A Multicenter, Prospective, Observational Study to Evaluate the Effectiveness and Safety of Sofpironium Bromide in Japanese Pediatric Patients

A Study with Severe Axillary Hyperhidrosis In CHIldren (AICHI study)

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ABSTRACT

Background: There is limited study which evaluate the pediatric use of sofpironium bromide (referred to as sofpironium) in real-world clinical practice.

Objectives: To evaluate the effectiveness and safety of sofpironium in pediatric patients with severe primary axillary hyperhidrosis in Japan. Additional epidemiological survey of severe primary axillary hyperhidrosis in children was also conducted.

Methods: This study was conducted as a multicenter, prospective, observational

Key words: Effectiveness and safety, Pediatric patients, Prevalence, Severe primary axillary hyperhidrosis, Sofpironium bromide

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study. Patients aged 6–14 years who visited one of 14 dermatology institutions were included. Patients with severe axillary hyperhidrosis having a hyperhidrosis disease severity scale (HDSS) score ≧3 for axillary sweating were screened, and those diagnosed using Hornberger's diagnostic criteria were eligible for the study.

Results: Overall, 39 pediatric patients with severe primary axillary hyperhidrosis were treated with sofpironium and included to evaluate the effectiveness and safety of sofpironium. Mean age was 12.1 years, and 69.2% were female. After treatment with sofpironium, the proportion of patients with HDSS score ≦2 at week 2 and 4 was 76.3% and 87.2%, respectively, which were significantly higher than those at week 2 (28.3%) and week 4 (41.2%) in the placebo group of previous phase 3 confirmatory study of sofpironium. No adverse events were observed during 4-week treatment period. In the questionnaire, 64.1% were very/moderately satisfied with the treatment. Epidemiological survey estimated that the prevalence of severe primary axillary hyperhidrosis in Japanese children is 2.5%.

Conclusions: Sofpironium is suggested to be an effective, safe, and satisfactory therapy for Japanese pediatric patients with severe primary axillary hyperhidrosis.

INTRODUCTION

Primary axillary hyperhidrosis is defined as a condition characterized by excessive sweating in the axillae, through which patients experience difficulties in daily activities with or without heat or mental burden, according to the Japanese clinical guideline for primary focal hyperhidrosis[1]. A previous Japanese epidemiological questionnaire survey conducted between 2009 and 2010 with 5807 respondents estimates the prevalence of primary axillary hyperhidrosis to be 5.75%[2]. A web-based survey conducted in 2021 on 608 patients with axillary hyperhidrosis in Japan shows that approximately 18% of the survey participants responds to being aware of their excessive axillary sweating symptoms when they are in elementary school (age 6–12 years)[3]. Therefore, it is assumed that a certain number of Japanese children suffer from axillary hyperhidrosis.

The Japanese guideline recommends two topical anticholinergic drugs, sofpironium bromide gel 5% (hereafter referred to as sofpironium) and glycopyrronium tosylate hydrate wipes as the first-line treatment for primary axillary hyperhidrosis in addition to conventional topical aluminum chloride[1]. These topical anticholinergic drugs are expected to be effective treatment options also for pediatric patients with primary axillary hyperhidrosis.

Sofpironium has been approved in 2020 in Japan as the first insurance-covered topical anticholinergic drug for the treatment of primary axillary hyperhidrosis. The clinical efficacy and safety of the drug have been demonstrated in phase 3 studies conducted in Japan in patients with primary axillary hyperhidrosis aged 13–72 years[4,5]. There is no report of the multicenter, prospective study which evaluate the pediatric use of sofpironium in real-world clinical settings in Japan, although only one study reports about the pediatric (age 9–14 years) use of sofpironium in real-world clinical settings, based on findings from a retrospective study with a small number of patients[6].

