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Cross-Sectional Survey to Assess Tobacco and Nicotine Product Use since the Introduction of Heated Tobacco Products in Japan: Wave 2*

by

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SUMMARY

Providing data on usage patterns is key to assessing the reduced-risk potential of novel tobacco and nicotine products as compared to conventional cigarettes at a population level. A pilot cross-sectional survey was conducted in 2018 across 3 areas of Japan (Tokyo, Osaka, and Sendai) to assess tobacco and nicotine product use after the introduction of Heated Tobacco Products (HTPs). Following successful completion of the pilot study, two nationwide cross-sectional surveys were conducted using the general population in Japan to assess use patterns after the introduction of HTPs. The first (Wave 1) was conducted in 2019, and the second in 2020. In Wave 2, the concern of this publication, additional population-level data was obtained on use patterns and behaviour relating to tobacco and nicotine products in Japan. Eligible participants were Japanese residents, aged 20 years or older who consented to complete the survey. A 3-stage probability sampling method was applied that was geographically stratified by street blocks proportionate to population density. Respondents self-reported patterns of product use and reasons for HTP use. Complete responses were available from 5307 individuals, of whom 889 (16.7%) were current users, 1012 (19.1%) were former users, and 3407 (64.2%) were never users of tobacco products (weighted respondent totals). Of current tobacco users, 63.5% smoked cigarettes exclusively and 17.9% used HTPs exclusively. HTP dual use in combination with conventional cigarettes was 12.7%. The remaining 5.9% of users were categorised as poly users (i.e., use of 2 or more tobacco products). The most common reasons reported for HTP use were perceived reduction in harm to others and self - compared to cigarettes. These findings are consistent across pilot and Wave 1 conducted in Japan as part of this survey programme. Cigarettes were still the most frequent tobacco product used (13.4% in the pilot to 15.5% in Wave 1) within the general population, the usage prevalence for HTPs (5.3% to 5.4%) being considerable in comparison to other tobacco or nicotine-containing products like cigars, cigarillos, pipe, kiseru, and oral tobacco, where usage prevalence was close to zero. As with the previous Waves, no gateway effect (use of non-traditional combustible tobacco use – such as e-cigarettes and in this case HTP use – leading to subsequent tobacco smoking) was observed in this study.

The findings presented here are indicative of the results from the initial study in 2018 and the nationwide Wave 1 study in 2019 but with a larger population, where the market is now more established with new-generation products. In conclusion, the prevalence of cigarette use in Japan is decreasing and HTPs seem to be increasingly used as an alternative to cigarette smoking. [Contrib. Tob. Nicotine Res. 34 (2025) 16–25]

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KEYWORDS

Post Market Surveillance; Cross-sectional survey; Heated Tobacco Product; Tobacco harm reduction

ZUSAMMENFASSUNG

Die Erhebung von Daten zu Konsummustern auf Bevölkerungsebene ist für die Beurteilung des im Vergleich zu herkömmlichen Zigaretten geringeren Risikopotenzials von neuen Tabak- und Nikotinerzeugnissen von großer Bedeutung. 2018 wurde in drei japanischen Regionen (Tokyo, Osaka und Sendai) eine Pilot-Querschnittsstudie zur Beurteilung des Konsums von Tabak und Nikotinprodukten nach der Einführung von erhitzten Tabakerzeugnissen (heated tobacco products, HTPs) durchgeführt. Nach dem erfolgreichen Abschluss der Pilotstudie erfolgten zwei landesweite Querschnittserhebungen zur Bewertung von Konsummustern nach der Einführung von HTPs in der japanischen Allgemeinbevölkerung. Die erste Erhebung fand 2019 statt (Welle 1), die zweite erfolgte 2020. In Welle 2, mit der sich dieser Artikel befasst, wurden auf Bevölkerungsebene zusätzliche Daten zu Konsummustern und -verhalten im Zusammenhang mit Tabak- und Nikotinerzeugnissen in Japan erhoben. Zur Teilnahme zugelassen waren in Japan wohnhafte Personen im Alter von 20 Jahren oder älter, die sich bereit erklärten, an der Erhebung teilzunehmen. Hierbei wurde ein dreistufiges Wahrscheinlichkeits-Stichprobenverfahren angewandt, das geografisch nach Straßenblöcken im Verhältnis zur Bevölkerungsdichte geschichtet war. Die Befragten gaben selbst darüber Auskunft, wie sie die Erzeugnisse verwendeten sowie über ihre Gründe für den Konsum von HTPs. Vollständige Angaben machten 5307 Personen, wovon 889 (16,7%) derzeit, 1.012 (19,1%) in der Vergangenheit und 3.407 (64,2%) nie Tabakerzeugnisse konsumierten (gewichtete Gesamtzahl der Befragten). Von den derzeitigen Tabakkonsumenten rauchten 63,5% ausschließlich Zigaretten und 17,9% verwendeten ausschließlich HTPs. Der Anteil der Befragten, die gleichzeitig HTPs und herkömmliche Zigaretten verwendeten, lag bei 12,7%. Die verbleibenden 5,9% der Konsumenten wurden als Polykonsumenten eingestuft (Konsum von zwei oder mehr Tabakprodukten). Als häufigste Gründe für die Verwendung von HTPs wurden die wahrgenommene Reduzierung der Gefährdung Dritter sowie der Eigengefährdung im Vergleich zu Zigaretten genannt. Diese Ergebnisse sind mit denen der Pilotstudie und der Welle 1 deckungsgleich, die ebenfalls im Rahmen dieses Erhebungsprogramms in Japan durchgeführt wurden. Zigaretten waren in der Allgemeinbevölkerung nach wie vor das am häufigsten konsumierte Tabakerzeugnis (13,4% in der Pilotstudie und 15,5% in Welle 1), jedoch ergab sich eine beträchtliche Konsumhäufigkeit von HTPs (jeweils 5,3% und 5,4%) im Vergleich zu anderen tabak- oder nikotinhaltigen Produkten wie Zigarren, Zigarillos, Pfeife, Kiseru und Tabak zum oralen Gebrauch, bei denen die Konsumprävalenz gegen Null ging. Wie bei den vorherigen Wellen konnte auch in dieser Studie kein sogenannter “Gateway”-Effekt (Effekt, bei dem der Konsum nicht-herkömmlicher brennbarer Tabakprodukte wie E-Zigaretten oder in diesem Fall HTPs in der Folge zum Rauchen von Tabak führt) beobachtet werden. [Contrib. Tob. Nicotine Res. 34 (2025) 16–25]

