

ORIGINAL ARTICLE

Patch testing with the Japanese baseline series 2015:
A 4-year experience

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Abstract

Background: The Japanese baseline series (JBS), established in 1994, was updated in 2008 and 2015. The JBS 2015 is a modification of the thin-layer rapid-use epicutaneous (TRUE) test (SmartPractice Denmark, Hillerød, Denmark). No nationwide studies concerning the TRUE test have previously been reported.

Objectives: To determine the prevalence of sensitizations to JBS 2015 allergens from 2015 to 2018.

Methods: We investigated JBS 2015 patch test results using the web-registered Skin Safety Care Information Network (SSCI-Net) from April 2015 to March 2019.

Results: Patch test results of 5865 patients were registered from 63 facilities. The five allergens with the highest positivity rates were gold sodium thiosulfate (GST; 25.7%), nickel sulfate (24.5%), urushiol (9.1%), *p*-phenylenediamine (PPD; 8.9%), and cobalt chloride (8.4%). The five allergens with the lowest positivity rates were

mercaptobenzothiazole (0.8%), formaldehyde (0.9%), paraben mix (1.1%), mercapto mix (1.1%), and PPD black rubber mix (1.4%).

Conclusions: Nickel sulfate and GST had the highest positivity rates. The JBS 2015, including a modified TRUE test, is suitable for baseline series patch testing.

KEYWORDS

gold sodium thiosulfate, Japanese baseline series, multicentre study, nickel sulfate, patch test, patch test panel (S), positivity rate, TRUE test, web resister

1 | INTRODUCTION

A baseline series is a set of useful patch test allergens, and series content can vary according to country and region. The European Surveillance System on Contact Allergies (ESSCA) network and the North American Contact Dermatitis Research Group NACDRG have both reported baseline series positivity rates.^{1,2} The allergens in the Japanese baseline series (JBS), originally called the Japanese standard allergens, form the basis of a screening patch test for allergens in Japan. The Japanese Society for Contact Dermatitis (JSCD), currently called the Japanese Contact Dermatitis Research Group (JCDRG), first selected allergens for the JBS in 1994,³ with subsequent updates in 2008⁴ and 2015 (Table 1). Positivity rates for JBS allergens have been reported in multicentre studies from 1994 to 2014.^{3–6} Allergens in the JBS 1994 and in the JBS 2008 were petrolatum (pet.) base or aqueous solutions (aq.). The JBS 2015 (Table 1) comprises 22 allergens represented in the Patch Test Panel (S) (Sato Pharmaceutical Co. Ltd, Tokyo, Japan), which is a modification of the thin-layer rapid-use epicutaneous (TRUE) test (SmartPractice Denmark, Hillerød, Denmark) for the JBS, and two allergens from Torii Pharmaceutical Co. Ltd., Tokyo, Japan. There have been reports of individual evaluations of the TRUE test allergen^{7,8}; however, few multicentre studies have reported positivity rates using the TRUE test allergen as a baseline series. In this study, we report details concerning the patch test results for the JBS 2015.

2 | METHODS

2.1 | Patients

We collected the patch test results with the JBS 2015 from the Skin Safety Care Information Network (SSCI-Net; <http://info.sscinet.or.jp/registration.html>) in Japan. This network was founded in April 2016 with the aim of early identification and minimization of skin damage through cooperation with doctors (mainly dermatologists), enterprises, and administrators. Patch test results, age, sex, diagnosis, and the purpose for patch testing can be linked to anonymized data and are registered on the SSCI-Net website.

Patients had been patch tested with the JBS 2015 from April 2015 to March 2019 at 63 participating departments.

2.2 | Patch testing

There are 24 allergens in the JBS 2015, which comprises a Patch Test Panel (S)/TRUE test containing 22 allergens, and two allergens, namely, mercuric chloride 0.05% aq. and urushiol 0.002% pet. from Torii Pharmaceutical Co. Ltd., Tokyo, Japan. We tested mercuric chloride and urushiol using Finn Chambers on Scanpor Tape (SmartPractice, Arizona) or Patch tester Torii (Torii Pharmaceutical Co. Ltd., Tokyo, Japan). We applied the allergens to patients' upper back regions for 2 days (application day, day 0 [D0]). After removing the test units, readings were taken on D3 or D4, and D7 according to ICDRG criteria. We diagnosed a positive reaction if a + or stronger reaction was observed on D3/D4 or D7.