Therefore, we conducted a multicenter, prospective observational study to evaluate the

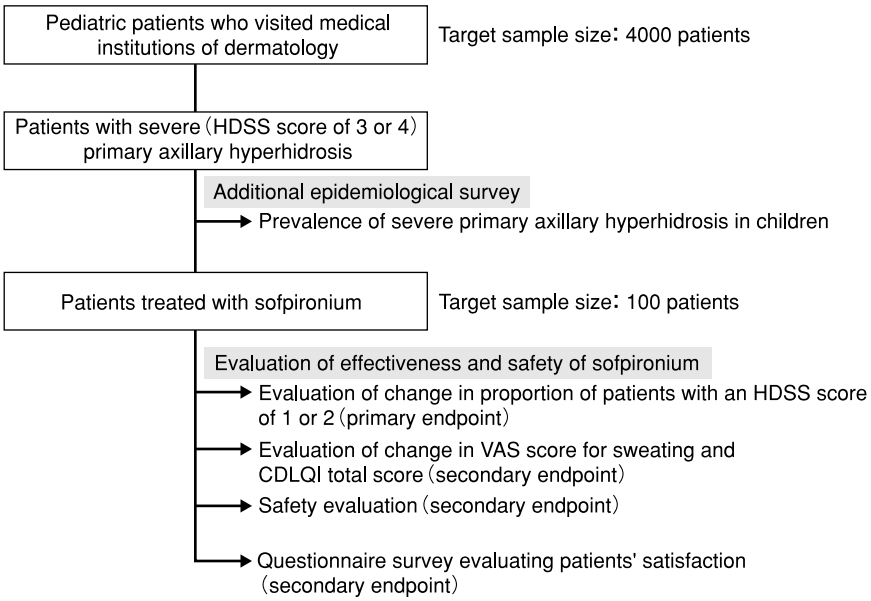

Fig. 1 Study design

CDLQI: children's dermatology life quality index, HDSS: hyperhidrosis disease severity scale, VAS: visual analog scale

effectiveness and safety of sofpironium in pediatric patients (aged 6–14 years) with severe primary axillary hyperhidrosis who visited dermatology institutions in Japan.

MATERIALS AND METHODS

1 Study design

This was a multi-institutional, prospective, observational study to assess the effectiveness and safety of sofpironium in the pediatric patients with severe primary axillary hyperhidrosis (Japan Registry of Clinical Trials identifier: jRCT1041230174). The prevalence of severe primary axillary hyperhidrosis was additionally investigated among children. The study design is illustrated in **Fig. 1**. The study was conducted in Japan between April 2023 and November 2023 after the approval of the Institutional Review Board of the Aichi Medical University School of Medicine (approval number: 2022-712), and was conducted in accordance with the principles of the Declaration of Helsinki and the ethical guidelines for medical and health research involving human subjects. Written informed consent was obtained from the guardians of the pediatric patients or the patients themselves who participated in the study to evaluate the effectiveness and safety of sofpironium. For the additional epidemiological survey, informed consent was obtained using the opt-out method.

2 Study patients

Patients aged 6–14 years who had not been treated for primary axillary hyperhidrosis and had visited one of the 14 dermatology institutions in Japan were eligible to participate in this study. Among them, patients with severe axillary hyperhidrosis with a hyperhidrosis disease severity scale (HDSS)[7] score ≧3 for axillary sweating was screened, and then diagnosed with primary axillary hyperhidrosis using Hornberger's diagnostic criteria[8] after excluding secondary axillary hyperhidrosis. Patients diag-

nosed with primary axillary hyperhidrosis were enrolled as the study patients for the evaluation of effectiveness and safety of sofpironium.

Exclusion criteria

Patients who used relevant medication/therapy within a stipulated time (as indicated in parentheses) before participation in the study were excluded if patients were prescribed medications as follows: (i) herbal medicines for reducing symptoms of hyperhidrosis (within 7 days); (ii) systemic and topical anticholinergics, oral cholinergic agonists, serotonin agonists, β-blockers, α-adrenergic agonists, dopamine partial agonists, tricyclic antidepressants, aluminum chloride, medications for hyperhidrosis approved outside Japan, and tap water iontophoresis (within 30 days); and (iii) botulinum toxin (within 9 months). Patients with angle-closure glaucoma, dysuria due to benign prostatic hyperplasia, or a history of hypersensitivity to sofpironium ingredients (active ingredient: sofpironium bromide; additives: hydroxypropyl cellulose, hexylene glycol, isopropyl myristate, anhydrous citric acid, and anhydrous ethanol) were excluded.

3 Endpoints

The primary endpoint was a change in the proportion of patients with an HDSS[7] score ≦2 from baseline to week 2 and week 4.