RESUME

La collecte de données relatives aux modes de consommation s’avère indispensable afin d’évaluer, au niveau d’une population, le potentiel de réduction des risques associé aux nouveaux produits de tabac et de nicotine en regard des cigarettes conventionnelles. En 2018, une enquête transversale sous la forme d’un pilote fut menée dans trois régions japonaises (Tokyo, Osaka et Sendai) dans le but d’évaluer les usages faits des produits de nicotine et de tabac à la suite du lancement des produits de tabac chauffé (ou HTPs en anglais). Après l’achèvement concluant de cette étude pilote, deux enquêtes transversales furent réalisées à l’échelon national ; elles eurent pour sujet la population japonaise générale et pour objet l’évaluation des modes de consommation après le lancement des HTPs. La première enquête (phase 1) fut bouclée en 2019 tandis que la seconde fut menée en 2020. Durant la phase 2, sujet de la présente publication, des données supplémentaires au niveau de la population furent récoltées quant aux modes et aux comportements de consommation des produits de nicotine et de tabac au Japon. Les participants éligibles à l’étude furent sélectionnés parmi les résidents japonais âgés de 20 ans et plus ayant consenti à répondre à l’enquête. Une méthode d’échantillonnage aléatoire en 3 phases fut appliquée et stratifiée géographiquement sur la base de pâtés de maison délimités proportionnellement selon leur densité de population. Les personnes interrogées précisèrent elles-mêmes leur modes de consommation des produits et les raisons les incitant à consommer des HTPs. Des réponses complètes furent récoltées auprès de 5307 individus, parmi lesquels 889 (16,7%) étaient des consommateurs actuels, 1.012 (19,1%) étaient d’anciens consommateurs et 3.407 (64,2%) n’avaient jamais consommé de produit de tabac (totaux pondérés des personnes sondées). Parmi les consommateurs actuels de tabac, 63,5% fumaient exclusivement des cigarettes tandis que 17,9% ne consommaient que des produits de tabac chauffé, sans exception. La consommation mixte de HTPs couplés à des cigarettes conventionnelles s’élevait à 12,7%. Les 5,9% de consommateurs restants furent classés dans la catégorie des poly-utilisateurs (consommation d’au-moins 2 produits de tabac). La raison la plus communément avancée quant au choix de HTPs fut la perception d’un moindre risque pour autrui et soi-même, comparativement à la cigarette. Ces résultats concordèrent avec l’enquête pilote et la phase 1 réalisées au Japon dans le cadre de ce programme d’enquête. Les cigarettes demeurèrent le produit de tabac le plus fréquemment consommé (entre 13,4% selon le sondage pilote et 15,5% lors de la phase 1) dans la population en général ; la prévalence du recours à des produits de tabac chauffé (entre 5,3% et 5,4%) se révéla considérable en comparaison des autres produits contenant de la nicotine tels que le cigare, le cigarillo, la pipe, le kiseru ou le tabac à usage oral, pour lesquels la prévalence de consommation s’approchait de zéro. A l’instar des phases précédentes, aucun effet dit d’escalade (consommation d’un produit de tabac non conventionnel tel que la cigarette électronique et dans le cas

présent, un produit de tabac chauffé conduisant ultérieurement au tabagisme) ne fut observé lors de la présente étude. [Contrib. Tob. Nicotine Res. 34 (2025) 16–25]

INTRODUCTION

During the past few decades, the global smoking landscape has changed substantially. Regulations restricting smoking have been introduced in many countries, with efforts made to reduce tobacco consumption and prevent initiation of use. In parallel, this has led to the emergence of alternative tobacco and nicotine products that reduce overall exposure to harmful toxicants and may offer reduced health risks as compared with cigarette smoking (1, 2).