2.3 | Statistical analysis

A chi-square test was used to determine sex differences in positivity rates, and a *P*-value <.05 was considered statistically significant. Statistical analysis was performed using EZR (Yoshinori Kand, Saitama, Japan) for medical statistics.⁹

2.4 | Ethical considerations

This study, performed as part of the Specified Clinical Research (jRCTs041180105) project, was approved by the Certified Clinical Research Review Committee of Fujita Health University. This study was undertaken in accordance with the Declaration of Helsinki, and written informed consent was obtained from the patients prior to their inclusion in the study.

3 | RESULTS

3.1 | Patients

In total, 5865 patients (1334 males [mean age, 49.2 ± 18.8 years] and 4531 females [mean age, 49.0 ± 17.5 years]) from 63 institutions in Japan were enrolled in this study (Table 2). The most frequent disease among the patients was contact dermatitis (*n* = 3113, 53%), followed

TABLE 1 Allergens included in the JBS 2015

		JBS 2015	
		Concentration/patch	Supplier
Metals	Nickel sulfate	0.2 mg/cm ²	SmartPractice
	Potassium dichromate	0.054 mg/cm ²	SmartPractice
	Gold sodium thiosulfate	0.075 mg/cm ²	SmartPractice
	Cobalt chloride	0.02 mg/cm ²	SmartPractice
	Mercuric chloride	0.05% aq.	Torii
Rubber additives	Carba mix	0.25 mg/cm ²	SmartPractice
		Diphenylguanidine 0.083 mg Zinc diethyldithiocarbamate 0.083 mg Zinc dibutyldithiocarbamate 0.083 mg	
	Thiuram mix	0.027 mg/cm ²	SmartPractice
		Tetramethylthiuram disulfide 0.0068 mg Disulfiram 0.0068 mg Tetramethylthiuram monosulfide 0.0068 mg Dipentamethylenethiuram disulfide 0.0068 mg	
	<i>p</i> -Phenylenediamine black rubber mix	0.075 mg/cm ²	SmartPractice
		<i>N</i> -isopropyl- <i>N'</i> -phenyl-paraphenylenediamine 0.012 mg <i>N</i> -cyclohexyl- <i>N'</i> -phenyl-paraphenylenediamine 0.031 mg <i>N,N'</i> -diphenyl-paraphenylenediamine 0.031 mg	
	Mercapto mix	0.075 mg/cm ²	SmartPractice
		Morpholinylmercaptobenzothiazole 0.025 mg <i>N</i> -cyclohexylbenzothiazyl sulphenamide 0.025 mg Dibenzothiazyl disulfide 0.025 mg	
	Mercaptobenzothiazole	0.075 mg/cm ²	SmartPractice
Fragrances	Myroxylon <i>pereirae</i>	0.8 mg/cm ²	SmartPractice
	Fragrance mix	0.5 mg/cm ²	SmartPractice
		Amylcinnamic aldehyde 0.022 mg Cinnamaldehyde 0.048 mg Cinnamic alcohol 0.078 mg Eugenol 0.048 mg Geraniol 0.1 mg Hydroxycitronellal 0.078 mg Isoeugenol 0.022 mg Oakmoss absolute 0.1 mg	
Dye	<i>p</i> -Phenylenediamine-free base (PPD)	0.08 mg/cm ²	SmartPractice
Base component	Lanolin alcohol	1 mg/cm ²	SmartPractice
Topical drugs	Caine mix	0.63 mg/cm ²	SmartPractice
		Dibucaine HCl 0.081 mg Tetracaine HCl 0.081 mg Ethyl aminobenzoate 0.47 mg	
	Neomycin sulfate	0.6 mg/cm ²	SmartPractice
Resin	Colophony	1.2 mg/cm ²	SmartPractice
	<i>p</i> -tert-Butylphenol formaldehyde resin (PTBPF)	0.045 mg/cm ²	SmartPractice
	Epoxy resin	0.05 mg/cm ²	SmartPractice
Plants	Urushiol	0.002% pet.	Torii
Preservatives	Paraben mix	1 mg/cm ²	SmartPractice
		Methyl para-hydroxybenzoic acid 0.2 mg Ethyl para-hydroxybenzoic acid 0.2 mg Propyl para-hydroxybenzoic acid 0.2 mg Butyl para-hydroxybenzoic acid 0.2 mg Benzyl parahydroxybenzoate 0.2 mg	
	MCI/MI (Kathon CG)	0.004 mg/cm ²	SmartPractice
	Thimerosal	0.007 mg/cm ²	SmartPractice
	Formaldehyde	0.18 mg/cm ²	SmartPractice

Abbreviations: aq., aqueous solution; HCl, hydrochloride; JBS, Japanese baseline series; JSCD, Patch test allergens prepared by the Japanese Society for Contact Dermatitis; MCI/MI, methylchloroisothiazolinone/methylisothiazolinone; pet., petrolatum.

by atopic dermatitis and metal allergy. The most common reasons for patch testing were to determine the cause of contact dermatitis, to test for metal allergy, to determine the cause of intractable dermatitis, and to identify aggravating factors in atopic dermatitis.

