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循環器疾患・糖尿病等生活習慣対策総合研究事業

改正健康増進法施行後における喫煙室の設置状況と受動喫煙環境の評価、及び  
課題解決に資する研究

令和 5～7( 2023～2025 ) 年度 総合研究報告書

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厚生労働科学研究費（循環器疾患・糖尿病等生活習慣病対策総合研究事業）  
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課題解決に資する研究

総合研究報告書

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研究要旨

令和 2(2020)年、改正健康増進法が全面施行され、屋内は禁煙とされ（喫煙専用室、既存特定飲食提供施設を除く）、屋外についても「望まない受動喫煙」を防止することが努力義務とされ、わが国の受動喫煙防止対策は「たばこの規制に関する世界保健機関枠組条約」が求める内容に近づいた。一方、経過措置として飲食が可能な加熱式タバコ専用室の設置が可能とされ、さらに新たな問題としてシーシャ（水タバコ）を提供する店舗が急増している。改正法の施行後に残された受動喫煙の課題を解決に資するために以下の研究を行った。

1. 屋外に喫煙コーナーを設置する場合、十分な高さ（約 3 メートル）のパーティションで四方から囲い、出入口は 2 重クランクとすることが必要（令和 5～6 年度）。
2. 屋外に喫煙室を設置する場合、微小粒子状物質（PM<sub>2.5</sub>）とニオイを除去する性能を有する空気清浄機を介して排気、あるいは、煙突で上方に排気することが必要（令和 5～6 年度）。
3. 喫煙専用室を清掃する業者は高い濃度の受動喫煙に曝露されており、その尿からニコチンとその代謝物、遺伝子付加体が検出されたことから、その作業に長期間従事する従業員への健康影響が懸念された（令和 5～7 年度）
4. 飲食が可能な加熱式タバコ専用室に滞在した非喫煙者の尿からニコチンとその代謝物が検出されたことから、長期間働く従業員への健康影響が懸念された（令和 7 年度）
5. シーシャ（水タバコ）を提供する作業により従業員への健康影響が懸念された（令和 7 年度）
6. 「たばこの規制に関する世界保健機関枠組条約」に基づき、わが国を含む主要 20 か国の受動喫煙対策の法規制を一覧表としてまとめ、英国のシガーバーの実態、および、韓国と中国など 5 か国の実態について報告した（令和 5～7 年度）
7. 166 自治体の特定屋外喫煙場所の有無、タバコ販売の有無を含む喫煙・受動喫煙、および、「上乗せ条例」の施行状況について調査をおこなった（令和 5～7 年度）
8. 喫煙室等の壁に付着したタバコ臭の消臭は困難であること（令和 6～7 年度）
9. 音楽フェスが若者への加熱式タバコの販売促進に利用されている実態の調査を行った（令和 7 年度）
10. 平成 15(2003)年の健康増進法で受動喫煙防止の規制が始まり、その前後の非喫煙者の健診（肺機能検査）のコホート調査で 1 秒量の年間低下量は有意に減少したことを認めた（令和 7 年度）

法律による受動喫煙防止対策は有効で、住民の呼吸機能に良好な効果をもたらし始めた。

「望まない受動喫煙」をなくすために残された課題を解決することは、さらに喫煙しにくい社会を実現し、喫煙率の低減と国民全体のタバコ関連疾患とその医療費の削減に寄与することが期待される。

## A. 研究目的

「たばこの規制に関する世界保健機関枠組条約」は屋内を完全禁煙とすることで非喫煙者を受動喫煙から保護することを締約国に求めている。法律で屋内を禁煙化することで国民全体の受動喫煙が防止され、その前後で心筋梗塞や狭心症、呼吸器疾患による入院数を減らすことが示されている。

わが国では、諸外国の様にすべての屋内を全面禁煙とする法律の成立は困難であり、平成 15(2003)年の健康増進法、令和 2(2020)年の改正健康増進法の施行により段階的に進んできた。

本研究は、改正健康増進法の施行後における喫煙室の設置状況と受動喫煙環境の評価、及び、新たに発生した課題の解決に資することを目的としている。

具体的には、研究要旨に記載した 10 の項目と課題について研究を行った。

- 1) 屋外の喫煙コーナーの受動喫煙防止対策
- 2) 屋外の喫煙室の受動喫煙防止対策
- 3) 喫煙室の清掃業者への受動喫煙の曝露実態と健康評価
- 4) 加熱式タバコ専用室の受動喫煙の実態
- 5) シーシャ（水タバコ）を提供する店舗の従業員の実態
- 6) 主要 20 か国の受動喫煙防止法の調査
- 7) 166 自治体の受動喫煙防止対策
- 8) タバコ臭の消臭対策
- 9) 音楽フェスにおける販売促進の実態
- 10) 住民健診の肺機能検査のコホート調査

最終目標は、喫煙と受動喫煙による生体への悪影響を明らかにすることで、「望まない受動喫煙」をなくすための社会的な風潮を醸成することである。

## B. 研究方法

### 1. 喫煙室、喫煙コーナーの内外の空気環境

#### 1) 微小粒子状物質 (PM<sub>2.5</sub>)

デジタル粉じん計 (PM2.5 テスター、光明理化学工業) を用いて微小粒子状物質 (PM<sub>2.5</sub>) のリアルタイムモニタリングを行った。

#### 2) ガス状物質

揮発性有機化合物 (VOC リアルタイムモニタ XP-3120-V、新コスモス電機) を用いて測定し、トルエン換算濃度で示した。

### 2. 尿中バイオマーカーの評価

ニコチン、コチニン、3-ヒドロキシコチニン、発がん性ニトロソアミン代謝物:NNAL) を LC-MS/MS により分析した。尿中の酸化的 DNA 損傷マーカー (8-OHdG)、ならびに DNA メチル化マーカー (m<sup>7</sup>Gua) は HPLC-ECD 法により分析した。

### 3. 主要 20 か国の調査

「たばこの規制に関する世界保健機関枠組条約」の報告書、および、研究関係者が訪問した際に調査を行った。

### 4. 166 自治体の受動喫煙防止対策

先行研究から引き続き、郵送法による調査、および、自治体のホームページから情報を得た。

### 5. 音楽フェスにおける販売促進の実態

2023 年に開催された 165 件の音楽フェス

の公式サイト、SNS、および、現地調査を行った。

## 6. 呼吸機能検査

一般住民（非喫煙者）の定期健診・ドック健診の呼吸機能検査の後ろ向きコホート調査（2 集団、各 17 年間）を行った。

（倫理面への配慮）

産業医科大学倫理委員会の承認（第 R1-037）、（第 H26-145）、熊本大学倫理委員会の承認（第 1753 号）、研究参加者への説明と同意を得た。

## C. 結果

### 1) 屋外の喫煙コーナーの受動喫煙防止対策

四方向から十分な高さ（約 3 メートル）があるパーティションで囲い、出入口を 2 重クランクにすることが必要であった。なお、パーティションと路面の間の隙間、および、スリットがあるパーティションは漏れの原因となることが分かった。

### 2) 屋外の喫煙室の受動喫煙防止対策

独立した部屋として喫煙室を設置する場合、微小粒子状物質（PM<sub>2.5</sub>）とガス状物質を除去する性能を有する空気清浄機で浄化された空気を排気する、あるいは、煙突を経由して上方へ排気する、どちらかの方法が必要であった。

### 3) 喫煙室の清掃業者への受動喫煙の曝露実態と健康評価

喫煙コーナー、あるいは、喫煙室を清掃する業者は職業的な受動喫煙に曝露されることが認められた。特に、喫煙室を清掃する場合、高性能な空気清浄機が設置されていても作業中は高濃度の受動喫煙に曝露

されることが認められた。

熊本の健診機関で定期健診を受ける清掃業者のうち喫煙室の清掃をする 11 名は、喫煙室の清掃がない 16 名よりも尿中に排泄されるニコチン、および、ニコチン代謝物の濃度が高かった。

清掃業者を保護する対策として、作業の前に喫煙室を閉鎖し、内部の PM<sub>2.5</sub> の濃度が十分に下がってから清掃作業を始める手順とすることで解決方法が考えられた。一般的な喫煙室（換気回数 10 回）の場合、作業前のクリアランスタイムは 18 分であることが見込まれた。

### 4) 加熱式タバコ専用室の受動喫煙の実態

室内は加熱式タバコを使用する際に呼気に呼出される PM<sub>2.5</sub> と揮発性有機化合物の濃度が上昇し、そこに滞在した非喫煙者の尿中からニコチン、および、ニコチン代謝物が検出された。そのような場所で長時間・長期間働く従業員への健康影響が懸念された。

### 5) シーシャ（水タバコ）を提供する店舗の従業員の実態

シーシャを客に提供する前に炭の温度を調整するために深呼吸を 10 回ほど繰り返す作業を行った従業員は、酸素飽和度が低下し、脈拍が増え、尿中に大量のニコチンとニコチン代謝物、発がん性物質（NNAL）が排出された。この作業を繰り返すことで健康への悪影響が発生することが懸念された。

6) 主要 20 か国の受動喫煙防止法の調査  
改正健康増進法の施行後、わが国の評価は 8 類型のうち、病院、学校、大学、政府機関が屋内禁煙と認められ、最低ランクの「不可」から 1 つ上の「可」とされた。

#### 7) 166 自治体の受動喫煙防止対策

主要な自治体の 36%が敷地内全面禁煙であり、64%の自治体に特定屋外喫煙場所が残っていることが認められた。屋外に喫煙場所がある自治体では庁舎内でタバコを販売している割合が有意に高いことも分かった。さらに、「上乗せ条例」も徐々に増え始めていることも認められた。

#### 8) タバコ臭の消臭対策

アンモニア臭はクエン酸水で若干の改善が認められたが、その他の成分（ホルムアルデヒド、揮発性有機化合物）の消臭に効果的な方法は認められなかった。

#### 9) 音楽フェスにおける販売促進の実態

2023 年に開催された 165 件の音楽フェスのうち、11 件（6%）がタバコ関連企業の協賛であることを明記していた。全体の 80%が分煙（指定喫煙場所あり）で、タバコ関連企業の協賛がある 11 件のうち 10 件で喫煙ブースが設置され、若者へのタバコ製品、特に、加熱式タバコのマーケティング（販売促進活動）に利用されていた。

#### 10) 住民健診の肺機能検査のコホート調査

2003 年に施行された健康増進法の前後でわが国の受動喫煙防止対策の強化が始まったが、その前後で熊本県の健診機関を定期健診とドック健診で肺機能検査を受けた 2 つの集団を 17 年間の後ろ向きコホート調査した結果、1 秒量の年間低下量が有意に改善したことが認められた。

### D. 考察

2003 年に施行された健康増進法、および、2020 年より全面施行された改正健康増進法により、わが国の受動喫煙防止対策は世界保健機関（WHO）の評価が「可」となり、一

定の改善が得られた。

今後解決すべき受動喫煙防止対策の課題を以下に列挙する。

- ・既存特定飲食提供施設
- ・喫煙目的施設を掲げて営業する飲食店
- ・飲食が可能な加熱式タバコ専用室
- ・シーシャバーの従業員の保護
- ・喫煙室等を清掃する作業者の保護
- ・喫煙場所の周囲の受動喫煙

### E. 結論

本研究により、改正健康増進法の基本的な考え方である「望まない受動喫煙をなくす」ために必要な屋内と屋外の対策に有効な物理的な手法と考え方が明らかとなった。今後、本研究の成果を周知することで非喫煙者の受動喫煙からの保護が進むことは、同時に喫煙しにくい社会環境となり、喫煙者の禁煙企図を高めることが期待される。

### F. 健康危険情報

飲食が可能な加熱式タバコ専用室、喫煙室の清掃を担当する作業員、シーシャバーの従業員における健康影響の発生が懸念された。

### G. 研究発表

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## H. 知的財産権の出願・登録状況

この研究において、知的財産権に該当するものはなかった。

研究成果の刊行に関する一覧表(2023年度～2025年度)

書籍

| 発表者名 | 論文タイトル名        | 書籍全体の編集者名     | 書籍名      | ページ  | 出版社 | 出版地 | 出版年月    |
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| Kataoka A, Muraki I, Nakamura M, Ito Y                                                                                                                  | How much progress has been made toward a smoke-free environment in the restaurants and bars of Japan? Limitations of partial bans and their enforcement.                           | BMC Public Health                    | 24     | 3327      | 2024.11 |
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| 朝長諒, 姜英, 藤本俊樹, 山根崇弘, 本多世麗, 横谷俊孝, 大和浩                                                                                                                    | 改正健康増進法の施行後に設置された屋外喫煙所の周囲の受動喫煙曝露評価                                                                                                                                                 | 日本公衆衛生雑誌                             | 73(1)  | 54-59     | 2026.1  |

その他

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| 大和 浩                               | 通行の多い場所・煙が漏れ出る喫煙所は、健康増進法に反しています                           | STOP受動喫煙新聞              | 46  | 2     | 2024.4  |
| 大和 浩                               | 禁煙NOW！あなたに合ったものを！                                         | けんぼフォトニュース              | 5月号 |       | 2024.5  |
| 大和 浩                               | 車内喫煙は論外、現代は三次喫煙の有害性も直視すべき＝喫煙後の乗車をやめなくてはいけない理由             | STOP受動喫煙新聞              | 47  | 3-4   | 2024.7  |
| 大和 浩                               | 外国と日本の喫煙所、受動喫煙被害は                                         | STOP受動喫煙新聞              | 48  | 2-3   | 2024.10 |
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| 大和 浩                               | 健康づくりQ&A 健康経営を進めていますが、喫煙率が下げ止まっています。どんな働きかけが有効でしょうか。      | 健康づくり<br>(健康・体力づくり事業財団) | 565 | 26    | 2025.5  |
| 大和 浩                               | 外国と日本の喫煙所、受動喫煙被害は＝その④<br>韓国・ソウルの最新情報(後編) 日本との相違点と共通点      | STOP受動喫煙新聞              | 51  | 3     | 2025.7  |
| 大和 浩                               | 外国と日本の喫煙所・受動喫煙・タバコ状況＝シリーズ⑤<br>スペインの規制・揭示、屋外喫煙、タバコ販売('25年) | STOP受動喫煙新聞              | 52  | 2-3   | 2025.10 |
| 大和 浩                               | 違反に負ける大阪？<br>テーマに反し喫煙所を増設した万博、「全域禁煙」「禁煙店拡大」条例施行後の課題と効果は   | STOP受動喫煙新聞              | 53  | 1-2   | 2026.1  |

## 公衆衛生活動報告

改正健康増進法の施行後に設置された屋外喫煙所の  
周囲の受動喫煙曝露評価

|            |            |           |                          |            |            |           |             |
|------------|------------|-----------|--------------------------|------------|------------|-----------|-------------|
| トモナガ<br>朝長 | リョウ<br>諒*  | キョウ<br>姜  | エイ<br>英*                 | フジモト<br>藤本 | トシキ<br>俊樹* | ヤマネ<br>山根 | タカヒロ<br>崇弘* |
| ホンダ<br>本多  | セイラ<br>世麗* | ヨコヤ<br>横谷 | トシタカ<br>俊孝 <sup>2*</sup> | ヤマト<br>大和  | ヒロシ<br>浩*  |           |             |

**目的** 改正健康増進法（2020年）では、屋外や家庭においても「望まない受動喫煙」をなくすことが努力義務とされた。これに伴い、都市部では屋外喫煙所の設置が進む一方、その効果や基準に関する評価は十分ではない。本研究は、屋外喫煙所の周囲で微小粒子状物質（PM<sub>2.5</sub>）濃度の測定により、受動喫煙の曝露状況を評価し、屋外喫煙所設置時の留意事項を明確にすることを目的とする。