To evaluate the modified-risk and tobacco harm reduction potential of a new product, a variety of studies are recommended to compare its effects with continued smoking combustible cigarettes, as well as the implications of its market introduction (3). Providing data to support the evaluation of behaviour/usage patterns of these new products is central to demonstrate tobacco harm reduction potential. For this purpose, not only current tobacco users but also non-users, e.g., never users and former users have to be considered. This holistic approach is pursued to demonstrate benefits of tobacco harm reduction at the population level.

In previous years, Japan was one of the nations with the highest smoking prevalence among men (4). However, the prevalence of cigarette smoking is declining year on year and is currently below 20% (5). On the one hand, this results from implementation of tobacco control instruments and increased concern about health risks and diseases caused by cigarette smoking (4). On the other hand, Japan provides a rather less restrictive environment compared to other countries for use of tobacco products and marketing in terms of advertisement and labelling of products. Also, e-cigarettes containing nicotine are classified as medicinal products and are regulated under the Japanese pharmaceutical affairs law (6), whilst other less risky alternatives to smoking such as snus are not popular in Japan. Therefore, Japan is one of the preferred markets for product launch and testing new innovative tobacco products, especially for heated tobacco products (HTPs). These products contain tobacco which is heated enough to release aerosol containing nicotine, glycerol, and some volatile tobacco flavour compounds but in contrast to cigarettes, not burnt. The lower temperature of operation results in reduced toxicant emissions (7), which in turn may result in reduced exposure to harmful or potentially harmful constituents, as compared to conventional cigarettes (8, 9).

Japan, the first country where HTPs were successfully introduced in 2014, has shown high levels of acceptance for this product category (10, 11). Therefore, Japan is a preferred location for investigating the impact of HTP introduction at a population level. A pilot cross-sectional survey was conducted in 2018 across 3 areas of Japan (Tokyo, Osaka, and Sendai) to assess tobacco and nicotine product use after the introduction of HTPs. Following successful completion of the pilot study, two nationwide multi-wave surveys were carried out in 2019 and in 2020 (10, 11). Here we report the results from the second (Wave 2).

METHODS

Study design and population

Wave 2 was performed between September 5th and October 18th, 2020. The eligible study population was comprised of current residents of Japan living in a private household who were aged 20 years (legal smoking age) or older, could speak and read Japanese, and were willing to participate after study information was provided. Institutionalised populations were excluded (e.g., prisons, military bases, mental facilities, and homes for the aged). This study was conducted in accordance with the latest version of the Declaration of Helsinki, Good Epidemiological Practice, the JMRA Marketing Research Guideline, and the Personal Information Protection Guideline (which also complies with the ICC/ESOMAR codes of conduct), as well as any relevant local laws and regulations. Approval was obtained from the independent ethics committee at Kitamachi Clinic, Tokyo, Japan.

Sampling design and procedures

A geographically stratified 3-stage probability sampling method was applied to select potential participants. Japan is classified into 9 regions containing 47 prefectures that are further separated into municipalities. Urbanization is stratified by 4 degrees – major cities, large cities, medium cities, and small towns – based on population data recorded by the residential registration program. The primary sampling units (PSUs) in this survey were street blocks selected by stratified random sampling. 500 PSUs were randomly selected and were proportionate in size to population density. Within each PSU, households were numbered in ascending order, using the Zenrin residential map database (Zenrin Co Ltd, Kitakyushu, Fukuoka, Japan). A starting number was chosen randomly from which 50 households, separated by regular numeric intervals, subsequently were selected. If there were not enough households in the selected PSU, households from the next street block listed on the residential map database in a neighbouring PSU of the same municipality were added.

If an interviewer could not complete 10 interviews within the 50 listed households, he or she visited the next household based on the regular numeric interval until 10 interviews were completed. Within each household, one respondent was selected by the next birthday method (13). To control for inclusion of participants in multiple waves, different PSUs were used in the pilot study and each wave of the survey.

Based on previous experience and results from the pilot study and Wave 1, it was expected that the age groups 20–24 years, 25–29 years, and 30–59 years would be under-represented in the sample (10, 13). Therefore, these age groups were oversampled by adding a quota to each assigned PSU. Once the target sample of 10 interviews was reached, the interviewer selected further households using the same method as for the main sample until the quota was met. Questionnaires from oversampling were specifically marked to differentiate them from the main sample to allow application of different weighting factors based on selection probability before they were merged into the final sample.

Table 1. A summary of relevant changes to questionnaire from Wave 1 to Wave 2, concerning tobacco use behaviour.

No.	Change description
1	The definitions of HTPs and e-cigarettes were clarified, and product names were updated.
2	A question was added to assess respective product use for the last 12 months.
3	Additional question for e-cigarette brand used was added to confirm correct categorization of used product.
4	Changes were made in the section about "Other Tobacco Products", including an additional question on use of other tobacco products 12 months ago.
5	In the section on "Risk Perception of Different Tobacco or Nicotine-containing Products" the glo product information used as a stimulus in Wave 1 was removed.
6	Additional questions were added to assess misuse of Ploom Tech HTP, with use being distinguished between capsules and sticks.