3.2 | The JBS 2015 positivity rates

The positivity rates concerning each allergen in the JBS 2015 are shown in Table 3. Of 5865 patients, 3408 (58%) were positive for one or more allergens, and 2246 (41.9%) were negative for all JBS allergens.

The five allergens with the highest positivity rates were gold sodium thiosulfate (GST; 25.7%), nickel sulfate (24.5%), urushiol (9.1%), *p*-phenylenediamine (PPD; 8.9%), and cobalt chloride (8.4%). The positivity rates of these five allergens differed depending on the age (Figure 1 and Table S1).

Nickel sulfate and GST had the highest proportion of ++/+++ reactions. The allergens with the highest percentage of “+ /IR” reactions were GST (20.2%), cobalt chloride (9.4%), nickel sulfate (8.0%), carba mix (7.1%), and mercuric chloride (6.6%).

The allergens that showed significantly higher positivity rates in females compared with males were nickel sulfate ($P < .001$), GST ($P < .001$), neomycin sulfate ($P < .01$), *p*-*tert*-butylphenol formaldehyde

resin ($P < .01$), and fragrance mix ($P < .01$). The allergens with significantly higher positivity rates in males compared with females were potassium dichromate ($P < .001$), carba mix ($P < .001$), urushiol ($P < .01$), and epoxy resin ($P < .05$).

The five allergens with the lowest positivity rates were mercaptobenzothiazole (0.8%), formaldehyde (0.9%), paraben mix (1.1%), mercapto mix (1.1%), and PPD black rubber mix (1.4%).

4 | DISCUSSION

The JBS, first established in 1994, was revised in 2008 and 2015.⁶ However, JBS allergens of 1994 and 2008 are not commercially available in Japan. The allergens for JBS 2008 were obtained from Brial allergens (Brial Allergen, Greven, Germany) and Torii patch test allergens (Torii Pharmaceutical Co. Ltd., Tokyo, Japan). The procedures for importing JBS allergens are complicated and costly, making it challenging for Japanese dermatologists to perform patch tests in daily practice using the JBS. In 2015, the Patch Test Panel (S) (Sato Pharmaceutical Co. Ltd, Tokyo, Japan), which is a modification of the TRUE test (SmartPractice Denmark, Hillerød, Denmark) and comprises 22 allergens of the JBS, began to be marketed with insurance approval in Japan. The positivity rate of urushiol was reported to be approximately 10% and that of mercuric chloride to be approximately 5% in the JBS 1994 and in the JBS 2008⁶; however, these allergens are not included in the Patch Test Panel (S)/TRUE test. Therefore, the JBS 2015 consists of the Patch Test Panel (S)/TRUE test, as well as urushiol and mercuric chloride. The JBS 2015 is covered by insurance and is economically cost-effective for patients and dermatologists. In total, 63 institutions in Japan were enrolled in this study. Data were collected from the SSCI-Net website and via an SSCI-Net website survey; thus, input errors were avoided.

In this study, the proportion of patients with a “+ /IR” to GST was as high as 20%, whereas 25.7% and 76% had a “+ or greater” and “+” response to GST, respectively. Furthermore, the GST allergen exhibited the highest “+ /IR” rate. Suzuki et al.¹⁰ examined the clinical relevance of 302 individuals with a positive reaction to GST up to 1 month after the application of the JBS 2015. They reported that the source of sensitization was unknown in 21 individuals (7%), and they could not rule out the possibility of an irritation reaction or sensitization by patch testing. Whether GST should be included in baseline series was controversial: American Contact Dermatitis Society recommends to applicate it as a 2% reagent,¹¹ whereas it was excluded in some regions and countries.

Suzuki et al.¹² previously reported that the GST positivity rate in the Patch Test Panel (S)/TRUE test (JBS 2015) was remarkably high and that there were many late reactions. The positivity rate for GST increased with age (Figure 1), which might be related to dental treatment. Suzuki et al.¹⁰ undertook a questionnaire survey of all patients concerning their history of piercing and the presence of dental metals for patients who had undergone JBS 2015 patch testing. They concluded that a history of piercing and dental metal were both associated with gold sensitization.

