thus affecting the health of patients [3]. The clinical incidence of chronic sinusitis is extremely high, and the course of the disease is recurrent and prolonged, which seriously affects the daily life of patients [4]. The etiology of chronic sinusitis is complicated. In the past, experts and scholars believed that the main factors leading to chronic sinusitis were respiratory tract infection,

abnormal anatomical structure of nasal cavity and paranasal sinuses, and respiratory allergic response [5]. Nasal scientists generally believe that these factors are often related to each other and affect the development of chronic sinusitis [6].

According to the different pathogenesis of chronic sinusitis, chronic sinusitis can be divided into two categories. One is sinusitis with nasal polyps, and the other is sinusitis without nasal polyps [7, 8]. The former is mostly a type of allergic reaction. The latter is not an allergic reaction, but non-infectious inflammation [9]. Clinically, patients will be given standardized drugs or surgical treatment according to the individual situation, but the effect of drug treatment alone is not ideal. With the development of endoscopic sinus surgery, its clinical value has been continuously improved in recent years, and it has become an important surgical treatment for chronic sinusitis [10]. This operation can thoroughly remove the lesioned tissue, enlarge the sinus opening, and promote the recovery of the physiological function of the sinus, thus improving the clinical symptoms and achieving the purpose of treatment [11]. However, endoscopic sinus surgery has some limitations. Some studies have pointed out that the combination of local drug therapy and endoscopic sinus surgery can effectively achieve complementary curative effects and improve the comprehensive efficacy of chronic sinusitis [12]. In this study, the patients were treated with desloratadine citrate disodium at the same time with endoscopic sinus surgery to observe the postoperative efficacy.

### Materials and methods

#### *Research subjects*

From June 2019 to December 2020, a total of 104 patients with chronic sinusitis who received treatment in Chaohu Hospital of Anhui Medical University were selected and randomly divided into a control group and an experimental group (CG and EG). Inclusion criteria: (1) All the selected patients met the relevant diagnostic criteria of chronic sinusitis [13] (repeated nasal congestion, purulent nasal discharge, headache and other clinical symptoms, which lasted for more than 2 years and lasted for more than 12 weeks every year); (2) Endoscopic examination showed edema of middle nasal

meatus, lower and middle turbinate mucosa and obstruction of nasal meatus; (3) CT examination showed changes of nasal sinus mucosa without nasal polyps. Exclusion criteria were as follows: (1) Patients with other allergic diseases, severe heart and lung, liver and kidney insufficiency, malignant tumors, glucocorticoid and H1 receptor antagonist before admission; (2) Patients with drug contraindications and poor compliance; (3) Patients who had undergone surgery in the last 3 months. The research plan was approved by the hospital ethics committee, and patients were informed of the specific treatment plan and volunteered to participate in this study.

#### *Treatment methods*

CG: After general anesthesia, the patients were given endoscopic sinus surgery. The diseased sinus was opened to remove the nasal obstruction. At the same time, the normal sinus mucosa was retained during the operation, and antibiotics (roxithromycin: half of the conventional antibacterial dose, for 4 weeks) were used to prevent infection and wash the nasal cavity after the operation.

EG: On the basis of treatment given to the CG, the patients were treated with desloratadine citrate disodium. Treatment plan: the desloratadine citrate disodium (8.8 mg) was given to the patients preoperatively, orally, once per day, for 4 weeks.

#### *Outcome measures*

All patients were followed up for 3 months to evaluate the efficacy of chronic sinusitis. The criteria were as follows: complete control: the clinical reaction disappeared, and the position of the sinus orifice was open well after endoscopic examination. Partial control: the clinical response was improved, and there was edema in the sinus cavity by endoscopy. Uncontrolled: there was no improvement in clinical symptoms. Among them, the cases of complete control and partial control were treated effectively.

According to the visual analogue scale (VAS) score, the higher the score, the more serious the lesion.

Before and after treatment, the fasting venous blood of patients was drawn, and the levels of serum TlgE, ECP, hs-CRP, TNF- $\alpha$ , IL-6, IL-8 and

**Table 1.** Comparison of efficacy between the two groups

	Complete control	Partial control	Uncontrolled	Total effective rate
CG (n=45)	25 (55.5)	12 (26.7)	8 (17.8)	37 (82.2)
EG (n=59)	42 (71.2)	14 (23.7)	3 (5.1)	56 (94.9)
$\chi^2/t$				4.3491
P				0.0370

other inflammatory factors were detected and compared between the two groups by ELISA.