Study instrument

Participants completed a self-administered paper-and-pencil questionnaire that was provided with instructions for completion. The questionnaire was adapted, as necessary, based on the results of Wave 1 study to cover topics that evolved during the study run time and which were found to be essential for tobacco use behaviour (Table 1) (12).

Survey distribution and data collection

Interviewers visited target households and posted a card explaining the purpose of the study, a request to participate, and contact information. They returned on a different day to make first personal contact. Once the selected respondent in the household had been identified and consented to hear about the study, the interviewer explained the purpose of the study, provided a participant information letter, and answered questions, if necessary. If the respondent agreed to participate in the study, the interviewer provided the questionnaire and requested completion. By completing the questionnaire, the participant implicitly gave consent to participate.

The interviewer checked the returned data for completeness and correctness and, if necessary, asked the participant to clarify any unclear information and/or complete missing parts of the questionnaire. Completed questionnaires were returned in person or securely posted to the fieldwork provider for data entry. For completion of the questionnaire, each participant received a cash voucher for JPY 1000 (approximately 7.41 US Dollars).

MEASURES

Characterization of usage pattern for different product categories

Participants were classified as never ever, current or former product users depending on if they had ever used the respective products, used them in the past, or were currently using them and if they smoked/used at least 100 cigarettes/consumables or used the equivalent amount of tobacco in their lifetime for the following products: manufactured cigarettes/'roll your own' cigarettes, pipes/kiseru, cigars/cigarillos, HTPs (separately for glo™, IQOS®, Ploom TECH), e-cigarettes, and smokeless tobacco products. In addition, the proportion of usage patterns (solus product use, dual product use, multi product use) was calculated.

Characterization of product usage by product type

For users of the respective product and partially for former users, the following details were collected: duration of product use, when they stopped using the product, frequency and amount of product used, flavour preferences, if applicable, and for current manufactured cigarettes/'roll your own' cigarettes and HTPs their motivation to quit, ever tried to quit, last quit attempt, misuse and duration. Motivation to quit tobacco product use was measured with the Contemplation Ladder (13), where 0 indicates no thought of quitting and 10 indicates taking action to quit. "Tar" level and time to smoke first cigarette in the morning were additionally collected for current users of manufactured cigarettes, and time to smoke first cigarette was collected for users of 'roll your own' cigarettes. For the determination of nicotine dependency the Heaviness of Smoking Index (HSI) (14) was used. This index consists of two questions considering the amount of smoked cigarettes per day and time to first cigarette smoking in the morning. The composite measure of nicotine dependency is derived from a 6-point scale and then categorized as low (0–2), medium (3–4), and high (5–6) dependency.

The effect of the market introduction of HTPs on tobacco use behaviour among tobacco users was investigated by collating the following data:

- Initiation rate of HTPs among combustible tobacco users within the last 12 months
- Switching rate for HTPs: percentage of combustible tobacco users who switched from smoking to HTPs within the last 12 months
- Dual-use rate (smoking cigarettes and using an HTP): percentage of combustible tobacco users who started usage of HTPs in parallel to existing smoking behaviour within the last 12 months
- Poly-use of HTPs: Percentage of current HTP users using more than one HTP in parallel
- Switching rate from HTPs to cigarette smoking (gateway effect): percentage of HTP users without smoking history who initiated HTP use more than 12 months ago and who switched to solus cigarette smoking within the last 12 months
- Switching rate from HTPs to dual use (gateway effect): percentage of HTP users without smoking history who initiated use more than 12 months ago and who started smoking in parallel to usage of HTPs within the last 12 months
- Switch back rate from HTPs to smoking: percentage of HTP users with smoking history who initiated use more than 12 months ago and who re-initiated cigarette smoking in parallel to usage of HTPs within the last 12 months or who switched back to solus smoking within the last 12 months
- Cessation rate: percentage of tobacco users who quit using tobacco products in the last 12 months: overall

Table 2. Prevalence of tobacco usage behaviour by gender and age (weighted data).

	N	Never user (3406.8)	Current user (888.7)	Former user (1011.6)
Total	5307.1	64.2%	16.7%	19.1%
		Sex (M/F)		
Male	2562.4	43.6%	26.3%	30.1%
Female	2744.6	83.4%	7.8%	8.8%
		Age (years, in categories)		
20–24	306.9	84.3%	14.2%	1.4%
25–29	314.9	73.6%	17.2%	9.1%
30–39	759.1	65.5%	22.3%	12.2%
40–49	960.5	54.6%	22.6%	22.8%
50–59	800.1	60.4%	21.0%	18.6%
60–69	886.6	59.3%	16.9%	23.8%
70–79	877.6	66.7%	8.2%	25.1%
80+	401.4	74.7%	3.7%	21.6%

Percentages quoted refer to percent of row total.

and by product type.

The effect of the market introduction of HTPs on tobacco use behaviour among tobacco non-users was investigated by collating the following data:

- Initiation rate of HTPs among never and former tobacco users within the past 12 months
- Re-initiation rate of tobacco products: percentage of former tobacco users who reinitiated tobacco use after a stop period of at least 12 months

DATA ANALYSIS

All analyses were descriptive and exploratory in nature and were performed using appropriate epidemiological methods. The statistical evaluation was performed by using the software package SAS release 9.4 or higher (SAS Institute Inc., Cary, NC, USA). Clinical Data Interchange Standards Consortium Study Data Tabulation Model (CDISC SDTM) converted raw data were processed into analysis datasets according to CDISC Analysis Data Model (ADaM) specifications using ADaM Implementation Guide final version 1.1 and ADaM document final version 2.1 (CDISC, Austin, Texas, USA).