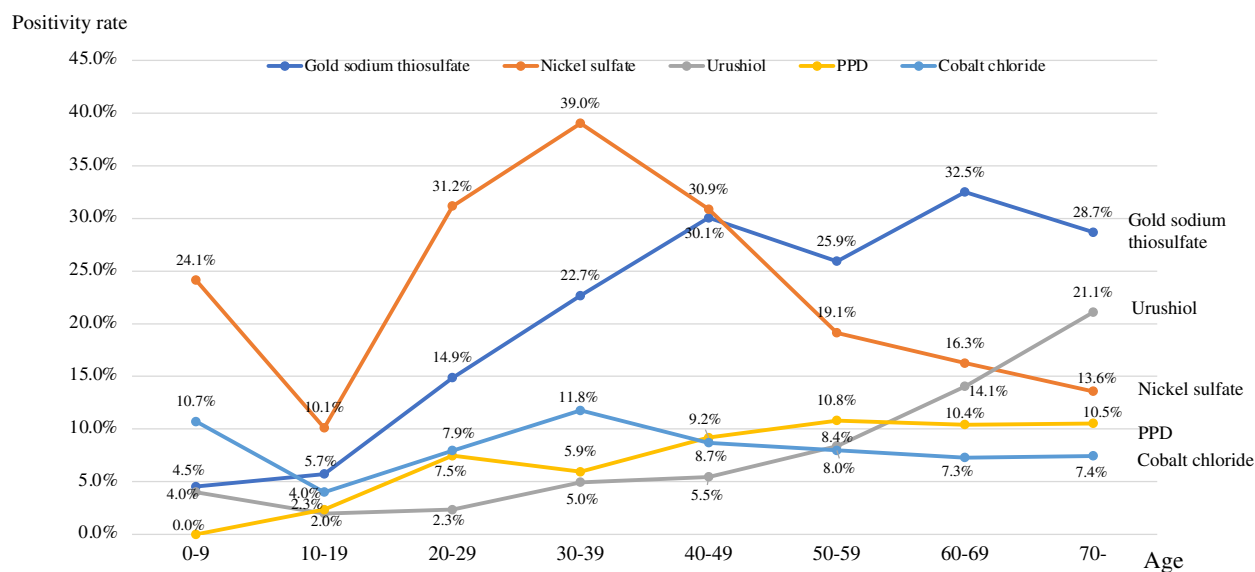
TABLE 2 Patient demographics and final diagnoses

Demographics	Total (n = 5865)
Sex, n (%)	
Male	1334 (22.7)
Female	4531 (77.3)
Age, mean ± SD	
Male	49.2 ± 18.8
Female	49.0 ± 17.5
Disease, n (%)	
Contact dermatitis	3113 (53.1)
Atopic dermatitis	497 (8.5)
Metal allergy	386 (6.6)
Palmoplantar pustulosis	222 (3.8)
Photoallergic dermatitis	7 (0.1)
Other disease	1640 (27.9)
Purpose of patch test with the JBS 2015, n (%)	
To identify the cause of contact dermatitis	1956 (33.4)
To test for metal allergies	1277 (21.8)
To identify the cause of intractable dermatitis	484 (8.3)
To identify aggravating factors in atopic dermatitis	204 (3.5)
To identify the cause of prurigo	33 (0.6)
To identify the cause of a drug eruption	43 (0.7)
Others	51 (0.87)
Blank	1826 (31.1)

TABLE 3 The JBS 2015 positivity rates (2015-2018)

