Efficacy of seasonal allergic rhinitis using an 810 nm diode laser system

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Background and Aims: Allergic rhinitis annually reach epidemic proportions in Japan. Approximately 30 to 40% of the population suffers from allergic rhinitis during the spring season. Symptoms comprise rhinorrhea, nasal congestion, and sneezing accompanied by irritation and itching of the eyes. The Ohshiro Clinic started using the conventional Nd:YAG laser for the treatment of allergic rhinitis in 1993, and from 2005 we started using a diode laser-pumped Nd:YAG laser. From 2010, we adopted a novel 810 nm diode laser, and the present retrospective study examined the efficacy rate of the treatment of allergic rhinitis in the 2018 season with this system, compared with a previous study in 2011. We aimed to confirm the degree of improvement for each symptom to evaluate effectiveness of the diode laser treatment.

Subjects and methods: Between January 8, 2018 and April 30, 2018, a large number of patients consulted our clinic with the major complaint of seasonal allergic rhinitis. They underwent a blood test, and the antigen-specific serum IgE antibody titers were measured for a definitive diagnosis of cedar pollinosis. A total of 211 target patients were treated during the trial period. The average age of the target group was 36.3 years, 134 males, and 77 females. The target patients were treated with lower nasal turbinate mucosal irradiation using a diode laser (ADL-20, Asuka Medical) delivering 810 nm at 7.5 W, with a total energy per treatment of 240 J/cm². We adopted a five-step evaluation in accordance with the Japanese Guidelines for Allergic Rhinitis 2014 for the symptoms of rhinorrhea, sneezing and nasal obstruction. We assessed the degree of improvement in the severity of these symptoms following diode laser treatment from baseline to one month after treatment, in addition to assessing patient satisfaction with the degree of improvement in their quality of life (QOL).

Results: The 211 patients positive for cedar pollinosis by the antigen-specific serum IgE antibody tests were broken down by month by number and by improvement, no change or exacerbation as follows. January, 18 patients: 33.4%, 44.4% and 22.2%, respectively. February, 29: 10.4%, 44.4% and 22.2%, respectively. March, 146: 60.3%, 31.5% and 8.2%, respectively. April, 18: 77.8%, 16.7% and 5.5%, respectively. The monthly respective improvement, no change or worse patient QOL as percentages were as follows: January: 16.7%, 44.4% and 38.9%. February: 17.3%, 13.8% and 68.9%. March: 61.6%, 29.5% and 8.9%. April: 94.4%, 0.0% and 5.6%. The values for prevention of exacerbation versus exacerbation for each month were: January, 77.8% vs 22.2%; February, 41.4% vs 58.6%; March, 91.8% vs 8.2%; and April, 94.4% vs 5.6%. The mean efficacy rate for the trial period in the present study was therefore 52.6% which compared very favorably with the mean efficacy rate in the 2011 study of 53.4%.

Conclusions: The results showed that the 810 nm diode laser offered a safe and effective solution for the uncomfortable symptoms of allergic rhinitis and could be well applied during the season of Japanese cedar pollen dispersion. Furthermore, a tendency towards high efficacy was demonstrated for laser treatment in class 6 cedar pollinosis patients, based on the specific IgE antibody test.

Key words: Seasonal Allergic Rhinitis · Cedar pollinosis · diode laser · immunoglobulin E · RAST test · type 1 allergic reaction · anti-histamine

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Introduction

The incidence of allergic rhinitis in Japan is reportedly 30-40% of the population. The main culprit is pollen released in the early part of the year from two species of tree, the Japanese cedar, sugi in Japanese, which is actually a member of the cypress family (Cryptomeria japonica) and the binoki cypress (Chamaecyparis obtusa). Figures suggest that the rates of incidence of allergic rhinitis (specifically cedar pollinosis) with conjunctivitis, (an affliction also commonly known as hay fever) for both species are steadily increasing. It is believed that the volume of cedar pollen released by the trees in a year will be lower than the previous year, provided the volume of pollen released in the previous year is high with the opposite also holding true, but that is not in fact the case. It depends more on the weather. Pollen is released only from the male trees, and their growth season is from July until autumn each year. The degree of solar radiation and precipitation during the growth phase, during which the days are long with the potential for prolonged sunshine, have a major effect both on the growth of the male trees, and the amount of pollen released in the early part of the following year. The summer of 2017 had more daylight hours with sunshine than in previous years, thus the volume of pollen released in early 2018 was almost twice that of the previous year. Furthermore, more than 90% of the sugi and hinoki trees are over 30 years old, when their capacity for pollen production starts to peak. Figure 1 shows the figures for the volume of air-born

pollen in Tokyo in particles per cm 2 from the beginning of January, 2018 till the end of April. The first major reading was on February 24th, and the phenomenon peaked on March 13th.