Weightings were applied to adjust for probabilities of selection of a respondent and non-response, with adjustments made according to known characteristics of the population (10).

RESULTS

Population characteristics

From the 22,510 listed households visited, 3,829 (17%) interviews were completed successfully. Out of the failed interviews from the listed main sample, 11,045 households (49% of all households visited) could not be reached, 7,494 (33%) refused to complete, and 142 (1%) returned an incomplete questionnaire. In cases where the number of completed interviews from the listed households was insufficient, the interviewers visited unlisted households, with the same approach as for the listed sample, until reaching the required number of completions. From the 14,754 unlisted households visited, 1,485 interviews (10%) were completed. The overall number of interviews completed includes 3 booster samples (153 participants in the 20–24 age group, and 152 in the 25–29 age group and 309 participants in the 30–59 age groups).

Seven participants with insufficient information to classify current tobacco use were excluded from the final analysis. Thus, the final analysis included 5,307.1 respondents, of whom 3406.8 (64.2%) were never users of tobacco products, 1011.6 (19.1%) were former users and 888.7 (16.7%) were current users (weighted respondent totals). The results are presented in Table 2 after weighting and, therefore, numbers of participants are given to one decimal place.

An overview of prevalence of tobacco usage behaviour by gender and age group is presented in Table 2. Other demographic data is provided in the Supplementary Table.

Of the individuals interviewed, nearly two-thirds (64.2%) never used tobacco or nicotine-containing products. Approximately equal proportions of the remaining one-third were current (16.7%) and former tobacco or nicotine product users (19.1%).

A much larger proportion of females identified themselves as never users than males (females: 83.4%; males: 43.6%), with the proportion of females being lower than that of males for current users (females: 7.8%; males: 26.3%) and former users (females: 8.8%; males: 30.1%).

The vast majority of participants aged 20–24 years were never tobacco users (84.3%), followed by the age groups 80 years and older (74.7%) and 25–29 years (73.6%), while for the remaining age groups the proportion of never tobacco users ranged from 54.6% to 66.7%. The greatest proportion of current users were in the age groups of 40–49 years with 22.6% and 30–39 years with 22.3% current tobacco users. Among former tobacco users, the greatest proportion were in the 70–79 age group, with 25.1% former users.

The most common highest level of education obtained was high school in all usage groups (never users: 39.5%; current users: 48.8%; former users: 43.4%). When comparing the user groups, a notable difference could be observed in the category college, university, or graduate course, which applied for more never users (27.6%) and former users (26.5%) compared to current users (20.7%). In all user groups, more males than females completed college, university, or graduate course. The most common employment status in all behaviour usage groups was regular employee (never users: 28.3%; current users: 46.8%; former users: 35.3%). Of the never users, full-time homemaker was the second most common employment status (20.2%), and this group was composed almost entirely of female participants. For current users, the second most common employment status was non-regular (part-time) employee (16.1%), while for former users this was pensioners (21.0%). The majority of participants from all behaviour usage groups were married (never users: 68.5%; current users: 66.5%; former users: 82.3%). Similar proportions of users had most commonly an annual household income of 5 million to < 10 million yen (never users: 21.0%; current users: 27.4%; former users: 25.2%) or 3 million to

Table 3. Product-specific current use prevalence among the general population by sex and age (N = 5,307.1, multiple responses).

	N	Cigarette	HTP	E-cig	OTP
Total	5307.1	13.4%	5.4%	0.4%	0.5%
Sex (M/F)					
Male	2562.4	21.0%	8.7%	0.7%	1.0%
Female	2744.6	6.3%	2.4%	0.3%	0.1%
Age (years, in categories)					
20–24	306.9	12.1%	5.6%	1.7%	0.0%
25–29	314.9	13.4%	8.5%	0.2%	0.5%
30–39	759.1	16.0%	10.5%	0.3%	0.6%
40–49	960.5	16.7%	8.6%	0.7%	0.3%
50–59	800.1	16.4%	7.2%	0.6%	0.8%
60–69	886.6	14.8%	2.7%	0.3%	1.1%
70–79	877.6	8.1%	0.0%	0.1%	0.3%
80+	401.4	3.6%	0.1%	0.0%	0.1%

N: total number of participants (row total), HTP: heated tobacco product, OTP: other tobacco product

< 5 million yen (never users: 18.4%; current users: 27.4%; former users: 24.4%), followed by < 3 million yen (never users: 18.2%; current users: 18.1%, former users: 19.9%).