The secondary endpoints were a change in the mean visual analog scale (VAS) score for sweating from baseline to weeks 2 and 4, and a change in the mean children's dermatology life quality index (CDLQI)[9] total score from baseline to week 4. The VAS scores for sweating ranged from 0 (no sweat volume) to 10 (maximum amount of sweating ever experienced). The CDLQI is a modified version of the DLQI questionnaire[10] designed for children, and is used to evaluate skin disease-related QOL (measured on a scale of 0-30)[9]. Higher CDLQI scores are associated with lower QOL. In this study, we modified the CDLQI by changing the word "skin" in the questionnaire to "axillary" to make it more suitable for the assessment of primary axillary hyperhidrosis. Patient satisfaction was assessed using a questionnaire survey. Safety was evaluated on the basis of adverse events (AEs) incidence. As an epidemiological survey, the prevalence of severe primary axillary hyperhidrosis (with an HDSS score ≧3) was investigated in Japanese children.

4 Statistical analysis

For each endpoint, statistical values such as the mean, standard deviation (SD), median, minimum, maximum, and proportion (%) of patients at each assessment time point were calculated. The proportions of patients with an HDSS score ≦2 were statistically compared with the proportions of patients with an HDSS score ≦2 in the placebo group of the phase 3 confirmatory study of sofpironium at weeks 2 and 4[4,11] using a one-sample proportion test. The VAS scores for sweating and CDLQI total scores were statistically compared between the baseline and each evaluation point using a paired t-test (with Bonferroni correction for comparison of the VAS score for sweating). Statistical significance was determined using a two-sided alpha level of $p < 0.05$. R software version 3.4.0 (The R Development Core Team) was used for data analysis.

RESULTS

1 Patient disposition and characteristics

A total of 39 Japanese pediatric patients with primary axillary hyperhidrosis were included to evaluate the effectiveness and safety of sofpironium. Mean age±SD was 12.1±2.0 years, and 69.2% were female. The age at which patients became aware of axillary hyperhidrosis (mean±SD) was 8.7±3.6 years. The baseline VAS score for sweating and CDLQI total score (mean±SD)

Table 1　Patient characteristics

Item		*n* (%)/statistics
Number of patients		39 (100.0)
Age, years	Mean±SD Min-max	12.1±2.0 7-14
Age at which patients become aware of axillary hyperhidrosis, years	Mean±SD	8.7±3.6
Sex	Male Female	12 (30.8) 27 (69.2)
HDSS score	3 4	31 (79.5) 8 (20.5)
VAS for sweating	Mean±SD	6.0±2.0
CDLQI total score	Mean±SD	6.9±3.6
Presence of family member with hyperhidrosis †	Yes No	25 (64.1) 14 (35.9)
Previous measure for axillary hyperhidrosis (Multiple answers allowed)	Commercially available antiperspirants Carry a towel Change of clothes Armpit sweat pad Others None	22 (56.4) 22 (56.4) 9 (23.1) 4 (10.3) 2 (5.1) 6 (15.4)

†: Judged with Hornberger's diagnostic criteria[8]
CDLQI: children's dermatology life quality index, HDSS: hyperhidrosis disease severity scale, max: maximum, min: minimum, SD: standard deviation, VAS: visual analog scale

were 6.0±2.0 and 6.9±3.6, respectively. The most common previous measures for axillary hyperhidrosis were "commercially available antiperspirants" and "carry a towel", both of which were reported in 56.4% of the patients (**Table 1**). Regarding anxious situations for excess armpit sweating, 51.3% of patients responded as "smell of my armpit", 48.7% as "can't concentrate on hobbies or club activities because worrying about my surroundings" and "when presenting in public at school etc.", and 38.5% as "when talking to or playing with friends" (**Supplementary Fig. 1**).

2　Effectiveness

1) A change in the proportion of patients with an HDSS score

The proportion of patients with an HDSS score ≦2 at week 2 and 4 was 76.3% and 87.2%, respectively, which were significantly higher than the proportions of patients with an HDSS score ≦2 at week 2 (28.3%) and week 4 (41.2%) in the placebo group of the phase 3 confirmatory study of sofpironium[4,11] ($p<0.05$) (**Fig. 2**)

2) Change in VAS score for sweating

The VAS score for sweating (mean±SD) was 6.0±2.0, 5.1±2.2, and 4.2±2.2 at baseline,