Allergic rhinitis is a Type 1 allergic reaction affecting the nasal mucous membrane. Symptoms consist of repetitive attacks of sneezing, rhinorrhea, and nasal obstruction. The most severe symptom-mediated effect is the inability to manage normal activities of daily living (ADL) resulting in a poor quality of life (QOL), and the severity of symptoms tends to increase in most patients, with statistics showing that the number of patients with severe symptoms is growing annually. The usual therapy for pollinosis in the ENT clinic is prescription of oral anti-histamines and topical nasal decongestants with steroids. The side effects of the medications are drowsiness and dryness of the throat which can disturb the QOL almost as much as the symptoms they are trying to alleviate. Recently the usual protocol for these medications is to start patients on them 2-3 weeks before the onset of the symptoms. Oral ingestion must be continued through the spring season. Additionally, the patients must protect themselves with masks and goggles to prevent exposure to high pollen counts.

Laser ablation of the mucosal lining of the inferior turbinate using the CO₂ laser was first reported as effective in reducing allergic rhinitis symptoms by Mittleman in 1982, ¹⁾ and showed promising results ranging from 60 to 85% efficacy in prevention of the onset of nasal symptom. However, CO₂ laser ablation has certain severe side

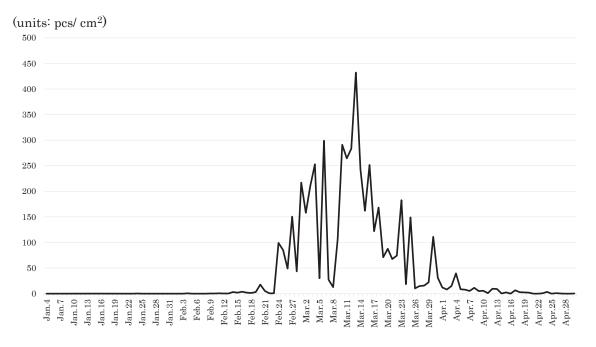


Fig. 1: Observations of cedar pollen levels from January to April 2018 in Chiyoda-ku, Tokyo, Japan

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effects. Therefore, the Ohshiro Clinic started using the conventional flashlamp pumped Nd:YAG laser for the treatment of allergic rhinitis in 1993. From 2005, we started using a diode laser-pumped Nd:YAG laser manufactured by Fibertech Co. We showed that this system was superior compared to the CO₂ laser and the conventional flash lump pumped system, with comparative efficacy and safety. ²⁾ Even more recently, since 2010, we have adopted a novel 810 nm diode laser system (ADL-20, Asuka Medical, Japan) for treatment of allergic rhinitis.

Surgical intervention (as distinct to conservative management) is a valid option for the treatment of severe allergic rhinitis. Laser ablation of the mucosa over the lower nasal turbinate mucosal is one of the surgical treatments and has been widely performed since the 1990s. The target of the allergic reaction is allergen-mediated protein modification at the mucosal surface of the lower nasal turbinates resulting in nasal discharge and nasal obstruction. Thus, in laser treatment for allergic rhinitis, coagulation-associated alteration of the characteristics of the mucosal surface is the goal as an effective treatment to reduce allergic reaction and thus control the associated symptoms, such as sneezing.

We have used the diode laser since 2010. We therefore designed the present study as a retrospective analysis to reevaluate the efficacy of the diode laser in our clinic in the treatment of cedar pollinosis-related symptoms, such as blocked nose, nasal discharge and sneezing, to compare the overall efficacy of the diode laser for each symptom and improvement of patient QOL against that achieved in a previous 2011 study using the predecessor laser system.

Subjects and Methods

This study was a retrospective study conducted at Ohshiro clinic, between January 8 and April 30 of 2018. The study protocol was approved by the institutional review board of the clinic and conducted in accordance with the Declaration of Helsinki. The approved number was RS18-35.