The saccharin test was used to detect nasal mucociliary clearing before and after treatment for 3 months. The patient was placed in a sitting position, and nasal secretions were cleared under a nasal microscope. The saccharin particles with a diameter of 0.5-1.0 mm were placed on the mucosal surface of the medial turbinate, and the patient was asked to swallow the saccharin particles twice per minute, and the time to consumption of saccharin particles until the patient tasted sweetness was recorded. A long cotton swab was inserted into the posterior wall of nasopharynx, and the distance between saccharin placement point and posterior wall of pharynx was measured. The mucociliary clearance rate, nasal mucociliary clearance rate and saccharin clearance time were calculated.

The incidence of complications (including bleeding, secretion aggregation, lacrimal duct injury and antrum jaws atresia) were compared between the two groups.

#### Statistical processing

SPSS 21.0 was used for analysis. The measurement data were expressed as mean number  $\pm$  standard deviation, and the t test was carried out. The counting data were expressed as rate (%), and chi-square test was carried out. The difference was statistically significant with  $P < 0.05$ .

## Results

### Comparison of general data between the two groups

There were 45 cases in the CG, including 23 males and 22 females, with an average age of (36.8 $\pm$ 7.9) years old and an average course of disease of (5.9 $\pm$ 2.1) years. They all had a sense

of smell. There were 59 cases in the EG, including 32 males and 27 females, with an average age of (37.2 $\pm$ 7.6) years old and an average course of disease of (6.0 $\pm$ 2.3) years. They all had a sense of smell. There was no statistic difference in general data between the two groups ( $P < 0.05$ ), indicating they were comparable.

### Comparison of efficacy between the two groups

The total effective rate in the EG (94.9%) was significantly higher than that in the CG (82.2%), and the difference was statistically significant ( $P < 0.05$ ) (Table 1).

### Comparison of VAS scores of symptoms between the two groups after treatment

The VAS score of symptoms showed that the scores of nasal congestion, nasal discharge, headache, cheek pain and dysosmia in the EG were significantly lower than those in the CG, and the statistical analysis showed that the differences between the groups were statistically significant ( $P < 0.05$ ) (Table 2).

### Comparison of serum TlgE and ECP levels

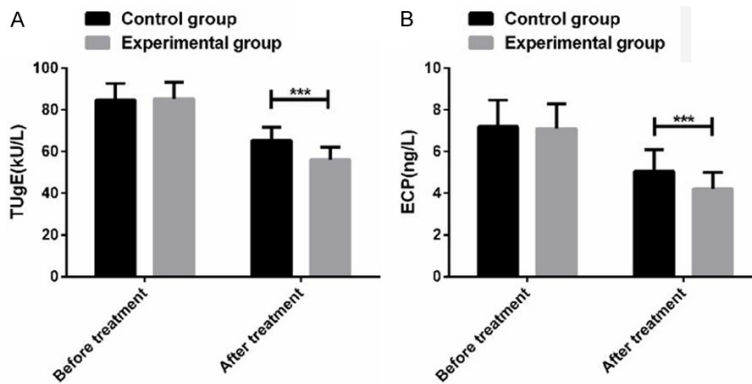
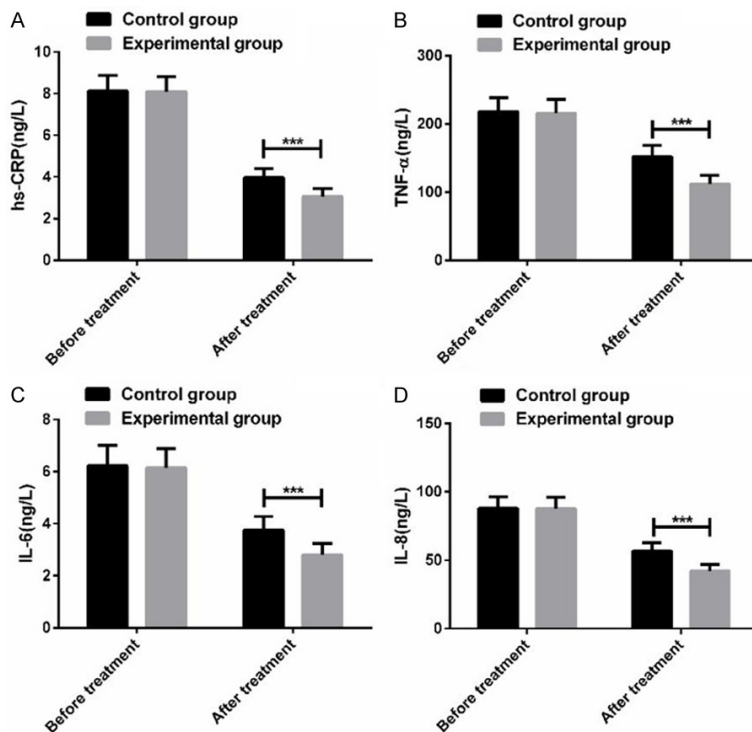
Before treatment, there was no statistical difference in the levels of serum TlgE and ECP between the two groups ( $P > 0.05$ ). After treatment, the above indexes of patients were decreased in both groups. Compared with the levels of serum TlgE (65.39 $\pm$ 6.26) kU/L and ECP (5.06 $\pm$ 1.02) ng/L in the CG, the levels of serum TlgE and ECP in the EG were (56.12 $\pm$ 5.81) kU/L and (4.21 $\pm$ 0.79) ng/L respectively after treatment. The levels of serum TlgE and ECP were significantly decreased in the EG. The difference was statistically significant (all  $P < 0.001$ ) (Figure 1).