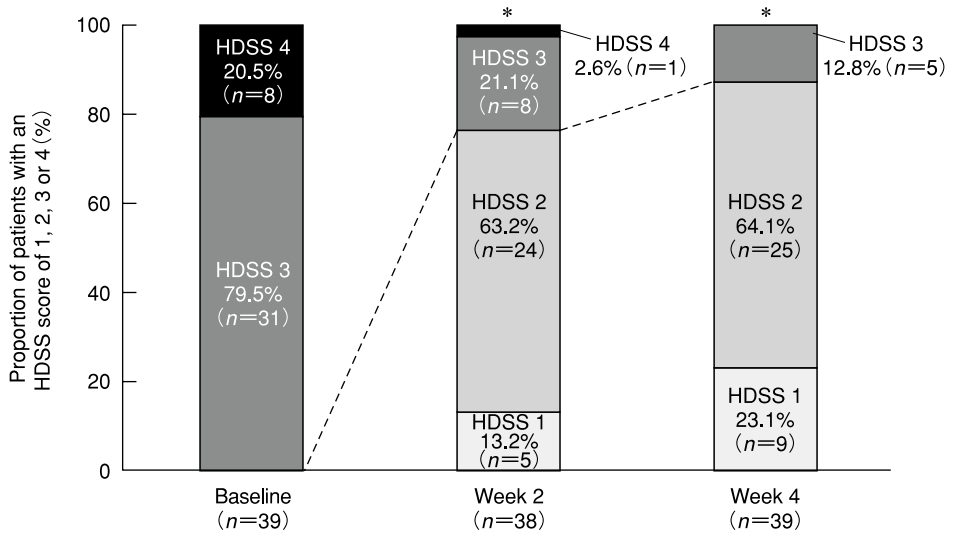

Fig. 2 Change in proportions of patients with an HDSS score of 1, 2, 3, or 4

*: In a one-sample proportion test to compare the proportion of patients with an HDSS score ≦2 at week 2 and week 4 of treatment with sofpironium (76.3% and 87.2%) with the proportion of patients with an HDSS score ≦2 at week 2 and week 4 in the placebo group of the phase 3 confirmatory study of sofpironium (28.3% and 41.2%)[4,11]; p value was <0.05.

HDSS: hyperhidrosis disease severity scale

week 2, and week 4, respectively, indicating significant improvement at weeks 2 and 4 (vs. baseline; $p<0.05$) (**Fig. 3A**).

3) Change in CDLQI total score

The CDLQI total score (mean±SD) was 6.9 ±3.6 at baseline and 3.9±2.9 at week 4, indicating significant improvement at week 4 ($p<0.05$) (**Fig. 3B**).

4) Patients' satisfaction

In the questionnaire, patients were asked, "How are you satisfied with your treatment?", and 64.1% reported as being "very satisfied" or "moderately satisfied" (**Fig. 4A**). Regarding the time when the patients felt the effectiveness, 61.5% of the patients reported that they felt effectiveness of sofpironium within 1 week of treatment (**Fig. 4B**). When patients were asked for the benefits of the sofpironium treatment, 41.0% of patients responded as "no longer worry about smell of my armpit", 33.3% as "no longer worry about surroundings and can concentrate on hobbies or club activities", and 30.8% as "no longer worry about surroundings and can concentrate on schoolwork","eliminates the needs to change clothes many times a day", and "no longer worry when presenting in public at school etc." (**Supplementary Fig. 2**).

3 Safety

No AEs were observed in the 39 patients included during the treatment period of 4 weeks.

4 Prevalence of severe primary axillary hyperhidrosis

It was estimated among 3983 pediatric patients aged 6-14 years who had not been treated for primary axillary hyperhidrosis and had visited each of the 14 dermatology institutions in Japan. The 3983 pediatric patients had a mean age±SD of 9.7±2.6 years, and 51.8% were female. Severe axillary hyperhidrosis symptoms defined as HDSS score ≧3 were

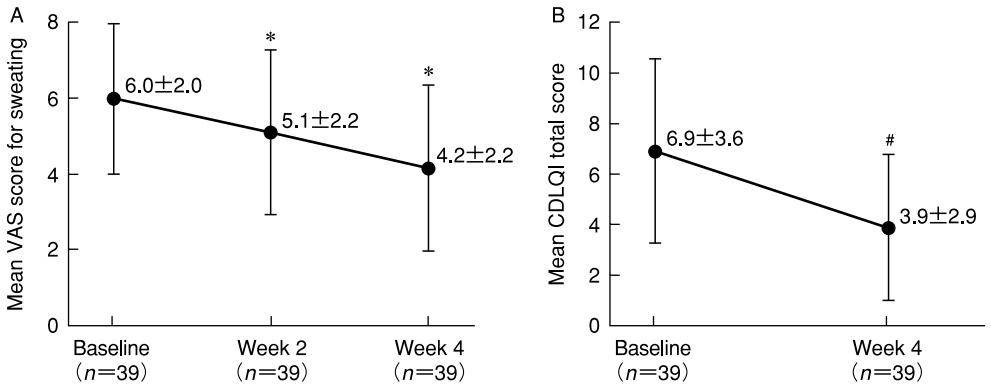

Fig. 3 Change in VAS score for sweating (A) and CDLQI total score (B)

Data are presented as mean±SD.