**方法** 2021年4月から2024年12月にかけて、四方を壁で囲み、出入り口がクランク状の屋外喫煙所34か所およびコンテナ型の屋外喫煙室10か所の内部と周囲のPM<sub>2.5</sub>濃度をデジタル粉じん計を用いて測定を行った。そのうち典型的な屋外喫煙所4か所とコンテナ型屋外喫煙室1か所について報告する。

**活動内容** 以下の4点について検討を行った。①壁の高さの効果については、壁高3.2 mでは、内部のPM<sub>2.5</sub>濃度は平均41 µg/m<sup>3</sup>、風下方向の平均濃度は5.4 µg/m<sup>3</sup>で、壁高2.5 mでは、内部濃度は平均38 µg/m<sup>3</sup>、風下方向の平均濃度は9.5 µg/m<sup>3</sup>に抑制された。②クランクの形状については、クランクの重なりが不十分で喫煙可能区域が外部から見通せる場合、喫煙所外での濃度が上昇した。③壁下部の隙間からの拡散については、隙間が2～5 cmであっても、隙間からの漏れにより、外部濃度が瞬間的に164～400 µg/m<sup>3</sup>まで上昇した。また、壁下部を完全に塞いだ場合、泥等の堆積を認めた。④コンテナ型喫煙室（HEPA フィルターを用いた空気清浄機を設置）については、HEPA フィルターを通じて排気された空気中のPM<sub>2.5</sub>濃度は、内部環境が平均548 µg/m<sup>3</sup>に対して、平均9.3 µg/m<sup>3</sup>であった。

**結論** 以下の点を踏まえた屋外喫煙所の適切な設計と基準は受動喫煙防止に効果的であることが示された。①4方向を十分な高さ（2.5 m 以上、可能な範囲で高く）の壁で囲う。②出入口は十分な重なりがある二重クランクとする。③壁と路面の間の空間は泥等の堆積を防ぐため1 cm 程度とし、一部のみ開放する。④コンテナ型喫煙室ではHEPA フィルターを用いた空気清浄機を用いる。

非喫煙者を受動喫煙から保護し、喫煙者には喫煙所の内部に禁煙外来などの啓発的な情報を掲示し、喫煙率の低下に寄与することが根本的な対策と考えられた。

**Key words**：受動喫煙対策、屋外喫煙所

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## I はじめに

2020年4月に施行された改正健康増進法により、公共の場における喫煙規制が大幅に強化された<sup>1)</sup>。この改正では「基本的な考え方」として、「望まない受動喫煙」をなくすることが示され、屋外や家庭においても受動喫煙に配慮することが努力義務とされた。

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これに伴い、都市部の駅前広場などにパーティションで囲まれた喫煙コーナーや空気清浄機を備えた喫煙室を設置する自治体が増加している。しかし、これらの喫煙所による受動喫煙防止の効果についての評価は十分になされていない。

本研究の目的は、既設の喫煙所周囲の受動喫煙の曝露状況を粉じん計で明らかにし、同様の設備を設置する場合に、推奨される喫煙所の構造を提案することである。

## Ⅱ 方 法

2021年4月から2024年12月の間、主に東京都23区内と名古屋市で、駅前広場やレストランのテラス席とキッチンカー広場の近傍で人通りが多い場所に設置された、四方を壁で囲われ、出入り口がクランク状である屋外喫煙所34か所およびコンテナ型の屋外喫煙室10か所について調査を行った。そのうち典型的な屋外喫煙所4か所（名古屋市3か所、関東の大規模事業場1か所）と空気清浄機メーカーの公表する定員人数を遵守していたコンテナ型屋外喫煙所1か所（東京都23区内）について報告する。

調査方法は、その内部とその周囲における微小粒子状物質（ $PM_{2.5}$ ）濃度を光散乱式デジタル粉じん計（Sidepak AM510, TSI社製；質量濃度変換係数0.295）<sup>2)</sup>、あるいは、AM510と相関を確認したデジ

タル粉じん計（PMT-2500, 光明理化学工業社製）を用いて測定した。測定点は、喫煙所内部に1点、周囲に2～6点とした。記録は5秒ごとに設定し、大気中の $PM_{2.5}$ 濃度をまず3～5分間測定した後に、30～60分間測定を行った。喫煙所測定時は不規則に微風～風速5 m/sの風が吹いていた。

## Ⅲ 活動内容

四方をパーティションで囲い、出入口を二重のクランクとした喫煙コーナー

### 1. 壁の高さの評価

1) 壁高3.2 m（幅8 m×奥行6 m, 図1-a）、喫煙者数（15～30人）、場所：関東の大規模事業場

所見1 喫煙コーナー内の $PM_{2.5}$ 濃度は、平均 $41 \mu\text{g}/\text{m}^3$ （最高 $285 \mu\text{g}/\text{m}^3$ ）に達する状態であったが、上部は開放されているため、 $PM_{2.5}$ 濃度は速やかに低下した。

所見2 喫煙コーナーの壁の外（図中②）、高さ1.2 mにおける $PM_{2.5}$ 濃度は平均 $7.4 \mu\text{g}/\text{m}^3$ （最高 $30 \mu\text{g}/\text{m}^3$ ）であった。

所見3 風下10 mの地点（図中③）における $PM_{2.5}$ 濃度は平均 $5.4 \mu\text{g}/\text{m}^3$ （最高 $36 \mu\text{g}/\text{m}^3$ ）で、周囲の大気環境（平均 $5.4 \mu\text{g}/\text{m}^3$ ）と同等であった。

図1 壁の高さの評価

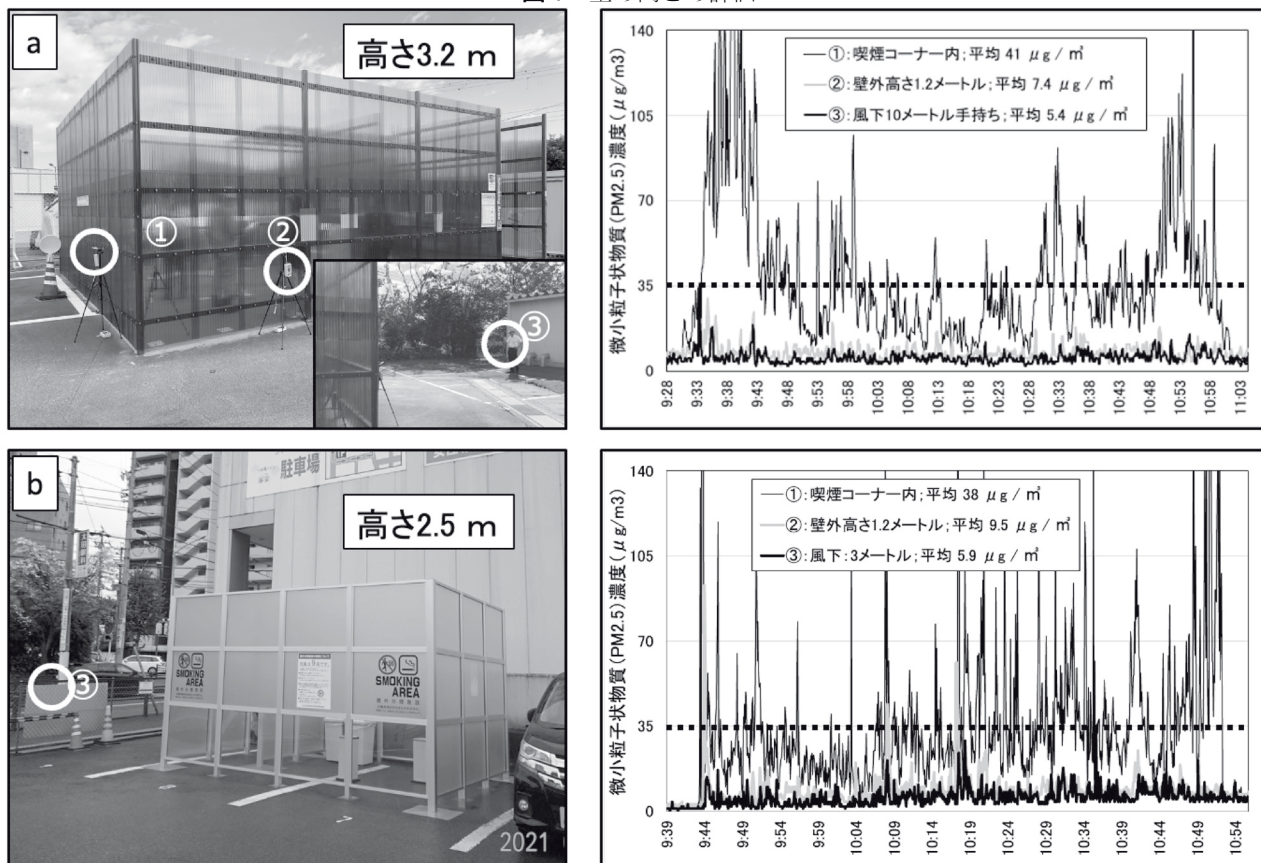
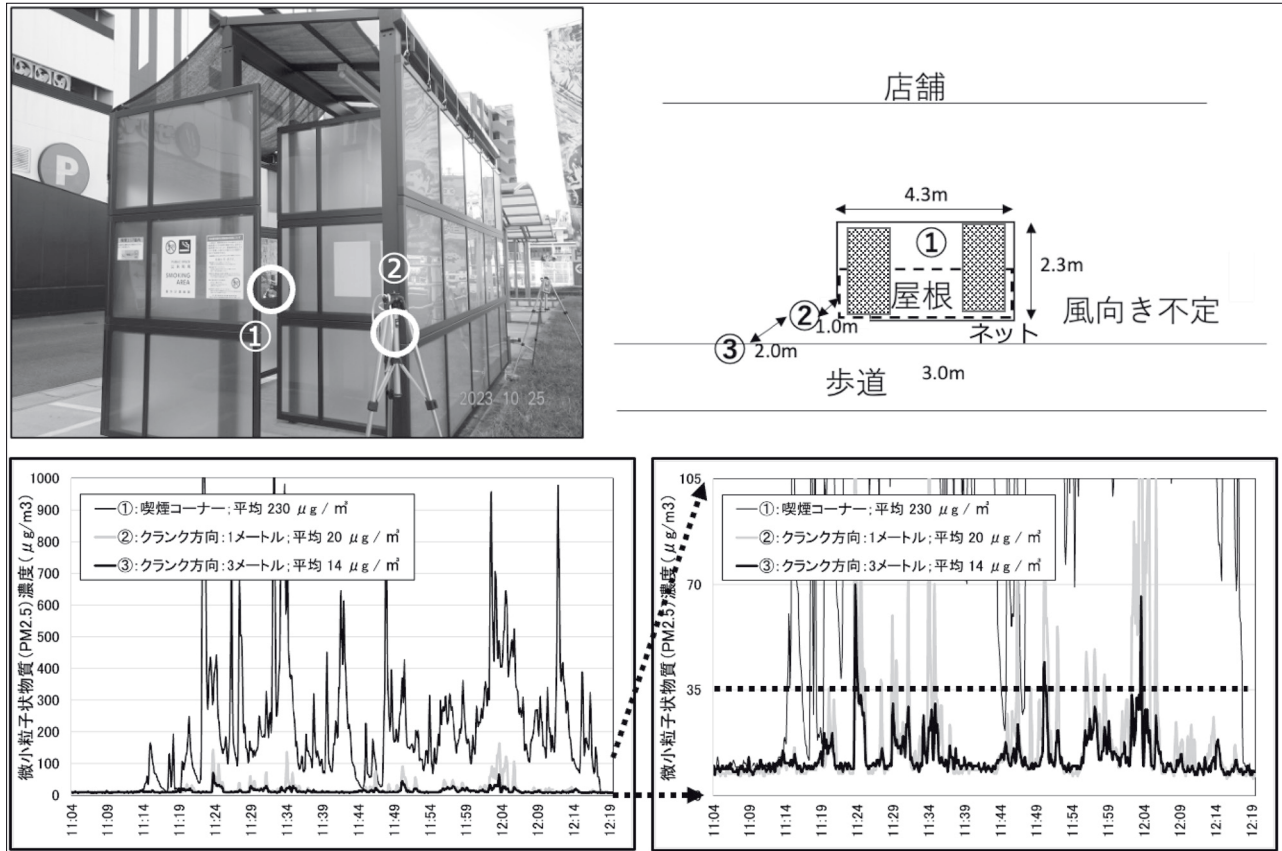


図2 出入口のクランクの形状の評価



2) 壁高2.5 m (幅 4 m × 奥行 3 m, 図 1-b), 喫煙者数 (4~5 人), 場所: 名古屋市

所見 1 喫煙コーナー内の PM<sub>2.5</sub>濃度は, 平均 38 μg/m<sup>3</sup> (最高 560 μg/m<sup>3</sup>) であったが, 上部は開放されているため, PM<sub>2.5</sub>濃度は速やかに低下した。

所見 2 喫煙コーナーの壁の外の PM<sub>2.5</sub>濃度は平均 9.5 μg/m<sup>3</sup> (最高 93 μg/m<sup>3</sup>) であった。3 m 地点の PM<sub>2.5</sub>濃度は平均 5.9 μg/m<sup>3</sup> (最高 33 μg/m<sup>3</sup>) で大気環境 (平均 2.1 μg/m<sup>3</sup>) よりも若干高かった。

いずれの事例も壁の外, および, 風下への煙の拡散は僅かであるが, 壁の高さは高い方が良好であると認められた。なお, 1 年後に施設管理者の判断により, 喫煙所を覆う形で屋根が設置されていた。屋根設置後に同様の測定を行った。上部が開放されていないため, 喫煙コーナー内に煙がこもり, PM<sub>2.5</sub>濃度は, 平均 238 μg/m<sup>3</sup> (最高 2,202 μg/m<sup>3</sup>) と高く, 周囲への PM<sub>2.5</sub>の拡散についても喫煙コーナーの壁の外の PM<sub>2.5</sub>濃度は平均 60 μg/m<sup>3</sup> (最高 299 μg/m<sup>3</sup>), 3 m 地点の PM<sub>2.5</sub>濃度は平均 21 μg/m<sup>3</sup> (最高 75 μg/m<sup>3</sup>) まで上昇していることがわかった (グラフ非掲載)。

2. 出入口のクランクの形状 (幅 4.3 m × 奥行 2.3 m, 図 2), 喫煙者数 (4~5 人), 場所: 名古屋市

所見 1 クランクの重なりが不十分で外から喫煙可能場所を見通せる形状では, クランク方向 1 m (図中②) での PM<sub>2.5</sub>濃度は平均 20 μg/m<sup>3</sup> (最高 164 μg/m<sup>3</sup>), クランク方向 3 m (図中③) では平均 14 μg/m<sup>3</sup> (最高 70 μg/m<sup>3</sup>) で大気環境 (平均 9.1 μg/m<sup>3</sup>) よりも高かった。