Allergen		Tested, n	%? +/IR	% +	% ++/+	% positive (95% CI)	Female, % positive (95% CI)	Male, % positive (95% CI)
Metals	Cobalt chloride	5163	9.4	6.8	1.6	8.4 (7.7-9.2)	8.4 (7.6-9.3)	8.3 (6.8-10.1)
	Nickel sulfate	5255	8.0	13.9	10.6	24.5 (23.3-25.7)	27.3 (25.9-28.6)	>>> 14.5 (12.6-16.7)
	Potassium dichromate	5113	4.9	2.1	0.4	2.5 (2.2-3.0)	2.1 (1.7-2.6)	<<< 4.2 (3.1-5.5)
	Mercuric chloride	4711	6.6	3.9	1.2	5.1 (4.5-5.8)	5.1 (4.4-5.9)	5.1 (3.9-6.6)
	Gold sodium thiosulfate	5118	20.2	19.2	6.5	25.7 (24.5-27.0)	28.8 (27.4-30.3)	>>> 14.5 (12.6-16.7)
Rubber additives	Thiuram mix	4955	1.5	2.5	1.1	3.6 (3.1-4.1)	3.7 (3.2-4.4)	3.1 (2.2-4.3)
	PPD black rubber mix	4941	1.8	1.3	0.1	1.4 (1.1-1.7)	1.1 (0.8-1.5)	2.1 (1.4-3.2)
	Mercapto mix	4939	1.2	0.9	0.2	1.1 (0.8-1.4)	1.1 (0.8-1.5)	1.0 (0.5-1.8)
	Mercaptobenzothiazole	4932	0.9	0.6	0.2	0.8 (0.6-1.1)	0.8 (0.5-1.1)	0.8 (0.4-1.6)
	Carba mix	4965	7.1	5.3	0.6	5.9 (5.3-6.6)	4.9 (4.3-5.7)	<<< 9.4 (7.8-11.3)
Topical medicaments	Caine mix	5046	1.9	1.7	0.3	2.0 (1.6-2.4)	2.0 (1.6-2.5)	2.0 (1.3-3.0)
	Neomycin sulfate	5072	2.8	3.2	0.8	3.9 (3.4-4.5)	4.7 (4.1-5.5)	>>> 1.0 (0.5-1.8)
Cosmetics	Myroxylon pereirae	4946	2.0	1.6	0.3	1.9 (1.6-2.3)	2.0 (1.6-2.5)	1.4 (0.9-2.3)
	Fragrance mix	5092	4.3	4.7	0.8	5.5 (4.9-6.1)	6.0 (5.3-6.8)	>>> 3.6 (2.6-4.9)
	PPD	4966	3.5	6.1	2.8	8.9 (8.1-9.7)	9.2 (8.4-10.2)	7.7 (6.2-9.4)
Vehicle ingredients	Lanolin alcohol	5056	2.6	1.9	0.3	2.2 (1.8-2.6)	2.2 (1.8-2.7)	2.2 (1.5-3.3)
Resin	Colophony	5067	1.3	1.4	0.3	1.8 (1.4-2.2)	1.9 (1.5-2.3)	1.4 (0.9-2.3)
	PTBPFR	4950	3.7	2.7	0.5	3.2 (2.8-3.8)	3.6 (3.0-4.2)	>> 1.9 (1.2-2.9)
	Epoxy resin	4940	2.9	1.4	0.2	1.7 (1.4-2.1)	1.4 (1.1-1.9)	< 2.6 (1.8-3.7)
Preservatives	Thimerosal	4955	1.6	2.3	0.6	2.9 (2.5-3.5)	3.1 (2.6-3.7)	2.3 (1.5-3.4)
	Paraben mix	5063	1.7	1.0	0.1	1.1 (0.9-1.4)	1.0 (0.8-1.5)	1.1 (0.5-1.8)
	Formaldehyde	4937	1.1	0.6	0.3	0.9 (0.7-1.2)	0.9 (0.6-1.2)	1.0 (0.5-1.8)
	MCI/MI	4959	1.9	2.5	1.5	4.0 (3.5-4.6)	4.2 (3.6-4.8)	3.6 (2.6-4.8)
Plants	Urushiol	4448	1.5	5.6	3.5	9.1 (8.3-9.9)	8.4 (7.5-9.3)	<< 11.5 (9.7-13.7)

Abbreviations: CI, confidence interval; JBS, Japanese baseline series; MCI/MI, methylchloroisothiazolinone/methylisothiazolinone; PPD, *p*-phenylenediamine-+; PTBPFR: *p*-tertiary-butylphenol formaldehyde resin. < or >, $P < .05$; << or >>, $P < .01$; <<< or >>>, $P < .001$.

**FIGURE 1** Gold sodium thiosulfate, nickel sulfate, cobalt chloride, urushiol, and *p*-phenylenediamine (PPD) positivity rates according to age

The positivity rate of nickel sulfate in our study was very high (24%) compared with recent reports from the ESSCA (17.6%)¹ or NACDG (16.2%).² Concerning the nickel age-related positivity rate, there was a peak for patients aged 30 to 39 years. In Japan, it is not customary to wear piercings from an early age; however, in recent years the number of teenagers and young adults with piercings has increased. Therefore, the high positivity rate of nickel sulfate may be related to this. In Denmark, the positivity rate of nickel sulfate decreased due to enforcement of regulations on nickel compounds in accessories and daily necessities in 1990.¹³ In the European Union, nickel compounding regulations have been more generally enforced, and one study reported that the nickel positivity rate had decreased.¹⁴ There is no legislation in Japan regulating the amount of nickel released from everyday products and, in the absence of legislation, the only option is self-regulation by manufacturers.