*: $p<0.05$ (vs. baseline; paired t-test with Bonferroni correction), #: $p<0.05$ (vs. baseline; paired t-test)

CDLQI: children's dermatology life quality index, SD: standard deviation, VAS: visual analog scale

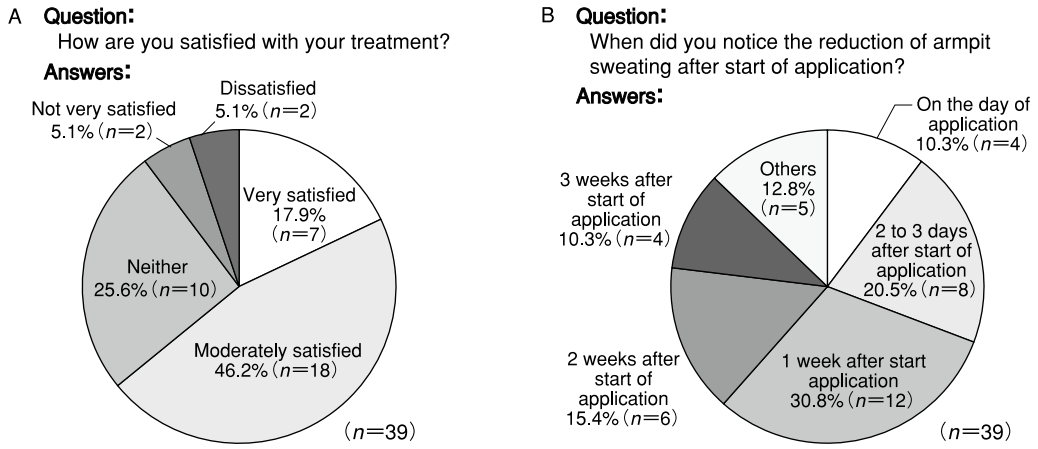

Fig. 4 Patients' satisfaction with sofpironium treatment (A) and time when patients felt the effectiveness (B)

reported in 107 patients (2.7%). In the 107 patients with HDSS score ≧3, 101 patients (2.5%) were and identified as pediatric patients with severe primary axillary hyperhidrosis using Hornberger's criteria[8] (**Table 2**). In short, the proportion of patients with primary axillary hyperhidrosis was 94.4% (101/107 patients) in the axillary hyperhidrosis patients. The identified 101 patients with severe primary axillary hyperhidrosis had a mean age±SD of 11.6±2.3 years, and 73.3% were female. A family history of hyperhidrosis was reported in 60.4% of the patients. When the patients were asked for the willingness to receive treatment, 54.5% of the patients responded as being "willing to receive treatment" and 29.7% as being "willing to consult a doctor" (**Supplementary Table 1**).

Table 2　Patients' composition in the epidemiological survey

Item		*n* (%)/statistics
Number of patients		3983 (100.0)
Age, years	Mean±SD	9.7±2.6
	Min–max	6–14
Sex	Male	1917 (48.1)
	Female	2063 (51.8)
	Unknown	3 (0.1)
HDSS score	1	3408 (85.6)
	2	458 (11.5)
	3	88 (2.2)
	4	19 (0.5)
	Unknown	10 (0.3)
	≧3	107 (2.7)
Diagnosis of axillary hyperhidrosis†	Primary	101 (2.5)
	Non–primary	6 (0.2)

†: Patients with an HDSS score[7] ≧3 (severe axillary hyperhidrosis) were diagnosed with Hornberger's diagnostic criteria[8].
HDSS: hyperhidrosis disease severity scale, max: maximum, min: minimum, SD: standard deviation

DISCUSSION

This is first report of the multicenter, prospective observational study to evaluate the effectiveness and safety of sofpironium in pediatric patients with severe primary axillary hyperhidrosis in real–world clinical settings in Japan.