Product specific prevalence of tobacco use among the general population

For the general population, the tobacco and nicotine containing product-specific prevalence by sex and age is presented in Table 3. Among the general population, the product-specific prevalence was highest for cigarettes (13.4%), followed by HTP (5.4%). There was minimal use of e-cigarettes (0.4%) or other tobacco products (0.5%). While the prevalence of cigarette use was notably higher in males than in females (males: 21.0%, females 6.3%), this difference was comparatively smaller for the prevalence of HTP use (males: 8.7%, females: 2.4%). In the 20–24 age group, the prevalence of cigarette use was low (12.1%), though this was even lower for HTP use (5.6%). In the four age groups between 25 and 59 years, the usage prevalence for cigarettes ranged from 13.4% to 16.7% and for HTP from 7.2% to 10.5%. In the older age groups from 60 years, the prevalence of cigarette use (range: 3.6% to 14.8%) was markedly higher than that of HTP use (range: 0.0% to 2.7%).

Detailed tobacco usage patterns among current users

In Table 4 the tobacco product usage patterns in terms of solus, dual or poly product use by sex and age are presented for current users. Dual use refers specifically to the use of manufactured or 'roll your own' cigarettes in combination with HTP. Solus use of any tobacco or nicotine containing product was reported by 82.5% of current users. Solus use of manufactured or 'roll your own' cigarette use was reported by 63.5% of current users, while solus use of HTP was reported by 17.9% of current users. Proportions of solus use of e-cigarettes (0.1%) or other tobacco products (0.9%) were much lower. The proportion of solus use of manufactured or 'roll your own' cigarettes was slightly higher for females (68.2%) than males (62.1%). This was also the case for solus use of HTPs (males 17.7%; females: 18.6%). The proportion of solus use of HTPs was highest in the age groups of 30–39 years (27.2%) and 40–49 years (23.7%). In contrast, the proportion of solus use of manufactured or 'roll your own' cigarettes was highest in the older age groups of 60–69 years (76.5%), 70–79 years (94.4%), and 80+ years (94.2%). Dual use of manufactured or 'roll your own' cigarettes with HTP was reported by 12.7% of current users and was more common in males (13.8%) than in females (9.3%).

Dual use was most common in the 25–29 age group (27.2%), followed by the 20–24 age group (20.5%), and ranged between 11.9% and 18.9% in the 30–59 age groups. Dual use was less common in the older age groups between 60 and 80+ years, ranging from 0.0% to 6.2%.

Poly use only accounted for the usage pattern of 4.8% of current users.

Table 4. Tobacco product usage patterns among current users by sex and age (N = 888.7).

		Solus use				Dual use	Poly use
Sex / Age group	Total (N)	Cigarette	HTP	E-cig	OTP	Cig + HTP	
	888.7	63.5%	17.9%	0.1%	0.9%	12.7%	4.8%
Sex (M/F)							
Male	673.6	62.1%	17.7%	0.2%	1.2%	13.8%	5.1%
Female	215.0	68.2%	18.6%	0.0%	0.0%	9.3%	3.9%
Age group (years)							
20–24	43.7	57.3%	10.1%	0.0%	0.0%	20.5%	12.1%
25–29	54.3	47.8%	20.9%	0.0%	0.0%	27.2%	4.1%
30–39	169.0	49.9%	27.2%	0.0%	0.0%	18.9%	4.0%
40–49	217.0	59.7%	23.7%	0.0%	0.2%	11.9%	4.4%
50–59	168.3	61.6%	18.8%	0.6%	1.6%	13.1%	4.3%
60–69	149.6	76.5%	9.3%	0.0%	2.8%	6.2%	5.2%
70–79	71.9	94.4%	0.0%	0.0%	0.6%	0.0%	5.0%
80+	14.8	94.2%	3.1%	0.0%	0.0%	0.0%	2.7%

N: total number of participants, HTP: heated tobacco product, OTP: other tobacco product

Manufactured and 'roll your own' cigarette use

Of the overall survey population, 13.4% reported currently smoking manufactured and 'roll your own' cigarettes, while the prevalence of former cigarette smoking was 21.7%. Most (93.5%) current cigarette smokers reported daily use whereas only 6.5% respondents reported smoking cigarettes occasionally.

Daily users smoked an average of 15.8 (0.34 SE) cigarettes per day, with number slightly lower for women than men (14.1 *vs* 16.3). Occasional smokers consumed a mean of 4.2 (0.47 SE) cigarettes on days they smoked. Among current cigarette smokers, most (46.8%) preferred no added flavour, 30.0% preferred menthol, and 22.9% preferred non-menthol flavours. The most common cigarette "tar" level was 1–3 mg (30.6%), followed by 4–6 mg (27.0%), 10 mg or higher (20.3%) and 7–9 mg (15.0%). More women than men preferred lower "tar" levels (1–3 mg; 38.6% *vs* 28.0%), while cigarettes with higher "tar" levels (10 mg or higher) were preferred by more males than females (22.2% *vs* 14.1%).

Over one-fifth (21.4%) of current cigarette smokers had not thought of quitting and over one-fourth (29.7%) reported they would consider quitting someday. Only 6.9% were taking action to quit. Previous quit attempts were reported by 58.3% current smokers, among whom 71.8% had tried more than 12 months ago.