The positivity rate of PPD in Japan is higher than that in Europe.^{15,16} We found no significant sex difference in the positivity rate, and that the positivity rate of PPD increased with age (Table 3 and Figure 1). Many adults in Japan, regardless of gender expression, frequently dye their hair every month using an oxidative hair dye to change the typical black colour of their hair.

We consider that this use of oxidative hair dyes may influence the age-specific positivity rates of PPD in males as well as females. Over the past 20 years, the positivity rate of PPD has remained at approximately 10% in Japan.⁶ Ito et al. reported the patch test results of 19 hair cosmetic allergens for 203 Japanese patients with suspected contact allergy to hair colouring or perming solutions.¹⁷ The Japanese hair colour manufacturers have attempted to reduce the content of PPD in hair colour products. However, it remains challenging to eliminate PPD completely, which is still frequently used in oxidative dyes in Japan.

The JBS 1994 and JBS 2008 fragrance mix contained sandalwood; however, the fragrance mix in the Patch Test Panel (S)/TRUE test does not contain sandalwood. Therefore, the JBS 2015 is unable to confirm an allergy to sandalwood. In Japan, sandalwood oil has been used in incense, incense sticks, and folding fans, for example, and is an allergen that Japanese people are often exposed to. Mortz¹⁸ reported that the fragrance mix in the TRUE test has a lower positivity rate than the petrolatum-based fragrance mix I (Trolab, Almirall Hermal GmbH, Reinbek, Germany). Uter¹⁹ concluded that false-negative results can occur using the TRUE test fragrance mix. The ESSCA network suggested that other fragrance allergens should be patch tested in combination with the European baseline series two fragrance mix.²⁰ As the current JBS 2015 may have missed sensitization to certain fragrances, we are considering adding other fragrance allergens to the JBS.

In this study, the lowest positivity rate allergen was mercaptobenzothiazole at 0.8%. In conclusion, the JBS 2015, using the Patch Test Panel (S)/TRUE test, is suitable as a baseline series for patch testing and the use of the Patch Test Panel (S)/TRUE test for the JBS has made patch testing easier for Japanese dermatologists.

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AUTHOR CONTRIBUTIONS

Akiko Ito: Conceptualization (equal); data curation (equal); investigation (equal); methodology (equal); project administration (equal); resources (equal); visualization (equal); writing – original draft (equal). **Kayoko Suzuki:** Investigation (equal); resources (equal); writing – original draft (equal). **Kayoko Matsunaga:** Conceptualization (equal); funding acquisition (equal); investigation (equal); methodology (equal); project administration (equal); resources (equal); writing – review and editing (equal). **Akiko Yagami:** Investigation (equal); resources (equal); writing – review and editing (equal). **Takashi Ito:** Investigation (equal); resources (equal); writing – review and editing (equal). **Risa Tamagawa-Mineoka:** Investigation (equal); resources (equal); writing – review and editing (equal). **Atsuko Adachi:** Investigation (equal); resources (equal); writing – review and editing (equal). **Mariko Sugiura:** Investigation (equal); resources (equal); writing – review and editing (equal). **Hitoshi Miyazawa:** Investigation (equal); resources (equal); writing – review and editing (equal). **Atsuko Kato:** Investigation (equal); resources (equal); writing – review and editing (equal). **Tokio Nakada:** Investigation (equal); resources (equal); writing – review and editing (equal). **Kazue Nishioka:** Investigation (equal); resources (equal); writing – review and editing (equal). **Yumiko Kubota:** Investigation (equal); resources (equal); writing – review and editing (equal). **Setsuko Matsukura:** Investigation (equal); resources (equal); writing – review and editing (equal). **Yuko Watanabe:** Investigation (equal); resources (equal); writing – review and editing (equal). **Hideo Asada:** Investigation (equal); resources (equal); writing – review and editing (equal). **Hiromi Kanto:** Funding acquisition (equal); investigation (equal); project administration (equal); resources (equal); supervision (lead); writing – review and editing (equal).

CONFLICTS OF INTEREST

K.M. is employed in an endowed department sponsored by Hoyu Co., Ltd. The rest of the authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data availability statement The data that the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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