Our study results showed that the proportions of the pediatric patients whose HDSS score improved from 3≧ to ≦2 was 76.3% at week 2 and 87.2% at week 4 after the sofpironium treatment. The study results demonstrated a significantly higher effectiveness compared to the placebo group (approximately 28%), and also show the higher tendency compared to the sofpironium group (approximately 50%) in the phase 3 confirmatory study[4]. A previous retrospective study of sofpironium in Japanese pediatric patients with primary axillary hyperhidrosis also shows a similar finding with our study results in the HDSS score improvement[6]. Considering these results, sofpironium treatment may improve HDSS scores in pediatric patients with primary axillary hyperhidrosis as well as, or better than in the population including adult and pediatric patients. Due to differences in the thickness of the skin between children and adults, sofpironium is presumably more easily absorbed through the axillary skin when administered to pediatric patients than in adult patients, which may have led to its high effectiveness.

In addition, the VAS score for sweating and the CDLQI total score significantly improved at week 4 in our study, supporting the effectiveness of sofpironium. Therefore, sofpironium is expected to be an effective treatment option for pediatric patients with primary axillary hyperhi-

drosis.

In the questionnaire, 64.1% of the patients responded to being "very satisfied" and "moderately satisfied" with sofpironium treatment, and 61.5% reported that they felt sofpironium treatment effectiveness within 1 week of starting treatment. These results suggest that the effectiveness of sofpironium is observed early in more than half of the patients, and this may contribute to the patients' satisfaction with sofpironium treatment. The questionnaire survey results also suggest that a certain number of patients experience improvement in situations where they feel anxious because of armpit sweating, which may also contribute to patient satisfaction with sofpironium treatment.

No AEs were reported in our study in pediatric patients with primary axillary hyperhidrosis, and no new safety signals for sofpironium treatment were observed during the 4-week treatment period. However, the previous report involving 15 Japanese pediatric patients and phase 3 confirmatory study have shown the incidence of adverse drug reactions (ADRs), such as contact dermatitis, erythema, and pruritus[4-6]. Therefore, it is important to pay attention and respond appropriately to these ADRs, in addition to the other ADRs indicated on the package insert when administering sofpironium in pediatric patients.

An epidemiological survey showed that the prevalence of severe (HDSS score ≧3) primary axillary hyperhidrosis in children was 2.5%. A previous web-based survey conducted in 2020 among 1258 patients with primary axillary hyperhidrosis demonstrates that 44.6% of the patients have severe symptoms of an HDSS score ≧3[12]. Considering this proportion of primary axillary hyperhidrosis with any of the HDSS scores, the prevalence of primary axillary hyperhidrosis in children can be calculated as 5.6% from our result. An epidemiological study by Fujimoto, et al. in a population aged 5-64 years demonstrates that the prevalence of primary axillary hyperhidrosis (with any of the HDSS scores) is 5.75%[2]. Therefore, our estimate of the prevalence of primary axillary hyperhidrosis in children is similar to that reported by Fujimoto, et al., suggesting that the prevalence of primary axillary hyperhidrosis is similar between adults and children. We speculate that many pediatric patients with primary axillary hyperhidrosis grow up to adulthood while experiencing disease burden, which emphasizes the importance of long-term care for primary axillary hyperhidrosis through the patients' lives. In our epidemiological survey, a family history of hyperhidrosis was reported in 60.4% of the pediatric patients with severe primary axillary hyperhidrosis. A previous report reveals that family histories of palmoplantar hyperhidrosis were confirmed in 147/410 patients (36%) in Japan[13]. The possibility of having an axillary hyperhidrosis may need to be more carefully considered in children who have a family member with hyperhidrosis.

This study had some limitations. The study design was a single-arm, observational study; therefore, the findings from this study need to be verified in a controlled study with a control (placebo) arm. In addition, the pediatric patients who visited dermatology institutions included in our study may not necessarily be representative of the pediatric population in real-world settings.

In conclusion, the findings of this multicenter, prospective, observational study suggest that sofpironium is an effective and safe therapy with high patients' satisfaction in Japanese pediatric patients with primary axillary hyperhidrosis. Epidemiological survey has estimated that the prevalence of severe primary axillary hyperhidrosis in Japanese children is 2.5%.