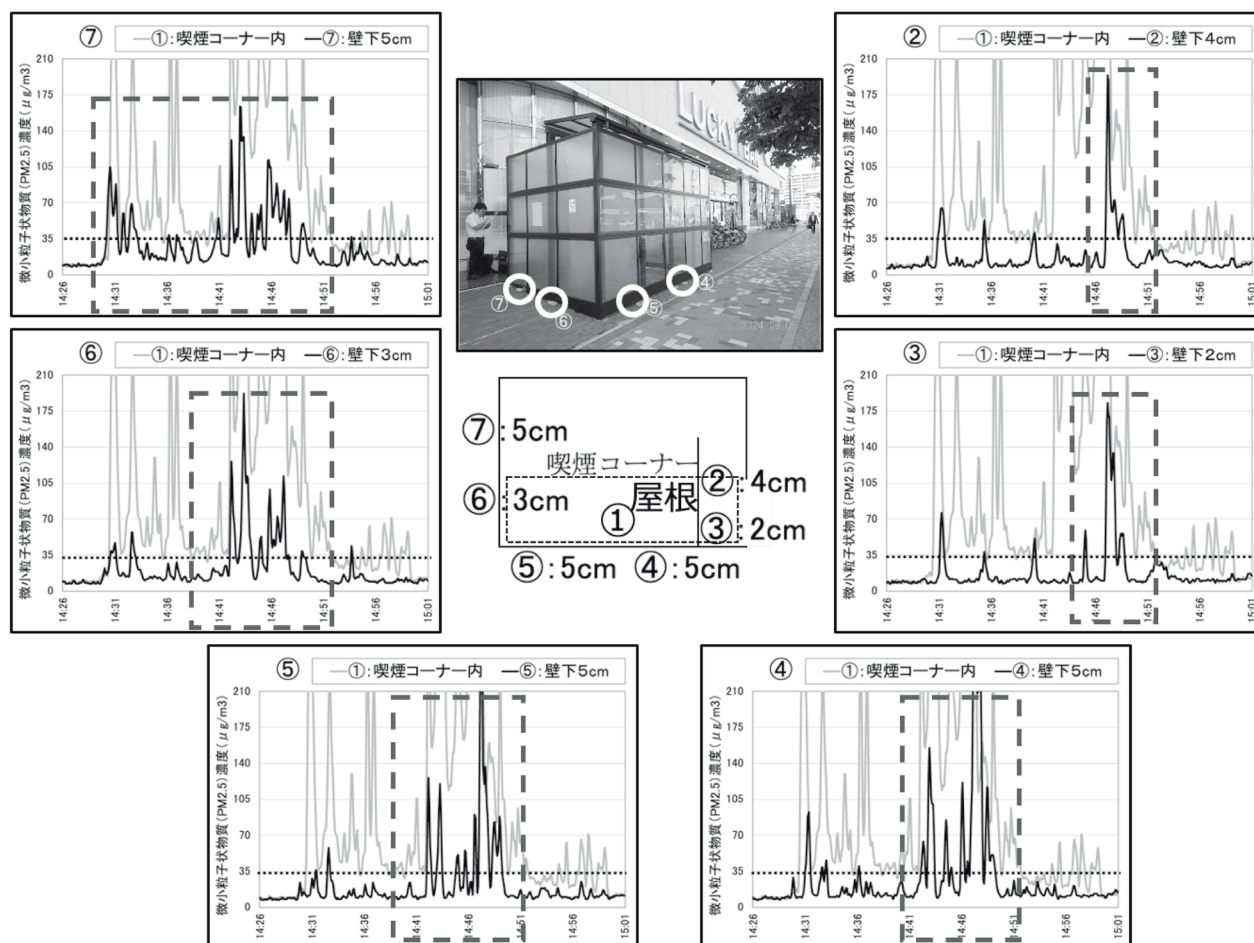
一方, 完全な 2 重クランク構造である図 1-a, クランクの重なりが十分で外から喫煙可能場所を見通せない形状である 1-b の場合, 入り口部から風下方向への拡散は僅かであった。

3. パーティションと路面の隙間からの拡散 (幅 4.3 m × 奥行 2.6 m, 図 3), 喫煙者数 (4~5 人), 場所: 名古屋市

パーティションの下の歩道に面した三方向の隙間は 2 cm から 5 cm であった。図 3 に示すように 6 台の粉じん計を路面に置き, 隙間からの漏れを測定した。

所見 1 喫煙コーナー内の PM<sub>2.5</sub>濃度は平均 107 μg/m<sup>3</sup> (最高 658 μg/m<sup>3</sup>) であったが, 上部は開放されているため, PM<sub>2.5</sub>濃度は速やかに低下した。

図3 パーティションと路面の隙間からの拡散の評価



所見2 パーティションと路面の下の隙間が2～5 cm であっても PM<sub>2.5</sub>濃度は、大気環境（平均9.6 μg/m<sup>3</sup>）よりも高く、平均18～31 μg/m<sup>3</sup>（最高164～400 μg/m<sup>3</sup>）まで上昇し、漏れが発生することを認めた。

なお、壁下の隙間を完全に塞いだ事例では、泥やゴミが堆積し、定期的な清掃が必要な状態であった。（図表非掲載）

#### 4. コンテナ型喫煙室（幅6.0 m × 奥行2.5 m, 図4）、喫煙者数（常時8人）、場所：東京都23区内

定員8人に対して常時8人が喫煙し、9人以降は外で待機する状況であった。内部のPM<sub>2.5</sub>濃度は平均548 μg/m<sup>3</sup>（最高951 μg/m<sup>3</sup>）であったが、HEPAフィルターを用いた空気清浄機を通過した排気口の真下では平均9.3 μg/m<sup>3</sup>（最高22 μg/m<sup>3</sup>）で、PM<sub>2.5</sub>濃度の上昇は大気環境（平均7.3 μg/m<sup>3</sup>）と比べ、僅かであった。

## Ⅳ 考 察

2020年に施行された改正健康増進法では、屋外であっても「何人も、喫煙をする際、望まない受動喫

煙を生じさせることがないよう周囲の状況に配慮しなければならない」とされている。最適な選択肢は、調布市のように条例で駅前広場などの公共的な空間を全面禁煙化することである<sup>3)</sup>。しかし、日本には約2,000万人の喫煙者が存在し（令和5年国民健康・栄養調査による成人喫煙率15.7%）、とくに人口密度が高い都市部の駅前広場等ではやむを得ず屋外喫煙所の設置をする自治体がある<sup>4)</sup>。

本調査から受動喫煙防止のための屋外喫煙所の構造には以下のポイントを踏まえる必要があることがわかった。（図5）

- ・ 4方向を十分な高さ（2.5 m 以上、可能な範囲で高く）の壁で囲う
- ・ 出入り口のクランクは外部から内部を見通せない形状とし、可能な限り二重クランクとする
- ・ 壁と路面の間の空間は周囲への漏れを防ぐため限りなく狭くする一方で、泥等の堆積を防ぐため1 cm 程度とし、四方向の一部のみ開放する
- ・ 上方への煙の拡散の妨げになる屋根は設置しない

図4 高性能空気清浄機を備えたコンテナ型喫煙室

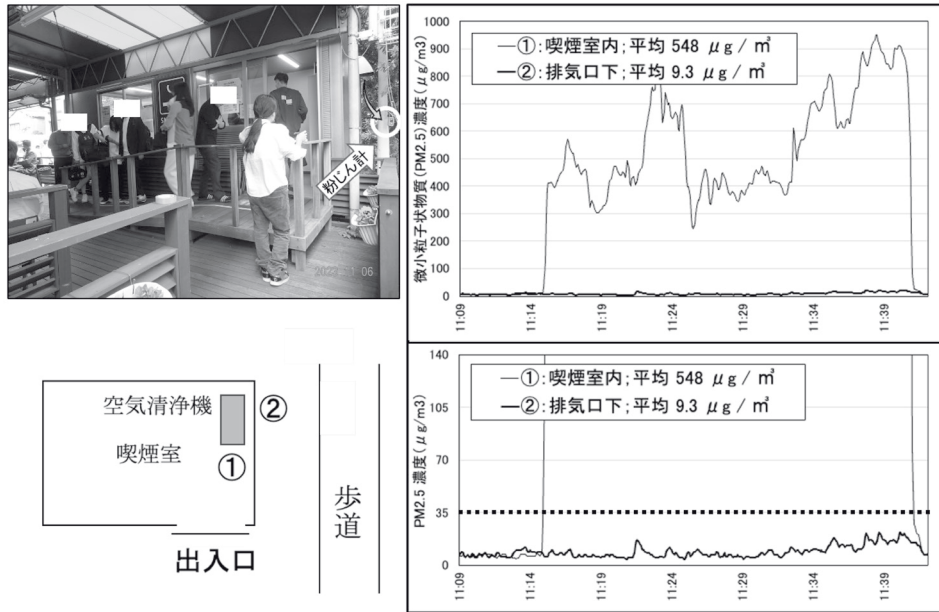
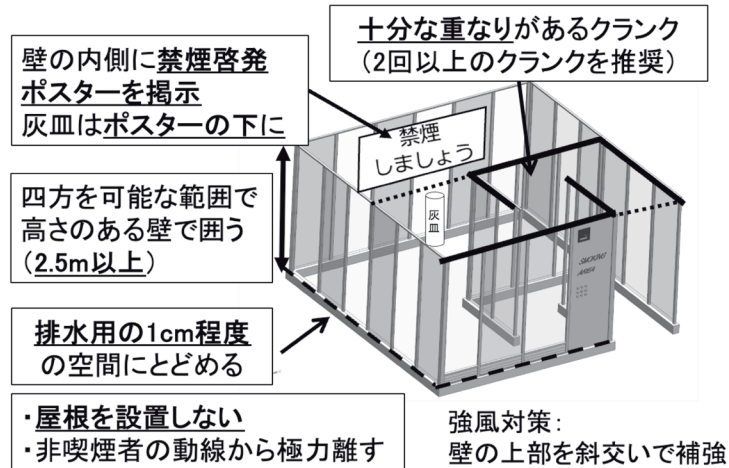


図5 屋外喫煙所の構造のポイント

## パーティション型喫煙コーナー：受動喫煙対策と禁煙啓発



今回、微風～5 m/s の風速下において、屋外喫煙所からタバコ煙が水平方向へ拡散することを確認した。無風時にはタバコ煙は上方に拡散するが、市街地環境では風や風および構造物により発生する渦等が影響し、水平方向への拡散を生じると考えられる。上記のポイントを考慮することで受動喫煙をある程度低減することは可能だが、受動喫煙を完全に防ぐことは不可能であることから、非喫煙者の動線から極力離す必要があると考えられた<sup>5)</sup>。

また、コンテナ型喫煙室の場合では以下のポイントを踏まえる必要があることがわかった。

- ・ HEPA フィルターを用いた空気清浄機を設置する（各メーカーが公表する仕様を元に設置する容積や人数に応じた設置台数が必要）
- ・ 使用状況（喫煙本数）に応じた空気清浄機のメンテナンスを実施する

（ただし、高額の初期費用と維持費が発生することに留意する必要がある。）

また、今回の測定中に喫煙室内を清掃する作業者が1,000 μg/m³を超える PM<sub>2.5</sub> に曝露されていることが確認された。喫煙室で通常設定される換気回数10回とした場合、少なくとも喫煙室内の清掃作業の20分前から喫煙禁止とし、粉じん濃度が低下するクリアランス時間経過後に作業を開始し、作業中にかけて喫煙を禁止する措置が必要であると考えられた<sup>6)</sup>。

根本的な受動喫煙の対策は喫煙者を減らすことにある。施設内部の壁面に以下の情報を掲示することが必要である。

1. 喫煙および受動喫煙による健康被害
2. 禁煙外来、および、薬局で購入可能なニコチンパッチ、ニコチンガムの情報
3. 禁煙による健康回復に関する情報

## V おわりに

屋外喫煙場所を設置せざるを得ない場合に、受動喫煙を低減するための必要最低限な構造を示した。また、そのような施設の内部に健康被害や禁煙支援の情報を掲示することで、禁煙啓発の場として活用し、喫煙者を減らすことが根本的な対策につながると考えられた。

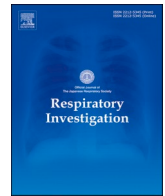
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## Original article

# Seventeen-year cumulative incidence of airflow limitation and lung function decline in two independent cohorts: The Japanese Red Cross Kumamoto study

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## ABSTRACT

**Background:** This study evaluated trends in the cumulative incidence of airflow limitation (AFL) and lung function decline over 17 years in two independent cohorts. Furthermore, this study focused on the possible effects of legal restrictions that came into effect in 2006 to prevent unwanted exposure to passive smoke on lung function decline in Japan.

**Methods:** Cohort 1 (1994–2011) and Cohort 2 (2002–2019) included 590 and 1012 participants, respectively. All participants were free of AFL at baseline, and they had no personal relationships each other. The association between the longitudinal category of smoking status and the cumulative incidence of AFL was assessed using logistic regression analysis. The annual FEV<sub>1</sub> decline was compared between Cohort 1 and 2, as well as before 2006 (pre) and after 2006 (post) within both cohorts.

**Results:** After adjusting for confounding factors, the odds ratio (OR) for developing AFL increased with smoking status and intensity in both Cohort 1 and 2. The annual FEV<sub>1</sub> decline in Cohort 2 was significantly slower than that in Cohort 1 for persistent never smokers. The annual decline in FEV<sub>1</sub> after 2006 (post) was significantly slower than that before 2006 (pre) in persistent never smokers in both Cohort 1 and 2.

**Conclusions:** Smoking remains a strong risk factor for the development of AFL and lung function decline in Japan. This study suggests that changes in the smoking environment may have preventative effects on lung function decline, especially in never smokers.

## 1. Introduction

Chronic obstructive pulmonary disease (COPD), which is characterized by airflow limitation (AFL), is a major cause of chronic morbidity

and mortality throughout the world [1,2]. According to the World Health Organization, COPD was the third leading cause of deaths worldwide in 2019 [2]. Although tobacco smoking is reported to be the main risk factor in COPD development, the involvement of genetic (G)

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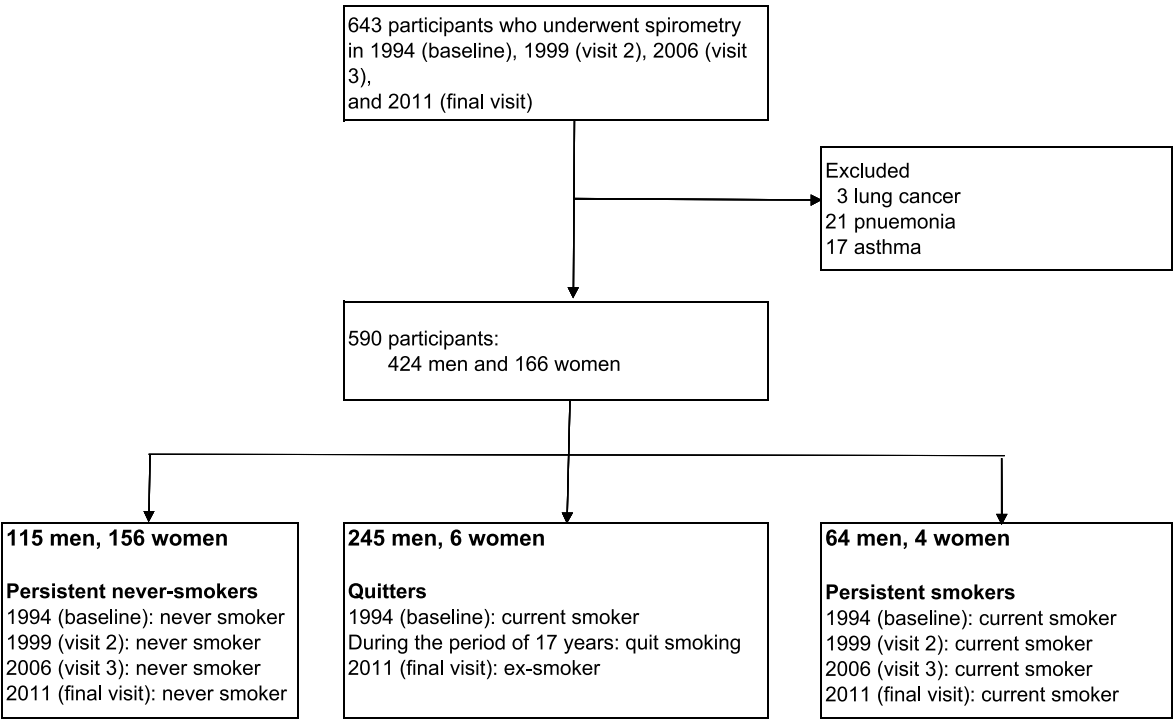
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and environmental (E) factors has also been noted, and COPD is proposed to develop throughout an individual's lifetime (T) as results of these factors (GETomics) [1,3]. Environmental factors can also contribute to COPD progression [1,4]. The Health Promotion Act was enacted in 2002 and came into effect in 2006 to prevent unwanted exposure to passive smoke in Japan [5]. The Workplace Smoke-Free

