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Original Article

Nationwide questionnaire-based survey of oral immunotherapy in Japan

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ABSTRACT

Background: Clinical trials on oral immunotherapy (OIT) have been increasing for nearly a decade; however, several national guidelines do not recommend OIT as a standardized procedure. The aim of this study was to obtain insights into the current use and practice of OIT in Japan.

Methods: A first questionnaire was mailed to 524 training and teaching facilities of the Japan Pediatric Society. The first survey requested information on the implementation of OIT, whereas the second survey aimed to gather more detailed information on OIT, such as its safety.

Results: In total, 360 facilities (69%) responded to the survey; among them, 102 (28%) provided OIT to 7973 patients [1544 received OIT while hospitalized (inpatient OIT), whereas 6429 received OIT without hospitalization (outpatient OIT)]. Approval for OIT was obtained from an ethics committee or institutional review board in 89% and 31% of facilities for inpatient and outpatient OIT, respectively. In inpatient OIT, immediate allergic reactions requiring treatment occurred in 68% of patients while hospitalized, and in another 56%, following discharge. In contrast, 11% of patients developed immediate allergic reactions in outpatient OIT. Adrenaline injections at home were required in 2%. Sixteen patients developed adverse reactions other than immediate allergic reactions, among which eosinophilic gastroenteritis was most common.

Conclusions: OIT is widely provided not only as clinical research but also as general practice in Japan. However, because there is a high risk of developing anaphylaxis at home, OIT should be conducted carefully as in a clinical research setting taking safety into consideration.

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Introduction

An increased prevalence of food allergies has been reported in Western countries as well as in Asia,¹ and the health and economic burden associated with such allergies has become significant.^{2,3} Oral immunotherapy (OIT), in which the immune system is desensitized to foods that cause allergic reactions,⁴ has attracted

attention as a new treatment for food allergies.⁴ Indeed, some patients who receive OIT could increase the threshold doses for developing symptoms resulting from accidental exposure, as noted in many clinical trials from Western countries^{5–11} and Japan.^{12–15} In a recent systematic review,^{16,17} OIT was found to be partially effective; however, studies investigating its therapeutic value vary widely in design, and many are poorly controlled. Accordingly, the safety and efficacy of OIT have not been conclusively demonstrated to be superior to food avoidance. However, the American Academy of Allergy, Asthma, and Immunology found that 14% of medical facilities in the US conducted OIT, in many facilities (48%) without approval from institutional review boards.¹⁸ Similar trends were noted in 2011 in Japan,¹⁹ where 49 (10%) of 514 training and

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teaching facilities of the Japan Pediatric Society conducted OIT. In 80% of these facilities, patients developed adverse reactions requiring treatment. Accordingly, the Japanese Society of Pediatric Allergy and Clinical Immunology does not recommend OIT as a standardized treatment.²⁰ The aim of this study was to assess the current practice styles of OIT and compare the findings with those of the previous survey.²¹

Methods

First survey

We collected data via two rounds of surveys, following the same methods used in 2011.¹⁹ In the first survey, we mailed questionnaires to training and teaching facilities of the Japan Pediatric Society from mid-July to mid-August 2015. The questionnaires requested information on the implementation of OIT by the end of March 2015, and consent to participate in the second survey.

Second survey

Between mid-August and the end of September 2015, we mailed questionnaires to the facilities that agreed to participate in the second survey. Clinical information of individual patients was obtained from the facilities that responded to a second survey. Questionnaire items are shown in [Table 1](#).

Definition of OIT

There were no standardized protocols for OIT. Previous studies included widely heterogeneous groups of patients.^{5–10,12,13} OIT was defined in this study as a treatment for patients (1) who hardly expect to acquire tolerance to foods soon, (2) for whom the threshold dose that induced allergic symptoms was determined by oral food challenge prior to OIT, and (3) who underwent OIT under a physician's supervision. Furthermore, we defined inpatient OIT as treatments provided while the patient was hospitalized, although the patient may have been subsequently followed up in outpatient clinics. In contrast, outpatient OIT was defined as treatments and follow-up provided without hospitalization.