### Comparison of inflammatory factor levels

Before treatment, there was no statistical difference in the levels of inflammatory factor between the two groups ( $P > 0.05$ ). After treatment, the above indexes of patients were decreased in both groups. After treatment, the levels of hs-CRP, TNF- $\alpha$ , IL-6 and IL-8 in EG were (3.06 $\pm$ 0.38) ng/L, (112.35 $\pm$ 12.36) ng/L, (2.81 $\pm$ 0.43) ng/L and (42.36 $\pm$ 4.56) ng/L, respectively. In the CG, the levels of hs-CRP,

**Table 2.** Comparison of VAS scores of symptoms between the two groups after treatment

	Nasal congestion	Nasal discharge	Headache	Cheek pain	Dysosmia
CG (n=45)	2.52±0.53	2.81±0.61	1.92±0.46	1.88±0.50	2.31±0.65
EG (n=59)	1.82±0.71	1.90±0.63	1.25±0.34	1.19±0.29	1.64±0.40
$\chi^2/t$	0.1264	0.1229	0.0784	0.0781	0.1035
P	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001

**Figure 1.** Comparison of serum TlgE and ECP levels between the two groups before and after treatment (A, Serum TlgE levels of patients in the two groups before treatment; B, Serum ECP levels of patients in the two groups before treatment; \*\*\* means  $P < 0.001$ ).**Figure 2.** Comparison of inflammatory factor levels between the two groups before and after treatment (A, Comparison of hs-CRP levels; B, Comparison of TNF- $\alpha$  level; C, Comparison of IL-6 level; D, Comparison of IL-8 levels; \*\*\* means  $P < 0.001$ ).

TNF- $\alpha$ , IL-6 and IL-8 were ( $3.97 \pm 0.43$ ) ng/L, ( $152.32 \pm 16.26$ ) ng/L, ( $3.76 \pm 0.52$ ) ng/L and ( $56.82 \pm 5.82$ ) ng/L, respectively. Compared with the CG, the levels were significantly reduced in the EG, and the difference was statistically significant (all  $P < 0.001$ ) (Figure 2).

#### Changes of nasal mucociliary clearing function in the two groups

Before treatment, there was no statistical difference in mucociliary clearance speed, clearance rate and saccharin clearance time between the two groups ( $P > 0.05$ ). After treatment, the mucociliary clearance speed and clearance rate in the EG were significantly higher than those in the CG, while the clearance time of saccharin was significantly lower than that in the CG ( $P < 0.001$ ) (Table 3).

#### Comparison of complication rate between the two groups

The total incidence of complications (bleeding, secretion aggregation, lacrimal duct injury and antrum jaws atresia) in the EG (5.1%) was significantly lower than that in the CG (17.7%) ( $P < 0.05$ ) (Table 4).

#### Discussion

As a surgical treatment for chronic sinusitis, endoscopic sinus surgery can clearly observe the local anatomical structure under direct vision, thoroughly remove the diseased tissues and restore the basic functions of nasal cavity and paranasal sinuses, but it may aggravate the inflammatory reactions [14]. Conventional drug therapy can antag-

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**Table 3.** Changes of nasal mucociliary clearing function in the two groups

		Mucociliary clearance speed (mm/min)	Mucociliary clearance rate (%)	Saccharin clearance time (min)
Before treatment	CG (n=45)	3.52±0.37	48.26±5.03	35.97±2.56
	EG (n=59)	3.53±0.40	49.72±5.11	35.21±2.35
$\chi^2/t$		0.0767	1.0046	0.4835
P		0.8965	0.1492	0.1191
After treatment	CG (n=45)	7.11±0.62	72.26±6.35	25.36±2.03
	EG (n=59)	8.19±0.75	83.58±6.68	20.23±1.72
$\chi^2/t$		0.1379	1.2943	0.3681
P		< 0.0001	< 0.0001	< 0.0001