Guideline (WSFG) was also enacted in 2003 [6]. This guideline emphasizes organizational implementation to effectively address passive smoking prevention based on the Health Promotion Act. A complete indoor smoking ban has been recommended over a partial smoking ban, especially after the Japanese government ratified the World Health Organization Framework Convention on Tobacco Control (FCTC) [7] in

Cohort 1



Cohort 2

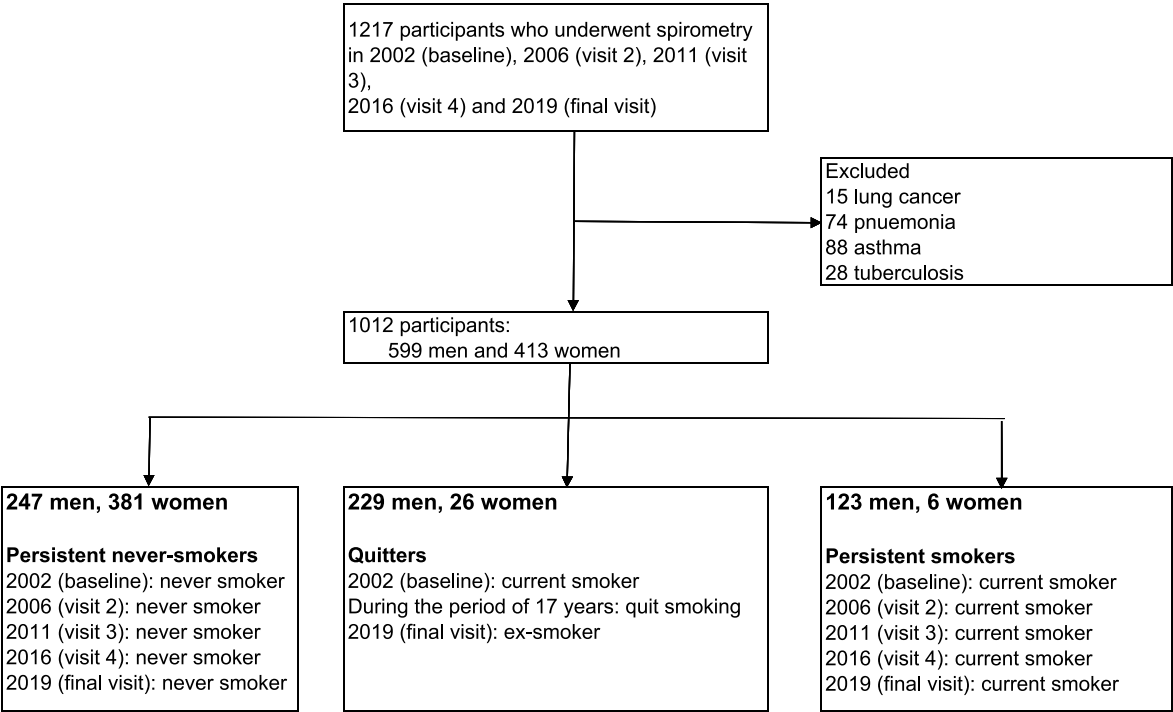


Fig. 1. Study flow diagram for selecting the participants according to the longitudinal smoking status in Cohort 1 and 2.

2005. As a result of these legal restrictions, smoking rates have been on a downward trajectory in recent decades in Japan [8–10], and passive smoking in workplaces and public facilities has decreased [11]. Therefore, this study focused on the possible effects of the legal restrictions that came into effect in 2006 on lung function decline in relation to preventing unwanted exposure to passive smoke in Japan.

Using two serial cross-sectional studies performed in 1967 and 2012, the Hisayama Study in Japan reported that the prevalence of AFL was significantly reduced over 45 years [12]. They speculated that a reduction in exposure to indoor and outdoor environmental pollutants in Japan could have increased the relative impact of smoking in recent years [12]. In the Yamagata–Takahata study, 5.4 % of nonsmokers and 20.5 % of smokers had AFL over a 6-year period, and the annual decline in the FEV<sub>1</sub> of smokers was larger than that of never smokers [13]. However, to our knowledge, no long-term longitudinal study has been conducted on the incidence of AFL and decline in lung function in Japan. Therefore, this study aimed to evaluate the trends in the cumulative incidence of AFL and lung function decline over 17 years in two independent retrospective cohort studies.

## 2. Materials and methods

### 2.1. Study design and participants

This retrospective observational cohort study included participants who underwent health checkups at the Japanese Red Cross Kumamoto Health Care Center. The checkups comprised interview questionnaires, physical examinations, spirometry, chest radiography, and blood tests. All data obtained from participants were strictly managed electronically as personal data [14,15]. This study was approved by the ethics committee of Kumamoto University (approval No. 84, approval date, 23 August 2023) and the Japanese Red Cross Kumamoto Health Care Center. Informed consent was obtained from all participants. This study was conducted in accordance with the Declaration of Helsinki and the STROBE Statement recommendations [16].

In Cohort 1, we analyzed 643 participants in 1994 (baseline) and conducted follow-up assessments in 1999 (visit 2), 2006 (visit 3), and 2011 (final visit). Participants with histories of lung cancer, pneumonia, or asthma were excluded. Cohort 1 included 590 participants (424 men and 166 women) aged 30–74 years in the final analysis (Fig. 1). In Cohort 2, we analyzed 1217 participants in 2002 (baseline) and conducted follow-up assessments in 2006 (visit 2), 2011 (visit 3), 2016 (visit 4), and 2019 (final visit). Patients with histories of lung cancer, pneumonia, asthma, or tuberculosis were excluded. Cohort 2 included 1012 participants (599 men and 413 women) aged 28–74 years in the final analysis (Fig. 1). None of the participants in either Cohort 1 or 2 had a history of workplace dust exposure.

### 2.2. Smoking assessment

According to the interviews at baseline and follow-up, the study participants were categorized into the following longitudinal groups: “persistent never smoker” (never smoked by the final visit), “quitter” (those who stopped smoking by the final visit), and “persistent smoker” (continued smoking by the final visit). Smoking intensity was assessed by pack-years (PY) over 17 years.

### 2.3. Lung function tests

Skilled technicians followed the recommendations and used the DISCOM-21 FX electric spirometer (CHEST MI, Tokyo, Japan) [17]. AFL was defined as a forced expiratory volume in 1 s (FEV<sub>1</sub>)/forced vital capacity (FVC) ratio <0.7 [1]. Predicted values were calculated using equations of the Japanese Respiratory Society (JRS) [18]. AFL severity was defined according to the GOLD criteria [1].

### 2.4. 17-Year cumulative incidence

This retrospective cohort study was conducted over a 17-year period. Therefore, we expressed the 17-year cumulative incidence as the proportion of the disease-free population (those free from AFL at the start of the study) who developed AFL during the 17-year period. We previously reported the cumulative incidence of AFL, which was determined using the same method [14,15]. The cumulative incidence was defined as in previous studies [19–23]. To detect the cumulative incidence of AFL during a 17-year period, this study did not include participants who dropped out. In this study, no participants were lost to follow-up.

### 2.5. Comparison of annual FEV<sub>1</sub> decline between the period before 2006 (pre) and after 2006 (post)

When passive smoking countermeasures were implemented, the effects did not appear immediately but took effect after several years [24]. This study focused on the possible effects of legal restrictions, which came into effect in Japan in 2006, to prevent unwanted exposure to passive smoke and its impact on lung function decline. Therefore, we compared the annual FEV<sub>1</sub> decline before and after 2006 in both cohorts.

### 2.6. Statistical analysis

The baseline characteristics were descriptively compared between Cohorts 1 and 2. The Shapiro–Wilk test was used to assess normality. Baseline characteristics and annual declines in FEV<sub>1</sub> in both cohorts were compared using Student’s *t*-test, Welch’s *t*-test, or the Mann–Whitney *U* test. A *t*-test with a significance level of 5 %, a power of 0.8, and an effect size of 0.8 resulted in a sample size of 26 [25]. A sample size of over 26 was required for each group. The sample size for comparing the annual decline in FEV<sub>1</sub> (mL/year) between the two cohorts was sufficient for analysis of persistent smokers.

We used multivariate logistic regression analysis, adjusted for age and BMI, to examine the associations between longitudinal smoking status, pack-years, and the cumulative incidence of AFL. The Hosmer–Lemeshow goodness-of-fit test was performed. We also calculated events per variable (EPV) for each model to assess the risk of inaccurate parameter estimation. EPVs greater than 10 are considered sufficiently high for estimation performance [26]. In our logistic regression analysis, the EPVs ranged from 5.7 to 10 for persistent smokers and from 12.7 to 16.3 for pack-years, indicating no serious problems with parameter estimation [26]. The level of statistical significance was set at *P* < 0.05. Analyses were performed using IBM SPSS Statistics version 29.0.

## 3. Results

### 3.1. Baseline characteristics

Participants in both cohorts were independent of each other and did not include former smokers or AFLs at baseline. Among men in both cohorts, there were 143 and 292 never smokers, and 281 and 307 current smokers, respectively (Table 1).

Among men, never smokers in Cohort 2 were significantly younger and had a higher BMI than those in Cohort 1. No significant difference in FEV<sub>1</sub> at baseline was observed between men and women in Cohorts 1 and 2. Among women in Cohorts 1 and 2, there were 156 and 392 never smokers and 10 and 21 current smokers, respectively. The mean FEV<sub>1</sub> and FVC in never smokers and smokers did not differ significantly between Cohorts 1 and 2 (Table 1).

Seventeen years later, the study groups among men in Cohorts 1 and 2 consisted of 115 and 247 persistent never smokers, 245 and 229 quitters, and 64 and 123 persistent smokers, respectively. Among women, the study groups in Cohorts 1 and 2 consisted of 156 and 381 persistent never smokers, 6 and 26 quitters, and 4 and 6 persistent

**Table 1**  
Baseline characteristics of the study participants without AFL by category of smoking status in Cohorts 1 and 2.

| variable                           | Never Smokers  |                |                |                |         |        | Smokers        |                |                |                |         |       |
|------------------------------------|----------------|----------------|----------------|----------------|---------|--------|----------------|----------------|----------------|----------------|---------|-------|
|                                    | Cohort 1       |                | Cohort 2       |                | P value |        | Cohort 1       |                | Cohort 2       |                | P value |       |
|                                    | Men            | Women          | Men            | Women          | Men     | Women  | Men            | Women          | Men            | Women          | Men     | Women |
| Number                             | 143            | 156            | 292            | 392            |         |        | 281            | 10             | 307            | 21             |         |       |
| Age, years                         | 50.1 (8.2)     | 51.9 (7.5)     | 47.2 (8.7)     | 48.2 (8.7)     | <0.001  | 0.18   | 45.5 (7.2)     | 43.1 (4.2)     | 45.2 (7.0)     | 46.1 (6.6)     | 0.982   | 0.136 |
| Height, cm                         | 166.9 (5.7)    | 153.7 (4.9)    | 168.6 (6.2)    | 155.9 (5.3)    | 0.007   | <0.001 | 167.9 (6.1)    | 155.2 (5.6)    | 169.9 (5.5)    | 159.3 (7.0)    | <0.001  | 0.111 |
| Weight, kg                         | 63.6 (8.2)     | 51.8 (6.7)     | 67.1 (9.1)     | 53.7 (8.6)     | <0.001  | 0.035  | 65.7 (8.2)     | 56.1 (8.8)     | 68.8 (10.5)    | 52.9 (6.4)     | <0.001  | 0.259 |
| Body mass index, kg/m <sup>2</sup> | 22.8 (2.6)     | 22.0 (3.0)     | 23.6 (2.7)     | 22.1 (3.2)     | 0.013   | 0.712  | 23.3 (2.6)     | 23.3 (3.4)     | 23.8 (3.2)     | 20.9 (2.5)     | 0.116   | 0.033 |
| Pack-years                         | 0              | 0              | 0              | 0              | –       | –      | 22.3 (14.7)    | 6.8 (6.0)      | 26.1 (15.1)    | 11.6 (9.5)     | <0.001  | 0.197 |
| Respiratory function               |                |                |                |                |         |        |                |                |                |                |         |       |
| FEV <sub>1</sub> , mL              | 3354.5 (465.7) | 2511.4 (382.1) | 3435.2 (533.5) | 2477.4 (404.2) | 0.124   | 0.368  | 3456.7 (518.5) | 2531.0 (333.3) | 3425.8 (554.8) | 2611.4 (406.4) | 0.487   | 0.446 |
| FVC, mL                            | 4103.3 (558.2) | 3030.5 (441.5) | 4291.4 (655.2) | 3038.5 (473.9) | 0.002   | 0.857  | 4239.0 (621.8) | 2984.0 (411.0) | 4333.6 (660.7) | 3210.5 (444.6) | 0.122   | 0.185 |
| FEV <sub>1</sub> /FVC, %           | 81.9 (5.1)     | 82.9 (4.9)     | 80.3 (5.1)     | 81.7 (5.7)     | <0.001  | 0.006  | 81.6 (4.9)     | 85.0 (4.5)     | 79.1 (5.0)     | 81.4 (5.2)     | <0.001  | 0.072 |
| FEV <sub>1</sub> , % predicted, %  | 104.0 (10.7)   | 106.2 (12.5)   | 102.3 (11.2)   | 103.1 (12.9)   | 0.115   | 0.006  | 102.7 (11.7)   | 102.7 (14.8)   | 99.0 (12.2)    | 102.9 (11.5)   | <0.001  | 0.673 |

**Notes:** Data are expressed as mean (standard deviation) or number (n).  
Pack-years = (number of cigarettes smoked per day × number of years smoked)/20.  
P-value: Comparison between men (or women) in never-smokers (or smokers) in Cohort 1 and men (or women) in never-smokers (or smokers) in Cohort 2.  
Abbreviations: AFL, Airflow Limitation; FEV1, forced expiratory volume in 1 s; FVC, forced vital capacity.

smokers, respectively (Table 2).

3.2. 17-Year cumulative incidence and odds ratios of AFL according to smoking status

Table 2 and Fig. 2 show the 17-year cumulative incidence and ORs for AFL. In men, AFL over the 17-year duration developed in 12 of 115 persistent never smokers (10.4 %), 27 of 245 quitters (11.0 %), and 17 of 64 persistent smokers (26.6 %) in Cohort 1. In Cohort 2, AFL developed in 18 of 247 persistent never smokers (7.3 %), 29 of 229 quitters (12.6 %), and 30 of 123 persistent smokers (24.4 %). The mean annual incidence of AFL in men was 0.61 % and 0.43 % in persistent never smokers, 0.65 % and 0.74 % in quitters, and 1.56 % and 1.43 % in persistent smokers in Cohorts 1 and 2, respectively. The adjusted ORs (95 % confidence interval [CI]) for AFL compared with persistent never smokers in Cohort 1 were as follows: quitters, 1.56 (0.73–3.32); persistent smokers, 6.66 (2.61–16.98) (Fig. 2). In addition, the adjusted ORs (95 % CI) for AFL compared with pack-year (PY) 0 in Cohort 1 were as follows: PY < 20, 0.74 (0.26–2.12); PY ≥ 20, 3.52 (1.65–7.51). The adjusted ORs (95 % CI) for AFL compared with persistent never smokers in Cohort 2 were as follows: quitters, 2.11 (1.11–4.01); persistent smokers, 6.12 (3.09–12.11). In addition, the adjusted ORs (95 % CI) for AFL compared with pack-year 0 in Cohort 2 were as follows: PY < 20, 0.91 (0.34–2.42); PY ≥ 20, 4.35 (2.40–7.91). The Hosmer-Lemeshow test did not indicate a lack of fit (P > 0.05).