CONFLICT OF INTEREST

This study was funded by Kaken Pharmaceutical Co., Ltd. Yuichiro Oshima received speaking fee from Kaken Pharmaceutical Co., Ltd. Hiromichi Okatsu and Hiroshi Miyama were employees of Kaken Pharmaceutical Co., Ltd. Statistical analysis and data management were provided by Nouvelle Place Inc. Medical writing support was provided by Medical Professional Relations Inc. Both statistical and medical writing support were funded by Kaken Pharmaceutical Co., Ltd.

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REFERENCES

1) Fujimoto T, Yokozeki H, Nakazato Y, Murota H, Murayama N, Oshima Y, et al. Guidelines of the Japanese dermatological association, clinical guidelines for primary focal hyperhidrosis (revised edition in 2023). Jpn J Dermatol 2023;133:157–88. (article in Japanese)
2) Fujimoto T, Kawahara K, Yokozeki H. Epidemiological study and considerations of primary focal hyperhidrosis in Japan: from questionnaire analysis. J Dermatol 2013;40:886–90.
3) Fujimoto T, Okatsu H, Miyama H, Oshima Y. Survey on awareness of axillary hyperhidrosis: results of internet questionnaire survey in 608 individuals. J JOCD 2022;39:431–9. (article in Japanese)
4) Yokozeki H, Fujimoto T, Abe Y, Igarashi M, Ishikoh A, Omi T, et al. A phase 3, multicenter, randomized, double-blind, vehicle-controlled, parallel-group study of 5% sofpironium bromide (BBI-4000) gel in Japanese patients with primary axillary hyperhidrosis. J Dermatol 2021;48:279–88.
5) Fujimoto T, Abe Y, Igarashi M, Ishikoh A, Omi T, Kanda H, et al. A phase Ⅲ, 52-week, open-label study to evaluate the safety and efficacy of 5% sofpironium bromide (BBI-4000) gel in Japanese patients with primary axillary hyperhidrosis. J Dermatol 2021;48:1149–61.
6) Goto Y, Nihei T. Effectiveness and safety of sofpironium bromide (ECCLOCK® Gel 5%) in pediatric patients with primary axillary hyperhidrosis. Med Cons New-Remed 2023;60:89–92. (article in Japanese)
7) Solish N, Bertucci V, Dansereau A, Hong HCH, Lynde C, Lupin M, et al. A comprehensive approach to the recognition, diagnosis, and severity-based treatment of focal hyperhidrosis: recommendations of the Canadian Hyperhidrosis Advisory Committee. Dermatol Surg 2007;33:908–23.
8) Hornberger J, Grimes K, Naumann M, Glaser DA, Lowe NJ, Naver H, et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. J Am Acad Dermatol 2004;51:274–86.
9) Lewis-Jones MS, Finlay AY. The children's dermatology life quality index (CDLQI): initial validation and practical use. Br J Dermatol 1995;132:942–9.
10) Finlay AY, Khan GK. Dermatology life quality index (DLQI) —a simple practical measure for routine clinical use. Clin Exp Dermatol 1994;19:210–6.
11) Kaken Pharmaceutical Co., Ltd. Internal document (Clinical study report of BBI-4000).
12) Maruho Co., Ltd. A web-based survey on primary axillary hyperhidrosis (July to August 2020). https://www.maruho.co.jp/medical/articles/hyperhidrosis/actual_situation/index.html#everyday_life (article in Japanese) (Accessed 22 March, 2024)
13) Yamashita N, Tamada Y, Kawada M, Mizutani K, Watanabe D, Matsumoto Y. Analysis of family history of palmoplantar hyperhidrosis in Japan. J Dermatol 2009;36:628–31.