HTP use

Current HTP use in the overall survey population was reported by 5.4% and former use was reported by 1.9%. Of brands available in Japan, 80.0% current smokers had heard of IQOS, 61.7% of glo, 53.9% of Ploom, and 13.2% of other HTPs. Among those who regularly used HTPs, current or former use of IQOS was the most frequent (74.2%), followed by glo (28.4%), and Ploom (24.0%). Daily use was highest among IQOS users (92.4%) followed by glo (82.7%), and Ploom (52.9%).

Among all current tobacco product users, 17.9% used HTPs exclusively and an additional 12.7% reported dual use with cigarettes. Average daily HTP consumption was 15.0 (0.7 SE) tobacco sticks for IQOS, 13.7 (0.87 SE) tobacco sticks for glo, and 3.3 (0.38 SE) capsules or 9.0 (1.21 SE) sticks for Ploom, depending on the device. Occasional use in the previous 30 days was reported by 7.6% IQOS users, 17.3% glo users, and 45.9% for Ploom users, on a mean number of 12.8 (0.87 SE), 9.1 (0.67 SE), and 7.6 (1.18 SE) days, respectively.

Among the current HTP users, 5.8% reported poly-use. Most used 2 HTPs (IQOS and Ploom, (2.2%)), followed by (glo and IQOS, (2.0%)). Use of all 3 HTPs was reported by 0.6%. Menthol was the most popular flavour of HTP consumables (71.0%), followed by no flavour (14.9%), and non-menthol flavours (14.1%). Proportionately more women than men preferred menthol (79.1% *vs* 68.2%).

Among current and former users, the most common reason for using a HTP was that "they might be less harmful to people around me than conventional cigarettes" (56.4%), followed by "they might be less harmful to me than conventional cigarettes" (55.2%) and "they produce no ash" (50.1%). The use of HTPs as a way to cut back on smoking conventional cigarettes, reduce cravings for cigarettes, or quit smoking were cited by small proportions of respondents (12.8%, 11.4%, and 8.2%, respectively).

Changes in tobacco product use

Product use 12 months before the survey was reported by 939.6 respondents. Among the 628.8 respondents who reported being exclusive cigarette smokers 12 months previously, 5.5% had initiated the use of a HTP at the time of the survey. Of 871.9 cigarette smokers 12 months ago, 2.4% had changed to dual use and 2.3% had switched completely to HTPs. The initiation rates were similar for men and women (5.4% and 5.7%, respectively). Among the 181.1 earlier dual users, 46.0% had switched completely to exclusive HTP use at the time of the survey.

Exclusive HTP use with no history of smoking 12 months previously was reported by 8.6 respondents, none of whom had switched to exclusive cigarette or dual cigarette and HTP use. 3.3% former smokers who had switched completely to using HTPs had re-initiated solus cigarette smoking within the previous 12 months. For former smokers 12 months ago, 1.3% had reinitiated the use of tobacco in the previous 12 months (dual use).

Among 888.0 former cigarette smokers with no history of HTP use, 0.1% had initiated using HTPs in the previous 12 months, and among 3444.2 never tobacco product users, 0.3% reported starting to use HTPs.

Quitting of all tobacco products in the previous 12 months was reported by 13.1% of 939.6 respondents, 11.6% having given up cigarettes, and 1.8% having quit the use of HTPs. Most (91.1%) users who quit all tobacco products had been using only one product (exclusive cigarette, HTP, or e-cigarette use) 12 months earlier. The quit rates overall among women and men were similar (14.4% *vs* 12.7%). No clear trends in tobacco cessation were observed by age.

When looking at exclusive users 12 months before the survey, 15.3% of 708.4 cigarette smokers and 16.1% of 58.2 HTP users quit using tobacco products altogether.

DISCUSSION

Although cigarette smoking in Japan has declined consistently since its peak in the 1970s, in 2018 smoking prevalence was estimated to be 17.9%, equating to about 18.8 million smokers nationwide (15). In this national survey, we found that cigarettes were by far the most frequent tobacco product used in the general population, but that HTP prevalence was notable at 5.4%. Small proportions of people used e-cigarettes, which are currently illegal in Japan if containing nicotine, or used other tobacco products besides cigarettes or HTPs. Thus, Japan can effectively be classed as a 2-category tobacco product market. We found minimal uptake of HTP use among respondents with no history of tobacco product use. Results showed no indication of gateway or switchback effect, as none of the HTP users with no history of smoking, reported initiation of cigarette use. Similarly, of the former smokers who switched completely to HTP use, 3.3% switched back to cigarette smoking only and 1.3% switched back to dual use.

The main reasons for HTP use in Japan were perceived reduction in harm, both to self and others, compared to conventional cigarettes. Similar observations have been reported in previous studies, which have proposed a link to Japanese cultural values, including cleanliness and respect for others (10, 13). Interestingly, in contrast to Wave 1 study one year earlier, reduction in harm to others was reported more frequently than reduction in harm to self, consistent with pilot study results (10). Remarkably low priorities were given to using HTPs as a way to cut back on cigarettes or quit smoking. We noted that the intention to quit was close to the overall and the combined proportions of respondents who had quit the use of cigarettes and all tobacco products in the 12 months prior to the survey.