In women, AFL over the 17-year duration developed in 6 of 156 persistent never smokers (3.8 %), 0 of 6 quitters (0.0 %), and 0 of 4 persistent smokers (0.0 %) in Cohort 1. In Cohort 2, AFL developed in 23 of 381 persistent never smokers (6.0 %), 1 of 26 quitters (3.8 %), and 3 of 6 persistent smokers (50.0 %). Due to the small number of quitters and smokers among women in Cohorts 1 and 2, an adequate multivariate logistic regression analysis could not be performed. The mean annual incidence of AFL in women was 0.23 % and 0.35 % in persistent never smokers, 0.0 % and 0.22 % in quitters, and 0.0 % and 2.94 % in persistent smokers in Cohorts 1 and 2, respectively.

The cumulative incidence of AFL in each 1994 (baseline) and follow-up assessments in 1999 (visit 2), 2006 (visit 3), and 2011 (final visit) in Cohort 1 were shown (Supplementary Fig. 1). The cumulative incidence of AFL in each 2002 (baseline) and follow-up assessments in 2006 (visit

2), 2011 (visit 3), 2016 (visit 4), and 2019 (final visit) in Cohort 2 were also shown (Supplementary Fig. 1).

3.3. Comparison of cumulative incidence and FEV<sub>1</sub> decline between the two cohorts

The 17-year cumulative incidence of AFL in Cohort 2 appeared to be lower than that in Cohort 1, although Cohort 2 included a few participants with moderate or severe AFL (Fig. 3). However, no significant differences were observed between the two cohorts. Owing to the small number of female smokers, an adequate analysis could not be performed.

Among men in Cohort 1, the annual FEV<sub>1</sub> decline (mL/year) for persistent never smokers, quitters, and persistent smokers was –33.1, –33.9, and –39.7, respectively (Table 3). Among women in Cohort 1, the annual FEV<sub>1</sub> decline (mL/year) for persistent never-smokers, quitters, persistent smokers was –28.1, –28.2, and –36.5, respectively. Among men in Cohort 2, the annual FEV<sub>1</sub> decline (mL/year) for persistent never smokers, quitters, and persistent smokers was –28.3, –29.6, and –32.7, respectively. Among women in Cohort 2, the annual FEV<sub>1</sub> decline (mL/year) for persistent never smokers, quitters, and persistent smokers was –24.5, –20.4, and –29.6, respectively. The annual decline in FEV<sub>1</sub> among persistent smokers was significantly faster than that among persistent never smokers in both Cohorts 1 and 2. The annual decline in FEV<sub>1</sub> in Cohort 2 was significantly slower than that in Cohort 1 for persistent never smokers, quitters, and persistent smokers (Table 3).

Table 4 and Fig. 4 show a comparison of FEV<sub>1</sub> decline before 2006 (pre) and after 2006 (post) in the two cohorts. The annual FEV<sub>1</sub> decline after 2006 was significantly slower than that before 2006 among persistent never smokers in both Cohorts 1 and 2.

4. Discussion

This study evaluated trends in the cumulative incidence of AFL and lung function decline using two independent cohorts. To the best of our knowledge, longitudinal data on lung function and estimates of the cumulative incidence of AFL over the past 17 years have been scarce in the last two decades.

**Table 2**  
17-year cumulative incidence, mean annual incidence, and odds ratio of AFL according to smoking status.

| Cohort 1 (1994–2011)                      |                       |            |                                   |          |                           |       |                  |                    |             |       |                       |                     |             |       |
|-------------------------------------------|-----------------------|------------|-----------------------------------|----------|---------------------------|-------|------------------|--------------------|-------------|-------|-----------------------|---------------------|-------------|-------|
| Smoking status from baseline to follow-up | Number of subjects, n |            | Number of subjects with AFL n (%) |          | Mean annual incidence (%) |       | OR (95 % CI)     |                    |             |       | Adjusted <sup>a</sup> |                     |             |       |
|                                           | Men, 424              | Women, 166 | Men                               | Women    | Men                       | Women | Crude            |                    |             |       |                       |                     |             |       |
|                                           |                       |            |                                   |          |                           |       | Men              | Women              | P value     |       | Men                   | Women               | P value     |       |
|                                           |                       |            |                                   |          |                           |       |                  |                    | Men         | Women |                       |                     | Men         | Women |
| Persistent never-smokers                  | 115                   | 156        | 12 (10.4)                         | 6 (3.8)  | 0.61                      | 0.23  | 1 (ref)          | 1 (ref)            |             |       | 1 (ref)               | 1 (ref)             |             |       |
| Quitters                                  | 245                   | 6          | 27 (11.0)                         | 0        | 0.65                      | 0     | 1.06 (0.52–2.18) | ND                 | 0.868       | ND    | 1.56 (0.73–3.32)      | ND                  | 0.253       | ND    |
| Persistent smokers                        | 64                    | 4          | 17 (26.6)                         | 0        | 1.56                      | 0     | 3.11 (1.37–7.02) | ND                 | 0.006       | ND    | 6.66 (2.61–16.98)     | ND                  | <0.001      | ND    |
| Pack-years 0                              | 115                   | 156        | 12 (10.3)                         | 6 (3.9)  | 0.60                      | 0.23  | 1 (ref)          | 1 (ref)            |             |       | 1 (ref)               | 1 (ref)             |             |       |
| <20                                       | 112                   | 7          | 6 (5.4)                           | 0        | 0.32                      | 0     | 0.49 (0.18–1.34) | ND                 | 0.164       | ND    | 0.74 (0.26–2.12)      | ND                  | 0.574       | ND    |
| 20≤                                       | 186                   | 3          | 38 (20.4)                         | 0        | 1.20                      | 0     | 2.20 (1.10–4.42) | ND                 | 0.026       | ND    | 3.52 (1.65–7.51)      | ND                  | 0.001       | ND    |
| Cohort 2 (2002–2019)                      |                       |            |                                   |          |                           |       |                  |                    |             |       |                       |                     |             |       |
| Smoking status from baseline to follow-up | Number of subjects n  |            | Number of subjects with AFL n (%) |          | Mean annual incidence (%) |       | OR (95 % CI)     |                    |             |       | Adjusted <sup>a</sup> |                     |             |       |
|                                           | Men 599               | Women 413  | Men                               | Women    | Men                       | Women | Men              | Women              | P value Men | Women | Men                   | Women               | P value Men | Women |
|                                           |                       |            |                                   |          |                           |       |                  |                    |             |       |                       |                     |             |       |
|                                           |                       |            |                                   |          |                           |       |                  |                    |             |       |                       |                     |             |       |
| Persistent never-smokers                  | 247                   | 381        | 18 (7.3)                          | 23 (6.0) | 0.43                      | 0.35  | 1 (ref)          | 1 (ref)            |             |       | 1 (ref)               | 1 (ref)             |             |       |
| Quitters                                  | 229                   | 26         | 29 (12.6)                         | 1 (3.8)  | 0.74                      | 0.22  | 1.85 (0.99–3.42) | 0.62 (0.08–4.80)   | 0.052       | 0.650 | 2.11 (1.11–4.01)      | 0.70 (0.09–5.68)    | 0.026       | 0.740 |
| Persistent smokers                        | 123                   | 6          | 30 (24.4)                         | 3 (50.0) | 1.43                      | 2.94  | 4.10 (2.18–7.72) | 15.57 (2.98–81.45) | <0.001      | 0.001 | 6.12 (3.09–12.11)     | 22.76 (3.46–149.89) | <0.001      | 0.001 |
| Pack-years 0                              | 247                   | 381        | 18 (7.3)                          | 23 (6.0) | 0.43                      | 0.35  | 1 (ref)          | 1 (ref)            |             |       | 1 (ref)               | 1 (ref)             |             |       |
| <20                                       | 111                   | 16         | 7 (6.3)                           | 3 (18.8) | 0.37                      | 1.11  | 0.61 (0.35–2.11) | ND                 | 0.779       | ND    | 0.91 (0.34–2.42)      | ND                  | 0.856       | ND    |
| 20≤                                       | 196                   | 5          | 49 (25.0)                         | 1 (20.0) | 1.47                      | 1.18  | 3.49 (2.00–6.17) | ND                 | <0.001      | ND    | 4.35 (2.40–7.91)      | ND                  | <0.001      | ND    |

**Notes:**

P-value: Comparison between persistent never smoker and other smoking status.

**Abbreviations:** AFL, Airflow Limitation; OR, Odd ratio; CI, Confidence Interval; ref, reference; ND, not detected.

<sup>a</sup> , Adjusted for age and body mass index.

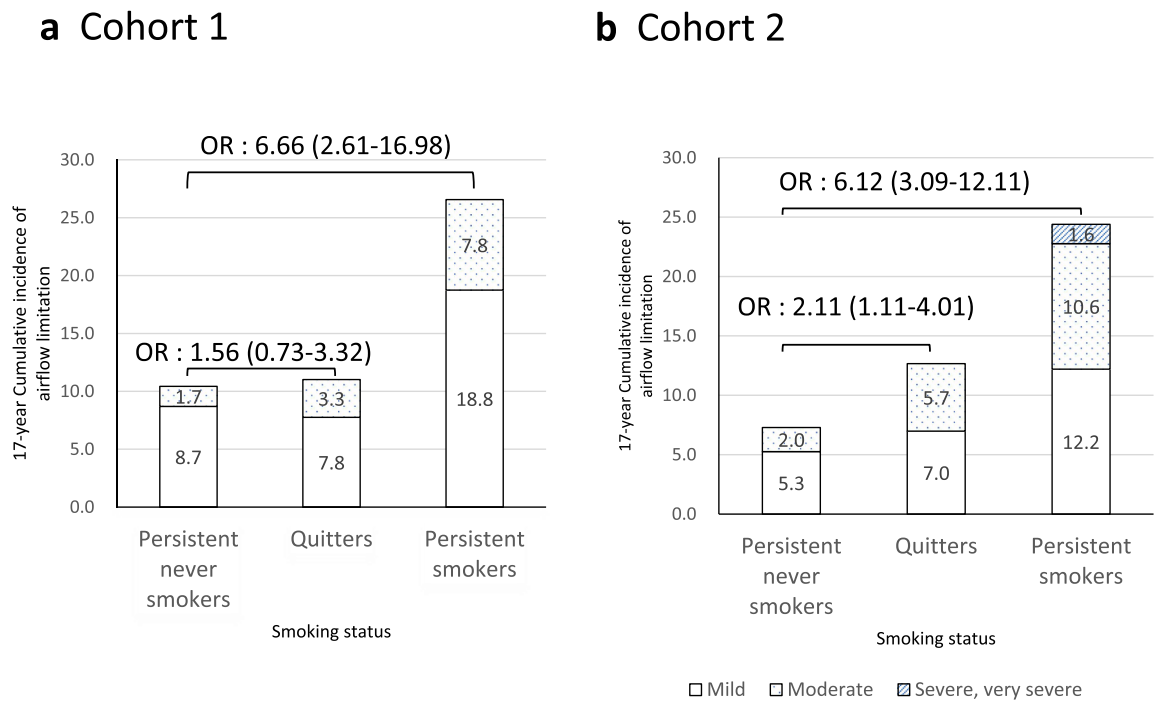


**Fig. 2.** 17-year cumulative incidence of AFL in men in the two cohorts Notes: a, Cohort 1; b, Cohort 2. Mild:  $FEV_1/FVC < 70\%$ ,  $FEV_1 \geq 80\%$  predicted, Moderate:  $FEV_1/FVC < 70\%$ ,  $50\% \leq FEV_1 < 80\%$  predicted, Severe:  $FEV_1/FVC < 70\%$ ,  $30\% \leq FEV_1 < 50\%$  predicted, and Very severe:  $FEV_1/FVC < 70\%$ ,  $FEV_1 < 30\%$  predicted. OR odds ratio, 95 % CI 95 percent confident interval. Odds ratio shown is adjusted for age and body mass index.

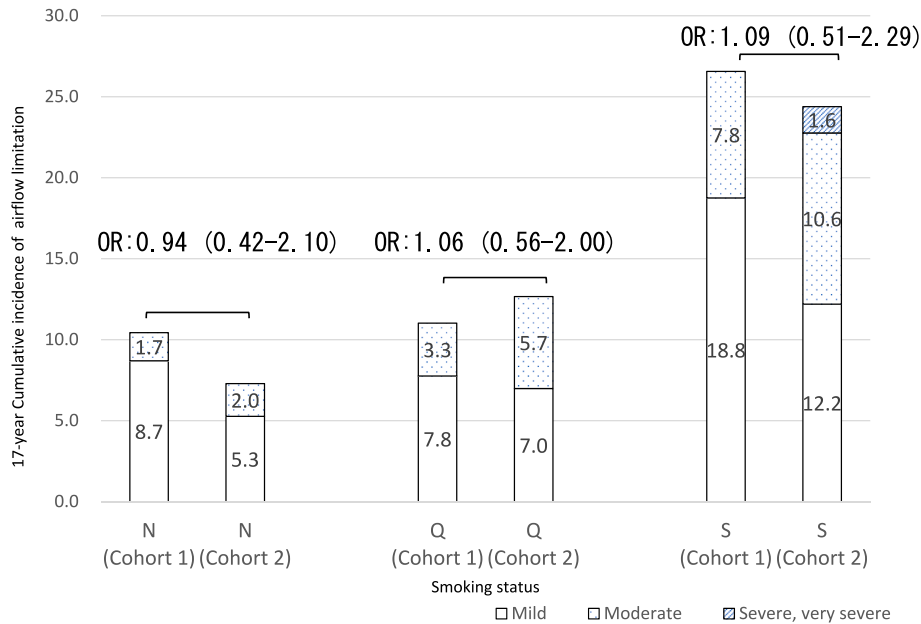


**Fig. 3.** Comparison of 17-year cumulative incidence of AFL in men between the two cohorts Notes: C1: Cohort 1, C2: Cohort 2, Mild:  $FEV_1/FVC < 70\%$ ,  $FEV_1 \geq 80\%$  predicted, Moderate:  $FEV_1/FVC < 70\%$ ,  $50\% \leq FEV_1 < 80\%$  predicted, Severe:  $FEV_1/FVC < 70\%$ ,  $30\% \leq FEV_1 < 50\%$  predicted, and Very severe:  $FEV_1/FVC < 70\%$ ,  $FEV_1 < 30\%$  predicted. OR odds ratio, 95 % CI 95 percent confident interval. Odds ratio shown is adjusted for age and Body mass index.

In this study, the cumulative incidence and mean annual incidence of AFL were significantly associated with smoking status and intensity, as assessed by PY (Table 2 and Fig. 2). Owing to the small number of female smokers, an adequate analysis could not be performed.

The annual decline in  $FEV_1$  among persistent smokers was significantly faster than that among persistent never smokers in both cohorts (Table 3). Thus, a key finding of this study is that smoking remains a strong risk factor for the incidence of AFL and lung function decline in

Japan. Furthermore, the annual decline in  $FEV_1$  after 2006 was significantly lower than that before 2006 (Table 4 and Fig. 4). These results suggest that changes in the smoking environment, such as the Health Promotion Act of 2002 and the WSFG implemented in 2003, may have been effective in preventing  $FEV_1$  decline due to passive smoking, particularly in persistent never smokers.