Patients consulted our hospital from the early part of 2018 with the major complaint of allergic rhinitis. They underwent a blood test, and their antigen-specific serum IgE antibody titers were measured for a definitive diagnosis of seasonal cedar pollinosis. Two hundred and eleven patients were identified as the target population from January 8th till April 30th, 2018, the trial period. The average age of the target group was 36.28 years, with134 males and 77 females. All patients were treated with the diode laser (ADL-20, Asuka Medical, Kyoto, Japan), at a wavelength of 810 nm in the near-infrared, delivering an output power of 7.5 W and a total fluence of 240 J/cm². The system is shown in **Figure 2**, and its specifications are given in **Table 1**.

We adopted a five-step evaluation of the severity of the patients' symptoms (rhinorrhea, sneezing, nasal obstruction) in accordance with the Japanese Guidelines for Allergic Rhinitis, 2014. 4) We recorded the severity of the symptoms at baseline and again at 1 month after treatment to assess the degree of improvement for each symptom (Table 2a). In addition, we assessed changes in patients' satisfaction with their QOL (Table 2b). In detail, the number of patients and changes in symptom severity (improvement, no change, exacerbation) and QOL were assessed on a monthly basis. Furthermore, we additionally looked at prevention of exacerbation (values for improvement and no change) versus exacerbation on a monthly basis to arrive at the mean overall efficacy of the treatment. The severity of Japanese cedar pollen allergy was classified by the specific IgE value in each patient, and any changes in these classes were also examined.



Fig. 2: The diode laser device as developed by Asuka Co. Japan. Maximum output 8 W with pulse preset at 0.5 s. Note the dimensions of the system were much smaller than the diode laser pumped Nd; YAG laser device used in 2005.

Table1: Specification of diode laser ADL-20 produced by Asuka Medical Co. Japan (Fig. 2)

Wave length	810 nm
Output Power	0.1-8W
Mode	Pulsed
Silica fiber core diameter	600 µm
SMA connecter Lase tip	round glass tip Ø 2 mm
Width	170 mm
Height	240 mm
Length	330 mm

Results

The total number of allergic rhinitis patients who were treated for the first time from January to April of 2018, including those patients who completed an examination one month after their treatment, was 327 (breakdown by month: January, 31; February, 48; March, 220; and April, 26). From among those 327 patients, the number of patients who tested positive for cedar pollinosis with antigen-specific serum IgE antibody test was 211 (breakdown by month: January, 18; February, 29; March, 146; and April, 18). These 211 pati8ents formed the target population.

As for the treatment effect based on changes in the severity of symptoms in January (18 patients), improvement was noted in 33.4% (6 patients), no change in 44.4% (8), and exacerbation in 22.2% (4). In February (29 patients), improvement was noted in 10.4% (3), no

change in 31.0% (9), and exacerbation in 58.6% (17). In March (146 patients), improvement was noted in 60.3% (88), no change in 31.5% (46), and exacerbation in 8.2% (12). In April (18 patients), there improvement was noted in 77.8% (14), no change in 16.7% (3), and exacerbation in 5.5% (1). **(Figure 3)**

Efficacy rates by changes in the degree of patient QOL in January (18 cases) were as follows: improvement was reported in 16.7% (3), no change in 44.4% (8), and worse in 38.9% of cases (7 cases). In February (29 cases), improvement was reported in 17.3% (3), no change in 13.8% (9), and worse in 68.9% (17 cases). In March (146 cases), 61.6% of patients reported improvement (90 cases), 29.5% reported no change (43), and 8.9% reported worse (13 cases). In April (18 cases), 94.4% of patients were improved (17), 0% had no change (0), and 5.6% were worse (1). **(Figure4)**

In prevention of exacerbation (improved + no

Table2a: Classification	of the severity	of allergic rhinitis	symptoms (Okubo K	, et al. 2014)

Severity		Paroxysmal sneezing or rhinorrhea				
Seven	iity	++++	+++	++	+	79
	++++	Most severe	Most severe	Most severe	Most severe	Most severe
_	+++	Most severe	Severe	Severe	Severe	Severe
Nasal blockage	++	Most severe	Severe	Moderate	Moderate	Moderate
(2007)	+	Most severe	Severe	Moderate	Mild	Mild
_	.,	Most severe	Severe	Moderate	Mild	No symptoms

Sneezing and rhinorrhea type, ______; Nasal blockage type, ______; Combined type, ______

Table2b: Classification of the severity of allergic rhinitis symptoms II: severity of the symptoms (Okubo K, et al. 2014)