In general, tobacco product use did not change dramatically in the 12 months before the Wave 2 survey. The proportion of respondents starting exclusive or dual HTP use was lower than in our pilot study and Wave 1 study but, because the proportion of users quitting HTPs was lower than the proportion initiating HTP use, the overall prevalence remained at around 5%. Almost two-thirds of current tobacco users exclusively smoked cigarettes. Solus HTP use was prevalent in 17.9% of tobacco users, while dual use was observed in 12.7% of tobacco users. The comparison of current usage behaviour and usage behaviour 12 months ago revealed a transition from cigarette to HTP use. The proportion of solus cigarette users who initiated HTP use in the last 12 months was 5.5%, with 2.3% switching completely to HTP use, while the remaining participants switched to HTP use in parallel with cigarettes. Among the dual users 12 months ago, a very high proportion of 46.0% switched completely to exclusive HTP use. The results of this study suggest that predominantly tobacco users in the age group ranging from 30 to 39 years are receptive to this type of new tobacco product. Generally, solus HTP use is more common in the age groups from 25 to 49 years. More than 13% of all tobacco users quit their use of tobacco products completely within the last 12 months. Furthermore, a considerable proportion of about 17% of smokers took action to quit or at least started to think about changing their smoking behaviour. However, HTPs seem to have less importance as means to quit or cut back on cigarette smoking. Perceived risk and concerns of harm to others may be potential drivers for this change in behaviour. Those who used HTPs on a regular basis (100 sticks or more in their lifetime) most frequently reported their reason for HTP use was considering potentially reduced harm to others around them or to themselves in comparison to smoking. These products were viewed as less disturbing for the surroundings and as having the advantage of no ash, no "tar", and not smelling bad, as opposed to cigarettes. In particular, the correct understanding of the risk profile of these new products is crucial for product acceptance. Indirect as well as the direct comparisons showed that current tobacco users and non-users understand correctly that the use of HTPs is likely to be less harmful compared to cigarettes, but also understand that HTPs are not risk free. Furthermore, it was understood that no tobacco consumption is still the best alternative for avoiding risks to health.

The study has various strengths. A comprehensive approach was applied to estimate product specific prevalence and to collect data on tobacco and nicotine product consumption nationwide, covering all 47 prefectures in Japan. Additionally, the data collection method was carefully selected to minimize any bias that could arise from social desirability for answers. The large sample size of this study allowed for precise and robust prevalence estimations and subgroup analyses to be conducted, and the selection of participants by a stratified 3-stage sampling method allowed for national generalizability of results. Furthermore, the data collected from this study on tobacco usage behaviour could be combined with data on self-reported health conditions and their change in the last 12 months and the assessment of risk perception. Also, despite the data being collected via paper-based questionnaires, the number of item non-responses and number of inconsistent data were very low. When compared with Japanese data from 2018, the overall and sex-stratified prevalence rates were similar and appeared to follow year-on-year trends (15, 16). Such data will be critical in aiding understanding of population use behaviours over time and are being used to support population modelling of long-term health impacts based on estimated transition rates across product use status.

Some limitations are also associated with this study. Since a self-administered questionnaire was used, respondents may not recall their behaviours accurately which could lead to a reporting bias in this cross-sectional survey. However, this is a limitation inherent to all survey methods. Furthermore, there was no benefit to participants from answering the questions inaccurately or untruthfully. Self-reporting surveys remain the cornerstone of international epidemiological tobacco research, and the results of previous studies have shown that self-administered questionnaires might adequately capture tobacco use in populations (17) and that smokers are able to estimate their average daily cigarette consumption relatively accurately (18). Nevertheless, collection of self-reported data in relation to 'undesirable behaviours' such as cigarette smoking and tobacco use may be biased as it is perceived as a taboo behaviour in specific cultural cohorts such as women in Asian countries (19).

CONCLUSIONS

This study was conducted to estimate tobacco product use prevalence and usage patterns in combination with the assessment of perceived health risk and short-term health outcomes of HTPs compared to cigarette smoking. While the prevalence of conventional cigarette use continues to decrease in Japan (for example, this study found 13.4% prevalence), the prevalence of HTP use (currently 5.4%) is increasing. The use of other tobacco/nicotine products, including e-cigarettes, pipe, cigars, cigarillos and others, appears to be negligible (0.5%). HTP use presents itself in two main forms: as solus use (17.9% of current tobacco users), or as dual use in combination with conventional cigarettes (12.7%). A sizable proportion of participants (5.5% of current smokers) initiated HTP use within the last 12 months. Switching from solus HTP use to combustible tobacco use was not observed in any of the participants,

suggesting there is no indication of gateway effect of HTPs. Participants correctly understood that there are substantial risks associated with the use of conventional cigarettes and also understood that in comparison to cigarette use, HTP use presents lower risk, but HTP use is not entirely without risk. Results suggest that a complete switch from cigarettes to HTP partially reduces short-term conditions associated with smoking. This second wave of nation-wide implementation of this study provided valuable estimates for tobacco product usage behaviour and insights into risk perception and health outcomes. Compared to the first wave of this study, the results were very similar and thus show a consistent pattern of HTP use (in regard to use patterns and behaviours such as risk perception, reasons for use and quit intention) between 2018 and 2020.

SUPPLEMENTARY INFORMATION

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