In our study, quitters showed a significant reduction in  $FEV_1$  compared to persistent smokers. Smoking cessation may prevent the

**Table 3**  
Annual decline of FEV<sub>1</sub> (mL/year) in the Cohorts 1 and 2.

| Smoking status from baseline to follow-up | Cohort 1 (1994–2011) |                            |        |                            | Cohort 2 (2002–2019) |                            |        |                            | P value |        |
|-------------------------------------------|----------------------|----------------------------|--------|----------------------------|----------------------|----------------------------|--------|----------------------------|---------|--------|
|                                           | Men                  |                            | Women  |                            | Men                  |                            | Women  |                            | Men     | Women  |
|                                           | Number               | FEV <sub>1</sub> (mL/year) | Number | FEV <sub>1</sub> (mL/year) | Number               | FEV <sub>1</sub> (mL/year) | Number | FEV <sub>1</sub> (mL/year) |         |        |
| Persistent never-smokers                  | 115                  | −33.1 (13.2)               | 156    | −28.1 (9.2)                | 247                  | −28.3 (12.9)               | 381    | −24.5 (11.0)               | 0.001   | <0.001 |
| Quitters                                  | 245                  | −33.9 (15.6)               | 6      | −28.2 (2.4)                | 229                  | −29.6 (14.9)               | 26     | −20.4 (1.8)                | 0.002   | <0.001 |
| Persistent smokers                        | 64                   | −39.7 (14.2)               | 4      | −36.5 (7.1)                | 123                  | −32.7 (15.9)               | 6      | −29.6 (2.7)                | 0.001   | 0.762  |
| All                                       | 424                  | −34.6 (14.9)               | 166    | −28.3 (0.7)                | 599                  | −29.7 (14.4)               | 413    | −21.7 (0.6)                | <0.001  | <0.001 |

**Notes:** Data are expressed as number and means (standard deviation).  
*P*-value: Comparison between participants in Cohort 1 and participants in Cohort 2.  
Abbreviations: FEV<sub>1</sub>, forced expiratory volume in one second

**Table 4**  
Comparison of annual FEV<sub>1</sub> decline (mL/year) between the period before 2006 (pre) and after 2006 (post) in persistent never smokers.

| Cohort | Sex   | Total number (n) | Pre (1994–2006) | Post (2006–2011) | P value |
|--------|-------|------------------|-----------------|------------------|---------|
| 1      | Men   | n = 115          | −35.2 (1.6)     | −28.0 (3.2)      | 0.047   |
|        | Women | n = 156          | −31.7 (1.0)     | −19.6 (1.8)      | <0.001  |
| Cohort | Sex   | Total number (n) | Pre (2002–2006) | Post (2006–2019) | P value |
| 2      | Men   | n = 247          | −39.7 (2.9)     | −24.8 (0.9)      | <0.001  |
|        | Women | n = 381          | −33.4 (1.9)     | −21.8 (0.6)      | <0.001  |

Pre: before changes in the smoking environment, Post: after changes in the smoking environment.  
Data are expressed as means (standard error).  
*P* value: between pre-2006 and post-2006.  
\* compared ‘post’ to ‘pre’.

development of AFL [15,27].  
Several previous longitudinal studies using pre-bronchodilation spirometry have reported the cumulative incidence of AFL in continuous smokers and never smokers [19–23]. For easier comparison with our results, we calculated the mean annual incidence of AFL. The Copenhagen City Heart Study, which followed participants for 25 years, demonstrated that the incidence of COPD in smokers was at least 25 %, with a mean annual incidence of 0.21 % in persistent never smokers and

1.56 % in continuous smokers [19]. According to a 30-year study by Pelkonen et al. [22], the mean annual incidence was 0.4 % in persistent never smokers and 1.07 % in continuous smokers. In our study, the mean annual incidence of AFL in continuous smokers in men in Cohort 1 was similar to that reported by Løkke A et al. [19]. The mean annual incidence of AFL in never smokers in men in Cohort 2 was comparable to that reported by Pelkonen et al. [22]. The mean annual incidence of AFL in continuous smokers in men in Cohort 2 was similar to that reported by Kohansal et al. [23].  
In our study, the mean annual incidence of AFL in men in Cohort 2 appeared lower than that in Cohort 1 in both persistent never smokers and persistent smokers. Additionally, the annual decline in FEV<sub>1</sub> in Cohort 2 was significantly slower than that in Cohort 1, especially among persistent never smokers.  
According to the Hisayama Study, the prevalence of AFL significantly decreased over 45 years, from 1967 to 2012 [12]. Strassmann et al. reported that nationwide indoor smoking bans are associated with reduced smoking and improved lung function in the general population [27,28]. A Polish study indicated that secondhand smoke (SHS) exposure in workplaces and other public places decreased dramatically following the introduction of a smoke-free policy [29]. Implementing an indoor smoking ban can improve lung function by influencing smoking behaviors and reducing SHS exposure [27]. Further investigation is needed to elucidate factors such as changes in the smoking environment related to differences or similarities in AFL incidence.

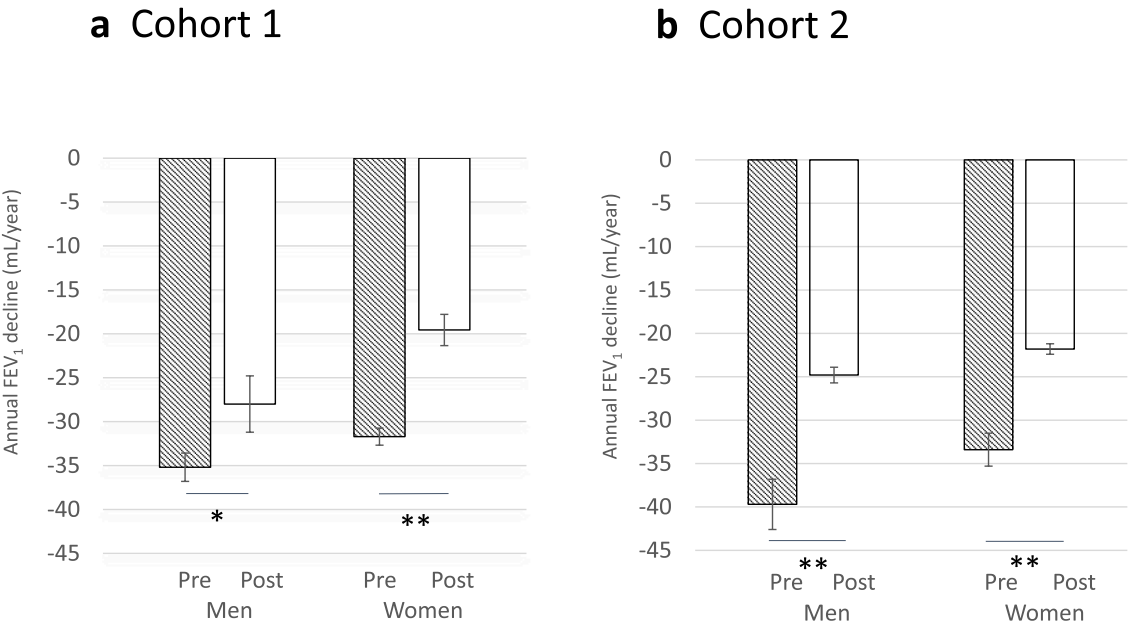


**Fig. 4.** Comparison of annual FEV<sub>1</sub> decline (mL/year) between pre and post changes in both Cohort 1 and 2. Notes: a, Cohort 1; b, Cohort 2; Pre, before 2006; Post, after 2006. \* *P*-value <0.05, \*\* *P*-value <0.01.

A major strength of this study is the high validity of the registries and the completeness of electronic databases for health examinations. These resources allowed for two independent, long-term, retrospective cohort studies.

This study has certain limitations. First, due to the small number of female quitters and smokers in Cohorts 1 and 2, an adequate multivariate logistic regression analysis with sufficient samples could not be performed. Further studies on sex-related differences are needed with a larger sample of women. Second, Heated Tobacco Products (HTPs) have been sold in Japan since 2014 [30,31]. In this study, the proportion of individuals using HTPs and their effect on the cumulative incidence of AFL remain unclear. Further studies are required to address this issue. Third, actual measurement data on passive smoking exposure were not available. However, passive smoking in workplaces and public facilities has decreased [11].

Despite these limitations, to our knowledge, this study is the first to reveal trends in the cumulative incidence of AFL and lung function decline. Furthermore, the findings indicate that smoking remains a strong risk factor for AFL and lung function decline in Japan. Providing a smoking cessation program for all smokers should be considered an important strategy for preventing COPD progression in Japan. This study also suggests that changes in the smoking environment, particularly legal restrictions, may have preventive effects on lung function decline, especially in never smokers.

## 5. Conclusions

Our study showed that smoking remains a strong risk factor for the development of AFL and lung function decline in Japan. Thus, smoking cessation programs should be considered an important strategy for preventing the progression of COPD in Japan. The annual FEV<sub>1</sub> decline in Cohort 2 was significantly slower than in Cohort 1. Furthermore, the annual FEV<sub>1</sub> decline after 2006 was significantly slower than before 2006 in persistent never smokers in both Cohorts 1 and 2. This study suggests the preventive effects of changes in the smoking environment (legal restrictions) on lung function decline, especially in never smokers.

## Author contributions

Y.S. and A.O. contributed equally to this work. Y.S., A.O. and H.O. made significant contributions to the design of the work, methodology, data analysis, the original draft preparation and interpretation. K.M. and H.I. contributed to the design of the work, the original draft preparation and interpretation. K.K. (Kenichi Kubota), M. Y., S.T., T.K., K.H., Y.M., K. W., K.K. (Kazuaki Kawai) and H.Y. contributed to the design of the work, analysis, methodology, writing – review and editing.

All authors have approved the submitted version of the manuscript and agreed to be accountable for any part of the work.

## Data availability statement

The datasets are not available.

## Declaration of competing interest

Hiromasa Inoue received honoraria (e.g., lecture fees) from Astra-Zeneca, Boehringer-Ingelheim, Kyorin, GlaxoSmithKline, Novartis, and Sanofi. Hiromasa Inoue received research fundings from Boehringer-Ingelheim, GlaxoSmithKline, and Omron. The other authors have no conflicts of interest.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.resinv.2025.06.019>.

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RESEARCH

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# How much progress has been made toward a smoke-free environment in the restaurants and bars of Japan? Limitations of partial bans and their enforcement

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## Abstract

**Background** In April 2020, the revised Health Promotion Act and Tokyo Metropolitan Ordinance to prevent second-hand smoke (SHS) exposure was fully enforced. The government has provided an exemption for small-scale, existing establishments by allowing them 'unregulated' status, and it is unclear to what extent indoor smoking bans have been applied in these small bars and restaurants. In this study, we report on indoor smoking status before/after the enforcement of the current legislation both regulated and unregulated restaurants and bars.

**Methods** Self-questionnaire surveys were conducted in March 2020 and 2021. We applied the questionnaire to 6,000 restaurants and bars in Tokyo, Osaka and Aomori in the first survey and to 3609 restaurants in the second survey, including those that had responded to the first survey as well as 2800 additional establishments. We calculated the proportions of indoor smoking status before/after enforcement both regulated and unregulated establishments. In addition, we calculated the national estimate of indoor smoking status in all restaurants and bars in Japan after the enforcement using a restaurant guide website and the results of this study.

**Results** The responded establishments were 879 to the first (response rate: 14.7%) and 837 to the second (response rate: 23.2%). Of all the establishments, 67.0% kept "separate smoking or smoking" status, and 62.1% of unregulated establishments kept "separate smoking or smoking". Although all the regulated establishments were required to change to "no smoking" by law, 78.4% that were "separate smoking or smoking" before the enforcement did not change their indoor smoking status. The national estimate of smoking status showed that the proportion of "no smoking" would change from 54.5% to 69.4% after the enforcement. If all regulated establishments changed smoking status to "no smoking", the ideal proportion of "no smoking" would be 85.8% in Japan.

**Conclusions** More unregulated restaurants and bars changed to "no smoking" than planned before the enforcement. In contrast, most of the regulated restaurants and bars continued to be "separate smoking or smoking" in non-compliance with the legislation. In order to prevent SHS exposure in all restaurants and bars, we need comprehensive legislation for indoor smoking bans in Japan.

**Keywords** Second hand smoking, Passive smoking, Smoke-free legislation, Restaurants, Smoking Cessation, Smoking Prevention

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## Introduction

Tobacco kills more than eight million people a year worldwide, and around 1.2 million of those deaths are the result of non-smokers being exposed to secondhand smoke (SHS) [1]. SHS exposure causes many negative health outcomes including cardiovascular disease, cerebrovascular disease, and cancer [2, 3]. In addition, it has been reported that occupational exposure to SHS causes respiratory symptoms and asthma in restaurants and bars [2]. To protect the public from the harms of SHS, the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) requires comprehensive smoking bans in all indoor public spaces [4]. In recent years, several countries have introduced smoke-free legislation in public spaces; however, although the framework was ratified by 195 countries, only 67 have the comprehensive smoke-free legislation FCTC calls for [5].

Although Japan has ratified FCTC, its smoke-free legislation for public spaces has not been comprehensive. While the revised Health Promotion Act of April 2020 strengthened smoke-free protections and prohibits smoking in public places such as schools, hospitals, and government offices, exceptions remain for restaurants and bars. The revised law allows restaurants and bars to set up indoor smoking-only rooms in which no eating or drinking takes place and to permit the use of heated tobacco products (HTPs) in smoking rooms where customers can eat and drink (Supplementary Fig. 1). However, it has been shown that separating smokers and non-smokers can lower elements of SHS exposure such as the nicotine concentration in non-smoking areas, but cannot eliminate it completely [3, 6]. Therefore, even if smoking rooms were established, the air was cleaned, and the building was ventilated, it would not adequately prevent non-smokers in non-smoking areas from exposure to SHS.

In addition, restaurants and bars which have an area of less than 100 m<sup>2</sup> or have capital of 50 million yen or less, and opened before April 2020 are except from the law, and can choose indoor smoking status by posting information signs [7]. Also in April 2020, the Tokyo Metropolitan Ordinance to prevent SHS exposure was enforced, and this was more restrictive than the revised law in that only restaurants and bars with no employees in addition to regulation of seating area, capital and year opening were allowed to choose indoor smoking by posting information signs [8].

The number of restaurants and bars not regulated by legislation was estimated at 20% in Tokyo and 50% in 46 other prefectures [9]. In these establishments, the owners decide whether or not to allow indoor smoking. Therefore, it is unclear how many have adopted smoke-free rules since the enforcement of the SHS exposure

legislation. Also, as the COVID-19 pandemic occurred at the same time as the enforcement of the law, bar or restaurant owners might have hesitated to adopt a smoke-free policy for fear of reducing sales at a time when business was already drastically curtailed.

We aim to examine the current status of indoor smoking in restaurants and bars before and after the enforcement of the anti-SHS legislation, and examine how much progress has been made with the implementation of smoking bans, especially in the unregulated restaurants and bars in Japan.

## Method

### Participants and data collection

The surveys were conducted twice, before and after the enforcement. The first survey (before the enforcement) was conducted in February–March 2020, and questionnaires were applied to 6,000 restaurants and bars operating in 20 cities in Tokyo, Osaka, and Aomori prefectures (detailed questionnaires shown in Appendix 1). The second survey (after the enforcement) was conducted in March 2021. Of the 879 restaurants and bars that responded to the first survey, 809 were still running in 2021 and were included in the second survey. A further 2,800 establishments that were still in operation in 38 cities in Tokyo, Osaka, and Aomori prefectures were added, resulting in a total sample of 3,609 restaurants and bars (detailed questionnaires shown in Appendix 2 and 3). For both surveys, we mailed a self-administered questionnaire to respondents which they could return by mail or complete online.

The sample prefectures were selected based on a combination of degree of urbanization and the status of enforcement of the anti-SHS legislation. Tokyo and Osaka prefectures were selected as the metropolitan samples, as the Tokyo Metropolitan Ordinance to prevent SHS exposure was enforced in April 2020 and the Osaka Prefectural Ordinance to prevent SHS exposure will be enforced in 2025. In contrast, as the rural sample, Aomori prefecture was selected because the ordinance has not been enforced and is currently under consideration. Furthermore, the adult smoking rate was the second highest among the 47 prefectures in 2019 [10], making smoking control a priority issue in health policy.