Types	++++	***	**	+	-
Paroxysmal sneezing (Average number of episodes of paroxysmal sneezing in a day)	≥21 times	20-11 times	10-6 times	5-1 times	Below +
Rhinorrhea (Average number of episodes of nose blowing a day)	≥21 times	20-11 times	10-6 times	5-1 times	Below +
Nasal blockage	Completely ob- structed all day	Severe nasal blockage causing prolonged oral breathing in a day	Severe nasal block- age causing occa- sional oral breath- ing in a day	Nasal block- age without oral breathing	Below +
Troubles with daily life+	Impossible	Painful and com- plicating daily life	Intermediate be- tween (+++) and (+)	Few troubles	Below +

[†]Troubles with daily life: Troubles with work, study, household work, sleep, going out, etc. Adapted from reference 1.

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Select more severe one, sneezing or rhinorrhea.

Severe, moderate, and mild symptoms are determined according to conventional classification. Uncontrollable severe symptoms are classified into the most severe symptoms, because they may occur during a heavy pollen dispersal period. Adapted from reference 1.

change vs exacerbation), the monthly rates were as follows: January, 22.2% vs 77.8%; February, 41.4% vs 58.6%; March, 91.8% vs 8.2%; and April, 94.4% vs 5.6% (**Figure 5**)

When the efficacy of diode laser intervention was compared according to the class of severity as classified by the antigen-specific serum IgE antibody titers, a high level of 70% efficacy was seen in class 6 patients. This result was significantly higher compared with 42.9% seen in class 1 patients. (**Figure 6**).

Finally, taking the preventative rates for the entire 2018 study period seen in **Figure 5** into consideration, the mean overall efficacy rate (ER) in the present study was

52.6%.

Discussion

The CO₂ laser treatment, which was performed for allergic rhinitis since 1980, results in the complete destruction of the mucosal structure by resection and ablation of the lower nasal turbinate mucosal surface. ⁵⁾ After the wound healing process that lasts for one month, it is replaced by scar tissue which is incapable of reaction to allergic stimuli. However, the patient had to endure severe nasal obstruction and rhinorrhea for about two weeks, then in a

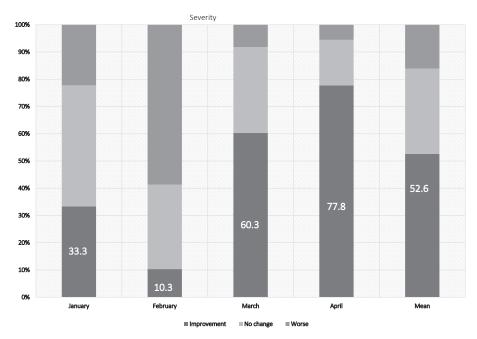


Fig. 3: Changes in the severity in the treatment effect from January to April 2018.

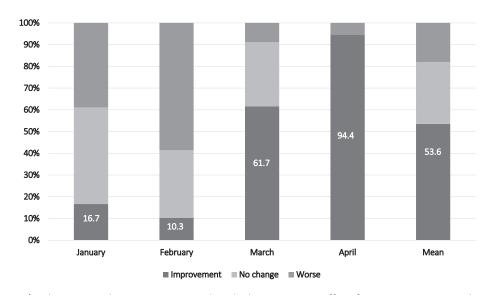


Fig. 4: Changes in the QOL associated with the treatment effect from January to April 2018.

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further two weeks the scab would separate off, with nasal bleeding and hypersensitivity also as potential sequalae to CO₂ laser intervention.

When efficacy was considered, however, despite the laser-associated side effects, the CO₂ laser demonstrated an effective rate of 60% to 85% in the prevention of expression of nasal symptoms. ^{8, 9)} In the flashlamp pumped Nd:YAG laser treatment, efficacy was also high in relief of nasal symptoms, reportedly from 70 to 90%. ^{10, 11, 12, 13)}

The use of the diode laser system in our clinic started from the 2011 season. In our experience, the pain associated with diode laser intervention is low enough for a child around ten years of age to endure. Treatment using an 810 nm diode laser system does not involve any risk

associated with the need for additional surgical instruments, and is a quick procedure.