**Table 4.** Comparison of complication rate between the two groups

	Bleeding	Secretion aggregation	Lacrimal duct injury	Antrum jaws atresia	Total rate
CG (n=45)	2 (4.4)	4 (8.9)	1 (2.2)	1 (2.2)	8 (17.7)
EG (n=59)	1 (1.7)	1 (1.7)	0	1 (1.7)	3 (5.1)
$\chi^2/t$					8.6973
P					0.0336

onize inflammatory reactions, but it cannot change the physiological function of pathological tissues. Studies have revealed that preoperative combination of antibiotics, glucocorticoids, antihistamines and other drugs can achieve synergistic effects with surgical treatment and reduce the development of complications [15].

This research was designed to investigate the efficacy of desloratadine citrate disodium in the treatment of chronic sinusitis by endoscopic sinus surgery. The results showed that the total effective rate was 94.9% in the EG, which was significantly higher than that in the CG (82.2%). The levels of serum interleukin-6 (IL-6), interleukin-8 (IL-8), high-sensitivity C-reactive protein (hs-CRP) and tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ) in the EG were significantly lower than those in the CG, and the levels of serum TlgE and ECP were also significantly lower than those in the CG. After treatment for 3 months, the mucociliary clearance rate and mucociliary clearance rate in the EG were significantly higher than those in the CG, while the saccharin clearance time was significantly shorter than that in the CG. The incidence of complications in the EG was significantly lower than that in the CG. Generally speaking, desloratadine citrate disodium combined with endo-

scopic sinus surgery has better curative effect for chronic sinusitis.

Endoscopic sinus surgery can accurately display the operation position through the endoscope, with wide and clear field of vision and small wound surface. It can remove the diseased tissue

without damaging the normal mucosa structure as much as possible, thus recovering the basic functions of the nasal cavity and paranasal sinuses and relieving the clinical symptoms of patients [16]. Approximately 1/2 patients with chronic sinusitis are accompanied by allergic reactions and inflammatory reactions of different degrees, which have certain adverse reactions to the operation and seriously affect the treatment effects. Therefore, it is of positive significance to ensure the clinical efficacy of endoscopic sinus surgery by effectively reducing the allergic reactions before operation [17, 18]. Desloratadine citrate disodium is a long-acting histamine antagonist, which has a rapid onset, high bioavailability and long-lasting drug properties. It can selectively antagonize peripheral H1 receptors and plays a strong anti-inflammatory role. By helping the body achieve a peak in drug concentration in the blood in a short time, it metabolizes hydroxyethoxy loratadine and inhibits histamine-mediated allergic reaction, so as to play a long lasting anti-allergic role [19]. The levels of serum TlgE and ECP are the most intuitive indicators that reflect the degree of allergy [19], in which the content of immunoglobulin E (IgE) is less in healthy organisms. When the body is stimulated by some emergency, IgE synthesis will increase significantly, thus promoting the increase of TlgE. ECP



is a common strong alkali I granule protein released by eosinophil activation, which can induce the release of histamine [20, 21]. Studies have shown that the levels of serum TlgE and ECP in patients with chronic sinusitis are significantly higher than those in healthy people [22]. Because chronic sinusitis is a chronic inflammatory disease, patients with chronic sinusitis are accompanied by eosinophil infiltration in the sinus mucosa, and a large number of inflammatory mediators are stimulated and released, resulting in serious inflammatory reaction and damage to body tissues. Therefore, the levels of serum related inflammatory factors such as TNF- $\alpha$  [23], IL-6 [24], IL-8 [25], and hs-CRP [26] are increased in patients with chronic sinusitis. Desloratadine citrate disodium combined with endoscopic sinus surgery can effectively inhibit the stimulation of histamine, reduce the release of a variety of inflammatory mediators, control the level of inflammatory factors in the body and play a better anti-inflammatory effect, thus improving dysosmia and promoting the recovery of olfactory function of patients. There are also some shortcomings in this study. The sample size of this study is small, and there are many choices for postoperative antibiotics, which may affect the final treatment efficacy. At the same time, a longer follow-up is needed to ensure treatment efficacy.

To sum up, endoscopic sinus surgery combined with desloratadine citrate disodium can significantly reduce serum inflammatory levels for patients with chronic sinusitis after treatment. It can significantly improve their clinical symptoms and has better curative effect, which is worthy of clinical application.

#### Disclosure of conflict of interest

None.

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