The sample selection of food and beverage establishments was conducted using Tabelog.com (operated by Kakaku.com Inc., Tokyo), a popular online restaurant guide in which restaurants and bars from all over Japan are registered.

First, we focused on restaurants and bars that were not regulated by law and selected them based on the definitions for small establishments: in Osaka and Aomori prefectures restaurants with fewer than 50 seats and bars

which were less than 100 m<sup>2</sup> in size and in the Tokyo metropolitan area, restaurants with fewer than 20 seats and bars with no employees. Second, we conducted random sampling to avoid bias among food and beverage service categories of restaurants and bars. The proportion of each service category was based on the number of establishments per service category registered on the website. To ensure the number of establishments in each service category would be approximately the same, the sampling was conducted with the following proportions as the target: 20% for Japanese food, 15% each for Japanese gastropubs, cafes, and ramen shops, 10% for western food, 4% for family restaurants, 12.5% for bars and pubs, 6% for Asian and international cuisine, and 2.5% for barbecue restaurants. These service categories have been adopted by the major restaurant guide websites in Japan and are defined as follows: Japanese food refers to a restaurant that serves traditional Japanese cuisine; Japanese gastro pubs, called Izakaya in Japanese, are informal Japanese bars that serve a variety of alcoholic drinks and accompanying food; cafes are small restaurants or coffeehouses that serve light meals, beverages, and desserts; ramen shops are restaurants that specialize in ramen dishes (wheat-flour Japanese noodles in broth); western food refers to restaurants that serve western cuisine (mainly European and American); family restaurants mainly target families and their menus include a wide variety of Japanese, Western and Chinese dishes at low prices; bars and pubs focus on serving alcoholic drinks; Asian and international cuisine refers to restaurants that serve Asian or multiethnic dishes; and barbecue restaurants, called Yakiniiku in Japanese, are restaurants where customers can grill their meat themselves.

### Measures

We recorded the indoor smoking status in restaurants and bars before/after the enforcement, and also, in the first survey, recorded plans for changing indoor smoking status after the enforcement. The indoor smoking status categories were “no smoking” and “separate smoking or smoking”; the latter comprised “complete smoking separation”, “area smoking separation”, “time limited smoking separation”, and “smoking”. In addition, we recorded the location (Metropolitan: Tokyo and Osaka, Rural: Aomori); seating area (less than 30 m<sup>2</sup>, 31–100 m<sup>2</sup>, more than 100 m<sup>2</sup>); year of opening (2010–March 2020: January–March 2020, 2015–2019, 2010–2014, before 2010, 2000–2009, before 1999); service category (serves mainly alcohol: Japanese gastropub, bars and pubs; serves mainly meals: Japanese food, cafes, ramen shops, western food, family restaurants, Asian and international cuisine, and barbecue restaurants); and the number of employees (zero–one employee, two or more employees).

### Data analysis

We calculated the proportion of the indoor smoking options in operation before and after the enforcement and conducted a chi-square test to compare differences in restaurant and bar characteristics between indoor smoking status in the first and second surveys: “stayed no smoking”, “changed from separate smoking or smoking to no smoking”, and “stayed separate smoking or smoking”. We conducted these analyses for both the regulated establishments that had been required to change to “no smoking” by the legislation and the unregulated establishments that could choose “no smoking”, “separate smoking or smoking” indoor smoking status.

To examine the impact of non-response on indoor smoking status, a sensitivity analysis was conducted. We focused on 86 nonresponding restaurants and bars about indoor smoking status in each 2019 and 2020, and we assumed the following for patterns for these 86 restaurants and bars, and calculated the proportion of no smoking for each of the patterns: 1) if all nonresponding restaurants and bars were no smoking in 2019 and 2020, 2) if nonresponding restaurants and bars in 2019 are no smoking and in 2020 are separate smoking or smoking, 3) if nonresponding restaurants and bars in 2019 are separate smoking or smoking and in 2020 are no smoking, 4) if all nonresponding restaurants and bars are separate smoking or smoking both in 2019 and 2020.

In addition, we estimated the indoor smoking status of restaurants and bars before/after the enforcement both nationally and for establishments that mainly served meals and those that mainly served alcohol (Standardized Proportion of Indoor Smoking Status: SPISS) using the calculation (detailed methods shown in Appendix 4),

$$SPISS_{ys} = \sum_i^I \sum_j^J p_{ijys} * w_{ij}$$

$$w_{ij} = T_i * R_{ij} / T$$

where  $i$  indicates location:  $i=0$  is Tokyo and  $i=1$  is 46 prefectures other than Tokyo;  $j$  indicates the regulated status by law:  $j=0$  is not regulated and  $j=1$  is regulated;  $y$  indicates survey point in time:  $y=0$  is 2019, and  $y=1$  is 2020;  $s$  indicates indoor smoking status:  $s=0$  is no smoking, and  $s=1$  is separate smoking or smoking.

$SPISS_{ys}$  was the sum of  $p_{ijys} * w_{ij}$ .  $p_{ijys}$  was the proportion of indoor smoking status observed in this survey, and  $w_{ij}$  was the distribution of restaurants and bars in Japan used as weighting.  $w_{ij}$  was calculated

using the Tabelog database ( $T$  was the total number of restaurants and bars,  $T_i$  was the number of restaurants and bars in Tokyo and in 46 prefectures) and  $R_{ij}$  was the expected proportion of regulated or unregulated establishments after the enforcement in Japan (the number of restaurants and bars not regulated by law was estimated at 20% in Tokyo and 50% in 46 other prefectures).

All analyses were conducted in R version 3.6.1 [11].

“Ethical Guidelines for Medical and Health Research Involving Human Subjects” were not applicable as this study examined restaurants and bars not human subjects, and ethics approval was waived by institutional review board of Osaka University: Ethical Review Board Osaka University Hospital. Information on each restaurant and bar was handled on personal computers with appropriate security measures such as setting passwords and installing security software, so that no disadvantage could arise from this study.

## Results

Of 6,000 restaurants and bars approached in the first survey, 879 responded to the questionnaire (response rate: 14.7%). Of 3,609 restaurants and bars, approached in the second survey, 837 responded (response rate: 23.2%). Of these, 707 were included in the analysis, after excluding those that did not answer questions about their indoor smoking status before the enforcement, seating areas, and the number of employees (Tokyo only), and those

that opened after April 2020. Of the 707 establishments, 457 were unregulated with less than 100m<sup>2</sup> of seating area and no employees (Tokyo only), and 250 were regulated (Fig. 1).

## Characteristics of the restaurants and bars

In terms of characteristics, a higher proportion of establishments were in a metropolitan location, opened before 2010, had 31–100 m<sup>2</sup> seating area, more than two employees, mainly served meals and did not allow use of HTPs. The significant differences in characteristics between the unregulated and regulated establishments were in location (metropolitan: 59.1% of the unregulated and 88.8% of the regulated establishments), seating area (31–100 m<sup>2</sup>: 60.6% of the unregulated establishments, 26.8% of the regulated establishments), number of employees (more than two employees: 48.6% in the unregulated, 68.4% in the regulated establishments) (Table 1).

## Indoor smoking status before and after enforcement of the legislation

Among the 707 establishments analyzed, the proportion of “no smoking” was 54.6% (386/707) before and 67.3% (476/707) after the enforcement (Supplementary Fig. 2). Results of the sensitivity analysis showed the following the proportion of “no smoking” before/after the enforcement: (1) if all nonresponding restaurants and bars are “no smoking” both in 2019 and 2020: 58.8% (458/779)

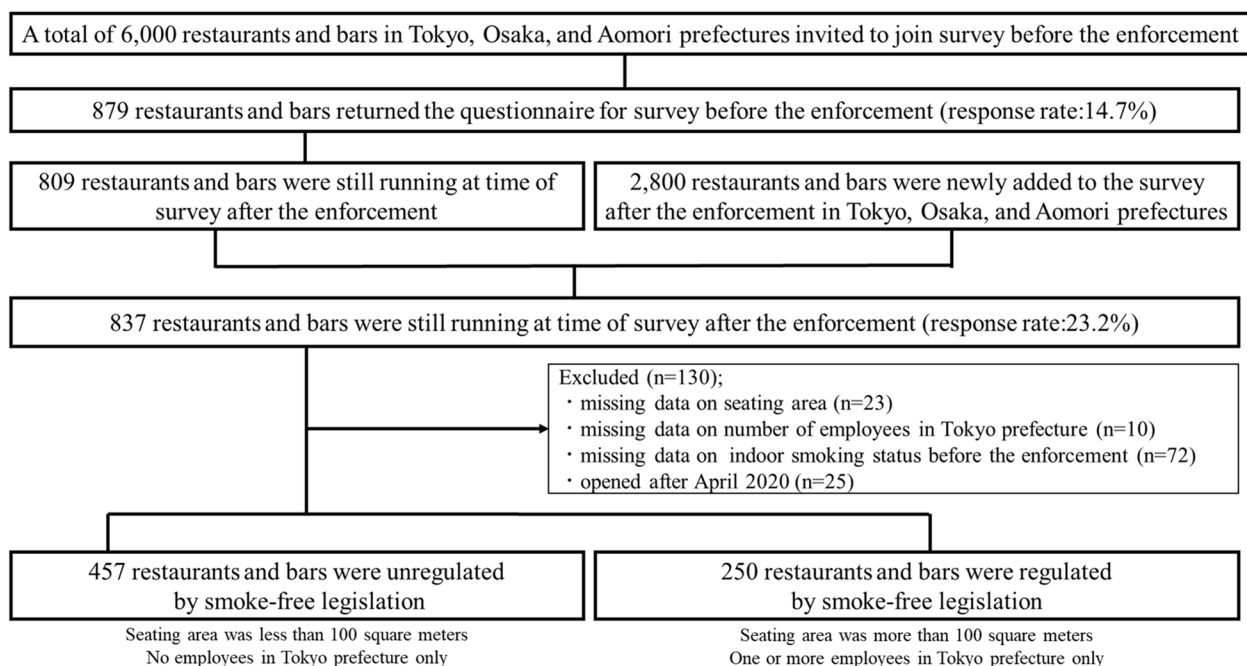


**Fig. 1** Flow diagram of the selected restaurants and bars in this study

**Table 1** Differences in characteristics between regulated and unregulated restaurants and bars

|                             | All establishments (n = 707) |      | Unregulated (n = 457) |      | Regulated (n = 250) |      | p-value |
|-----------------------------|------------------------------|------|-----------------------|------|---------------------|------|---------|
|                             | n                            | %    | n                     | %    | n                   | %    |         |
| Location                    |                              |      |                       |      |                     |      | < 0.01  |
| Metropolitan: Tokyo, Osaka  | 492                          | 69.6 | 270                   | 59.1 | 222                 | 88.8 |         |
| Rural: Aomori               | 215                          | 30.4 | 187                   | 40.9 | 28                  | 11.2 |         |
| Year of opening             |                              |      |                       |      |                     |      | 0.86    |
| before 2010                 | 361                          | 51.1 | 235                   | 51.4 | 126                 | 50.4 |         |
| 2010–March 2020             | 346                          | 48.9 | 222                   | 48.6 | 124                 | 49.6 |         |
| Seating area                |                              |      |                       |      |                     |      | < 0.01  |
| less than 30m <sup>2</sup>  | 326                          | 46.1 | 180                   | 39.4 | 146                 | 58.4 |         |
| 31–100m <sup>2</sup>        | 344                          | 48.7 | 277                   | 60.6 | 67                  | 26.8 |         |
| more than 100m <sup>2</sup> | 37                           | 5.2  | 0                     | 0.0  | 37                  | 14.8 |         |
| Number of employees         |                              |      |                       |      |                     |      | < 0.01  |
| zero–one employee           | 299                          | 42.3 | 221                   | 48.4 | 78                  | 31.2 |         |
| two or more employees       | 393                          | 55.6 | 222                   | 48.6 | 171                 | 68.4 |         |
| Service category            |                              |      |                       |      |                     |      | 0.10    |
| mainly served alcohol       | 182                          | 25.7 | 108                   | 23.6 | 74                  | 29.6 |         |
| mainly served meals         | 525                          | 74.3 | 349                   | 76.4 | 176                 | 70.4 |         |
| HTPs                        |                              |      |                       |      |                     |      | 0.74    |
| allowance                   | 47                           | 6.6  | 28                    | 6.1  | 19                  | 7.6  |         |
| not allowance               | 451                          | 63.8 | 292                   | 63.9 | 159                 | 63.6 |         |

p-value: chi-square test between unregulated and regulated establishments

HTPs: heated tobacco products

Unregulated establishments: restaurants and bars not regulated by law and able to choose indoor smoking status

Regulated establishments: restaurants and bars regulated by law and required to implement smoking ban after the enforcement

before and 70.7% (551/779) after, (2) if nonresponding restaurants and bars in 2019 are “no smoking” and in 2020 are “separate smoking or smoking”: 58.8% (458/779) before and 65.3% (509/779) after, (3) if nonresponding restaurants and bars in 2019 are separate smoking or smoking and in 2020 are “no smoking”: 49.5% (386/779) before and 70.7% (551/779) after, (4) if all nonresponding restaurants and bars are “separate smoking or smoking” both in 2019 and 2020: 49.5% (386/779) before and 65.3% (509/779) after (Supplementary Table 1).

In the unregulated establishments, the proportion of “no smoking” increased from 51.0% (233/457) to 67.4% (308/457). In particular, among the unregulated establishments which had “separate smoking or smoking” status before the enforcement, 34.8% (78/224) changed to “no smoking” (Fig. 2, with more detailed indoor smoking status is shown in supplementary Fig. 3). HTPs use was permitted in 76.0% (19/25) of the unregulated establishments that reported they were “staying separate smoking or smoking”, and in 2.7% (8/294) of those that were “staying no smoking” or “changing from separate smoking or smoking to no smoking” (Supplementary Table 2). In addition, 26% (33/127) of the unregulated establishments that were “separate smoking or smoking” planned

to change their status to “no smoking” in the first survey; however, after the enforcement, 40.2% (51/127) of them actually changed their status to “no smoking” (Supplementary Fig. 4).

Although all regulated establishments were required by law to change their indoor smoking status to “no smoking”, 78.4% (76/97) of those that were “separate smoking or smoking” before the enforcement did not change their status and were “staying separate smoking or smoking”. This was equivalent to 31.2% (78/250) of all the regulated establishments that were legally required to change their status (Fig. 3, with more detailed indoor smoking status shown in supplementary Fig. 5). HTPs use was allowed in 60.0% (12/20) of the regulated establishments that were “staying separate smoking or smoking”, and 4.4% (7/158) of those that were “staying no smoking” or “changing from separate smoking or smoking to no smoking” (Supplementary Table 3).