An evaluation method was set out in the Japan Allergic Society Japanese Guidelines for Allergic rhinitis, 2014 based on the severity of the symptoms of rhinorrhea, sneezing and nasal congestion, in addition, the severity of impairment of managing ADL was classified into five stages with an illustration showing varying facial expressions to allow patients to more easily classify assessment of their QOL. On the other hand, in 2007, Fujii's study classified objective patient evaluation as follows: extremely effective, elimination of the symptoms by 91% or more; effective, elimination of symptoms by 60-90%; the overall effective rate was calculated by combining the

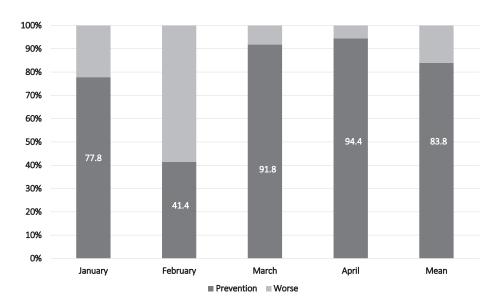


Fig. 5: Efficacy in the prevention of symptoms from January to April 2018.

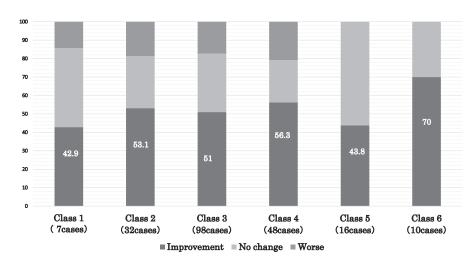


Fig. 6: Changes in the severity related to the treatment effect classified by the specific pollen allergy-related IgE antibody titer from January to April 2018.

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scores for extremely effective and effective. It is not possible to compare by the same standard as that study, but since no improvement in severity based on the 2014 Guidelines can be achieved if none of the symptoms improves, it is considered that the 2014 Guidelines are stricter than the evaluation standard before 2007.

Usually the period from January to April is the season for cedar pollen dispersion. In 2018, records show that cedar pollen dispersion began on February 24, and the peak was reached on March 4 (**Figure 1**). The effective rate of 52.6% in the present study was shown to be almost equal to that in Sasaki's previous 2011 study (**Table 4, Figure 7**). ³⁾ In addition, the change in the QOL satisfaction rates showed almost the same tendency as the severity change. It can be seen that the February effective rate was low: a possible reason for this is the

presence of an exceptionally heavy concentration of cedar pollen at the time of evaluation, which occurred one month after a period of fewer symptoms thereby negatively skewing the efficacy rates.

In addition, among patients with no deterioration after one month there were no patients who were re-treated, and an average of 84% was reached over four months. Improvement of symptoms after laser treatment was observed in patients with a high level of specific serum IgE antibodies associated with cedar pollen allergy symptoms. In those patients with an antibody titer of 100 UA/ml or more, a 70% efficacy rate was noted in the incidence of allergic rhinitis and deterioration was prevented in 100% of Class 6 patients: these were new findings. However no statistically significant difference was observed between the antibody titer of the lowest Class 1

Table 3: Classification of the severity of allergic rhinitis symptoms (Otuka H, et al. 1993)

	Class	Antibody Titer (UA/ml)
Positive	6	100.0 <
Positive	5	50.0 <
Positive	4	17.5 <
Positive	3	3.50 <
Positive	2	0.70 <
Pseudo Positive	1	0.35 <
Negative	0	< 0.34

Table 4: The comparison of the mean efficacy rate in this study with Sasaki's previous study in 2011.

	Sasaki's study 2011	This study 2018
Treatment Period	December 1, 2010 to April 6, 2011	January 8, 2018 to April 30, 2018
ER (Efficacy Rate)	53.4% (168/316)	52.6% (111/211)

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patient and the highest class 6 patients.

Conclusions

The 810 nm diode laser offers an excellent solution for the uncomfortable symptoms of allergic rhinitis and could be well applied during the Japanese cedar pollen dispersion season. Furthermore, a tendency was noted for high laser treatment efficacy among the patients who were assessed as class 6 in the IgE antibody test for cedar pollen allergy.

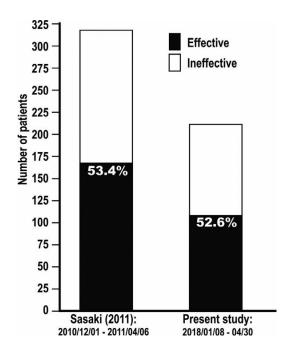


Fig. 7: The mean efficacy rate in the present study compared with that of Sasaki's previous study in 2011

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Conflict of Interest disclosure

No author has any conflicts of interest