Table 1
Questionnaire items.

No.	Question
1	Year of initiation of provision of OIT
2	Applicable age and exclusion criteria for OIT
3	Maintenance doses and products for OIT
4	Number of patients who underwent OIT, reached maintenance doses, and discontinued OIT
5	Number of patients who developed immediate allergic reactions and who received treatment during OIT
6	Number of patients who received adrenaline injection during OIT
7	Number of patients who developed adverse reactions other than immediate allergic reaction during OIT
8	Frequency of food intake at home
9	Interval of increasing dose of food at home
10	Place of increasing dose of food
11	Presence or absence of implementation of OFC after stopping OIT
12	Criteria for ceasing food avoidance at home
13	Criteria for ceasing food avoidance in school lunch
14	Presence or absence of symptom development after canceling food avoidance
15	Safety measures during OIT at home
16	Ethical approval from an institutional review board

OFC, oral food challenge; OIT, oral immunotherapy.

Statistical analysis

The statistical evaluation was performed in SPSS 24.0 (IBM Corporation, Armonk, NY, USA). To analyze differences between 2 groups, we used Fisher's exact test for statistical comparison, and we considered $p < 0.05$ statistically significant.

Ethical considerations

This study was approved by the Ethics Committee of Sagami National Hospital in Kanagawa, Japan (No.150706). Surveys were performed in accordance with the principles embodied in the Declaration of Helsinki of 1965 (as revised in Brazil 2013). This questionnaire did not include personal details of the patients, and clinical data were de-identified and handled as linked anonymized data.

Results

Response rate

We obtained information from 360 (69%) of the 524 training and teaching facilities surveyed ([Fig. 1](#)). Among them, 102 facilities (28%) provided OIT, and 78 facilities agreed to participate in the second survey ([Supplementary Fig. 1](#)). Among the facilities that agreed to participate in a second survey, 27 (79%) of 34 inpatient OIT facilities responded, and 67 (72%) of 93 outpatient OIT facilities responded.

Approval from institutional review boards and informed consent

OIT was provided with approval from institutional review boards in 89% of the facilities providing inpatient OIT, and 31% of those providing outpatient OIT ([Fig. 2](#)). Of these facilities, 100% and 42%, respectively, obtained informed consent.

Applicable age and exclusion criteria for OIT, as determined by the facilities

For inclusion criteria, 22 inpatient OIT facilities (81%) and 35 outpatient OIT facilities (52%) included a lower or upper age limit ([Supplementary Fig. 2](#)). Regarding the lower age limits, 1% of inpatient OIT facilities were performing OIT for patients under 3 years of age, whereas the respective proportion was 74% for outpatient OIT facilities. Regarding the upper age limits, 0% of inpatient OIT facilities and 10% of outpatient OIT facilities had upper age limits.

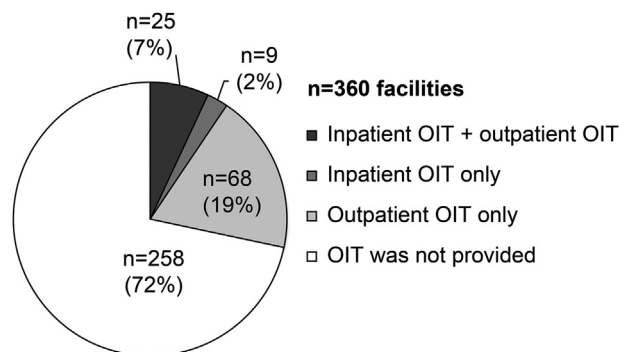


Fig. 1. Number of facilities that provide oral immunotherapy. This chart is based on the 360 facilities that responded to the first round of survey.

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