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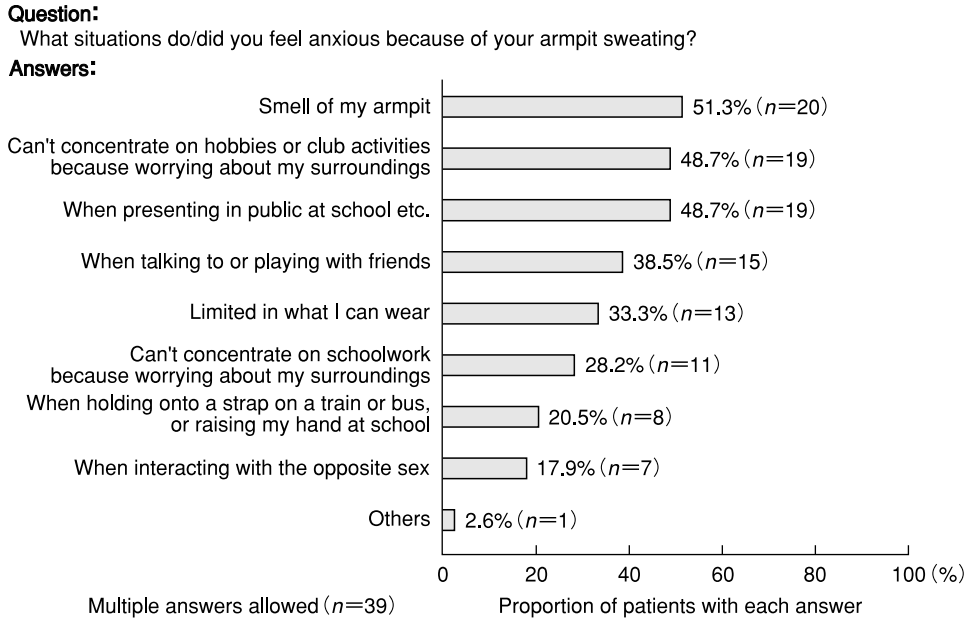
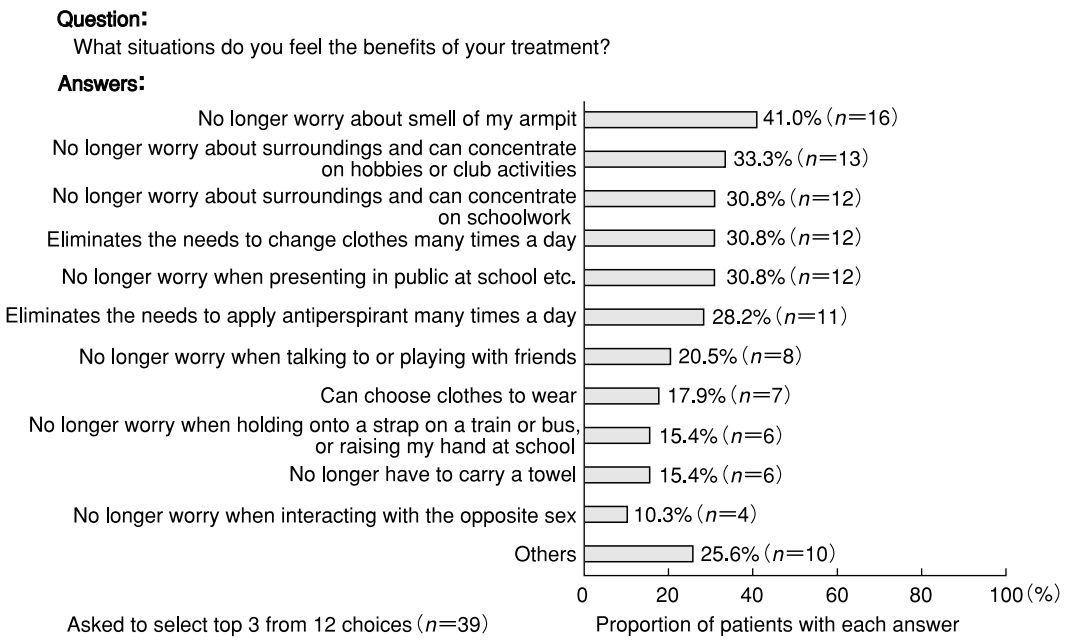


Supplementary Fig. 1　Anxious situations in patients with excess armpit sweating



Supplementary Fig. 2　Patient-reported benefits of sofpironium treatment

Supplementary Table 1　Characteristics for the pediatric patients with severe primary axillary hyperhidrosis in the epidemiological survey

Item		*n* (%)/statistics
Number of patients		101
Age, years	Mean±SD Min–max	11.6±2.3 6–14
Sex	Male Female	27 (26.7) 74 (73.3)
Presence of family member with hyperhidrosis†	Yes No	61 (60.4) 40 (39.6)
Willingness to receive treatment	Willing to receive treatment Willing to consult a doctor Not willing to receive treatment Unknown	55 (54.5) 30 (29.7) 12 (11.9) 4 (4.0)

†: Judged with Hornberger's diagnostic criteria[8)]

max: maximum, min: minimum, SD: standard deviation