#### Differences in the characteristics of restaurants and bars

In the unregulated establishments, there were significant differences in characteristics between “changing from separate smoking or smoking to no smoking” and “staying separate or smoking” in number of employees (more

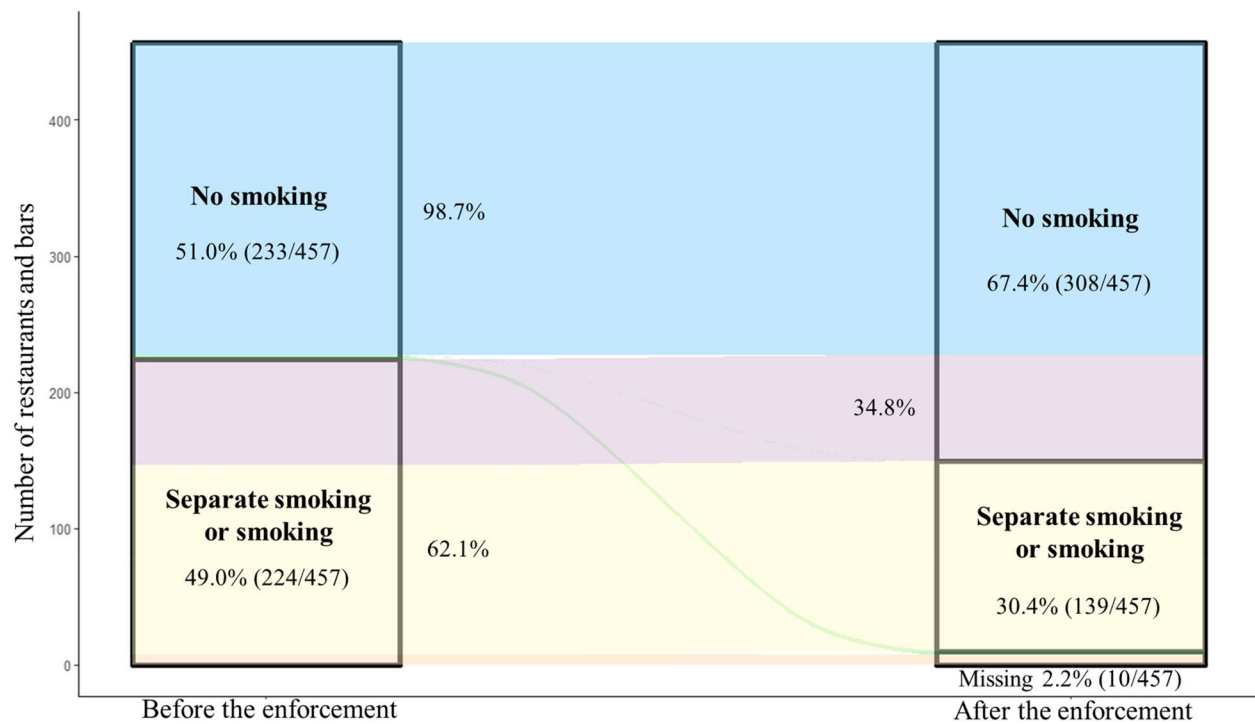


**Fig. 2** Changing indoor smoking status for the unregulated restaurants and bars before/after enforcement of smoke-free legislation. We observed the actual indoor smoking status in the unregulated restaurants and bars that were able to choose whether to implement smoking bans or continue to allow smoking in the survey before and after the enforcement, and calculated the proportion of indoor smoking status

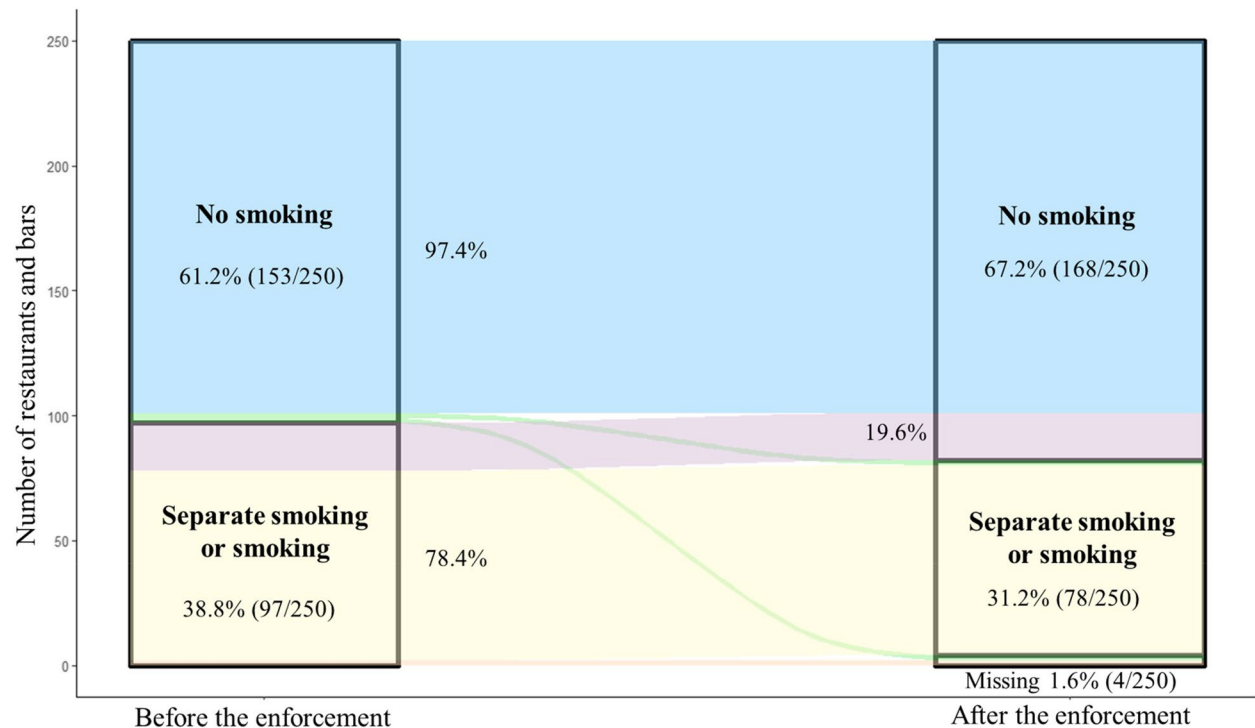


**Fig. 3** Changing indoor smoking status for the regulated restaurants and bars before/after enforcement of smoke-free legislation. We observed the actual indoor smoking status in the regulated restaurants and bars that had to implement smoking bans in the survey before and after the enforcement, and calculated proportion of indoor smoking status

than two employees; 60.3% “changing from separate or smoking to no smoking”, 43.9% “staying separate smoking or smoking”,  $p < 0.05$ ), seating areas (31–100 m<sup>2</sup>; 76.9% “changing separate smoking or smoking to no smoking”, 39.6% “staying separate or smoking”,  $p < 0.01$ ), and service categories (serves mainly meals; 79.5% in “changing separate smoking or smoking to no smoking”, 52.5% “staying separated or smoking”,  $p < 0.01$ ) (Supplementary Table 2). In the regulated establishments, the only significant difference in characteristics between “staying no smoking”, “changing separate smoking or smoking to no smoking” and “staying separate or smoking” was in the service category (serves mainly alcohol: 59.0% “staying separate or smoking”, 16.7% “staying no smoking”, “changing from separate smoking or smoking to no smoking”,  $p < 0.01$ ) (Supplementary Table 3). In terms of owner smoking status, among owners of unregulated establishments, more never or former smokers changed to “no smoking” than stayed “separate smoking or smoking”. Owners who were never or former smokers may be more likely to implement a change in indoor smoking status to a complete smoking ban (Supplementary Table 4).

#### National estimate of the indoor smoking status of all restaurants and bars in Japan

The estimated national proportion of “no smoking” in all establishments before the enforcement was 54.5% and 69.4% after. When we divided establishments by legal regulation status, 30% of regulated establishments continued to be “separate smoking or smoking” after the enforcement despite the legal requirement that they ban indoor smoking. If compliance with the legislation had been complete and all regulated establishments had changed to “no smoking” as an ideal situation, the estimated national proportion of “no smoking” would have been 85.8% after the enforcement (Table 2, Fig. 4, Supplementary Table 5, Supplementary Fig. 6).

In addition, the estimated national proportion of “no smoking” in establishments that mainly served meals changed from 59.1% to 75.3% after the enforcement, and the estimated ideal proportion of “no smoking” when full legal compliance was achieved was 90% (Supplementary Table 6, Supplementary Fig. 7-A, B). The estimated national proportion of “no smoking” in establishments that mainly served alcohol changed from 43.9% to 51.5%, and the estimated ideal national proportion of “no smoking” when full legal compliance was achieved was 73.4% (Supplementary Table 6, Supplementary Fig. 7-C, D).

#### Discussion

To our knowledge, this is the first study to report on indoor smoking status before and after the enforcement of the law to focus on both unregulated and regulated

establishments in Japan. Among the unregulated establishments that were “separate smoking or smoking” before the enforcement, more actually changed to “no smoking” after the enforcement than had originally expressed an intention to change. In contrast, almost 80% of the regulated establishments that were “separate smoking or smoking” before the enforcement became illegal afterwards as they maintained “separate smoking or smoking” status. In this study, we found that smoking bans were increasingly in operation in unregulated restaurants and bars; in contrast, indoor smoking was continuing in regulated establishments. The fact that smoking is continuing after the enforcement in regulated restaurants and bars may be a serious issue for public health. These findings may indicate shortcomings in communication of the law to restaurants and bars, and inadequate implementation of the law, which might have been exacerbated by the COVID-19 pandemic. It is necessary to ascertain, in detail, the reasons for bar or restaurant owners not changing their indoor smoking status, the degree of understanding of the current legislation, and the extent to which smoking rooms are still included in restaurants and bars. These findings can then be used to assist in the enforcement of comprehensive anti SHS legislation in Japan.

In our results, the proportion of all nonresponding restaurants and bars about indoor smoking status in 2019 and 2020 was 11.0% (86/779). If all non-respondents were “separate smoking or smoking”, the proportion of “no smoking” was 5.1% lower in 2019 and 2.0% lower in 2020 than the observed proportion. Therefore, the proportion of “no smoking” may have been overestimated compared with the actual proportion of “no smoking”.

According to the national estimate of indoor smoking status in Japan, establishments that mainly served alcohol made less progress in changing to “no smoking”. The estimated national proportion of “no smoking” in all mainly alcohol establishments was lower than in all mainly meals establishments. There was 23.8% difference in “no smoking” between mainly meals and mainly alcohol establishments in the current situation after the enforcement, and 16.6% difference in “no smoking” in the ideal situation after the enforcement. Since unregulated establishments can freely select indoor smoking status, little progress has been made in terms of voluntary smoking bans in the mainly alcohol establishments but the proportion of “no smoking” after the enforcement was higher in the unregulated mainly meals establishments. In addition, although all regulated establishments were required to impose an indoor smoking ban by the legislation, many did not comply. The proportion of regulated establishments which did not change smoking status was higher in mainly alcohol

**Table 2** National estimate of indoor smoking status before/after the enforcement. National estimate of no smoking (%) and separate or smoking (%) before the enforcement (2019)

| Location                                                                                     | Regulation by law | Number of establishments in Table-log $T_i$ | Expected % of regulated or unregulated establishments $R_j$ | Expected number of establishments $T_i * R_j$ | Expected % of establishments $w_{ij} = T_i * R_j / T$     | No smoking (%) before the enforcement observed in this study (2019) $P_{ijys}$ | National estimate of no smoking (%) before the enforcement (2019) $SPISS_{ys}$ | Separate smoking or smoking (%) before the enforcement observed in this study (2019) $P_{ijys}$ | National estimate of separate smoking or smoking (%) before the enforcement (2019) $SPISS_{ys}$ |
|----------------------------------------------------------------------------------------------|-------------------|---------------------------------------------|-------------------------------------------------------------|-----------------------------------------------|-----------------------------------------------------------|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Tokyo                                                                                        | unregulated       | $T_0$ : 129553                              | $R_0$ : 0.2                                                 | $T_0 * R_0$ : 25910.6                         | $w_{00}$ : 0.03                                           | $P_{0000}$ : 0.65                                                              | $P_{0000} * w_{00}$ : 0.02                                                     | $P_{0001}$ : 0.35                                                                               | $P_{0001} * w_{00}$ : 0.01                                                                      |
|                                                                                              | regulated         |                                             | $R_1$ : 0.8                                                 | $T_0 * R_1$ : 103642.4                        | $w_{01}$ : 0.13                                           | $P_{0100}$ : 0.62                                                              | $P_{0100} * w_{01}$ : 0.08                                                     | $P_{0101}$ : 0.38                                                                               | $P_{0101} * w_{01}$ : 0.05                                                                      |
| 46 prefectures other than Tokyo                                                              | unregulated       | $T_1$ : 694659                              | $R_0$ : 0.5                                                 | $T_1 * R_0$ : 347329.5                        | $w_{10}$ : 0.42                                           | $P_{1000}$ : 0.50                                                              | $P_{1000} * w_{10}$ : 0.21                                                     | $P_{1001}$ : 0.50                                                                               | $P_{1001} * w_{10}$ : 0.21                                                                      |
|                                                                                              | regulated         |                                             | $R_1$ : 0.5                                                 | $T_1 * R_1$ : 347329.5                        | $w_{11}$ : 0.42                                           | $P_{1100}$ : 0.56                                                              | $P_{1100} * w_{11}$ : 0.24                                                     | $P_{1101}$ : 0.44                                                                               | $P_{1101} * w_{11}$ : 0.19                                                                      |
| Total                                                                                        |                   |                                             |                                                             | $T$ : 824212                                  | 1.00                                                      | <b><math>SPISS_{00}</math>: 0.55</b>                                           |                                                                                | <b><math>SPISS_{01}</math>: 0.45</b>                                                            |                                                                                                 |
| National estimate of no smoking (%) and separate or smoking (%) after the enforcement (2020) |                   |                                             |                                                             |                                               |                                                           |                                                                                |                                                                                |                                                                                                 |                                                                                                 |
| Location                                                                                     | Regulation by law | Number of establishments in Table-log $T_i$ | Expected % of regulated or unregulated establishments $R_j$ | Expected number of establishments $T_i * R_j$ | Expected % of the establishments $w_{ij} = T_i * R_j / T$ | No smoking (%) after the enforcement observed in this study (2020) $P_{ijys}$  | National estimate of no smoking (%) after the enforcement (2020) $SPISS_{ys}$  | Separate smoking or smoking (%) after the enforcement observed in this study (2020) $P_{ijys}$  | National estimate of separate smoking or smoking (%) after the enforcement (2020) $SPISS_{ys}$  |
| Tokyo                                                                                        | unregulated       | $T_0$ : 129553                              | $R_0$ : 0.2                                                 | $T_0 * R_0$ : 25910.6                         | $w_{00}$ : 0.03                                           | $P_{0010}$ : 0.76                                                              | $P_{0010} * w_{00}$ : 0.02                                                     | $P_{0011}$ : 0.24                                                                               | $P_{0011} * w_{00}$ : 0.01                                                                      |
|                                                                                              | regulated         |                                             | $R_1$ : 0.8                                                 | $T_0 * R_1$ : 103642.4                        | $w_{01}$ : 0.13                                           | $P_{0110}$ : 0.68                                                              | $P_{0110} * w_{01}$ : 0.09                                                     | $P_{0111}$ : 0.32                                                                               | $P_{0111} * w_{01}$ : 0.04                                                                      |
| 46 prefectures other than Tokyo                                                              | unregulated       | $T_1$ : 694659                              | $R_0$ : 0.5                                                 | $T_1 * R_0$ : 347329.5                        | $w_{10}$ : 0.42                                           | $P_{1010}$ : 0.67                                                              | $P_{1010} * w_{10}$ : 0.29                                                     | $P_{1011}$ : 0.32                                                                               | $P_{1011} * w_{10}$ : 0.13                                                                      |
|                                                                                              | regulated         |                                             | $R_1$ : 0.5                                                 | $T_1 * R_1$ : 347329.5                        | $w_{11}$ : 0.42                                           | $P_{1110}$ : 0.71                                                              | $P_{1110} * w_{11}$ : 0.30                                                     | $P_{1111}$ : 0.29                                                                               | $P_{1111} * w_{11}$ : 0.12                                                                      |
| Total                                                                                        |                   |                                             |                                                             | $T$ : 824212                                  | 1.00                                                      | <b><math>SPISS_{10}</math>: 0.69</b>                                           |                                                                                | <b><math>SPISS_{11}</math>: 0.31</b>                                                            |                                                                                                 |

$SPISS_{ys}$  was the estimated proportion of nationwide indoor smoking status in restaurants and bars in Japan before/after the enforcement

$i$  indicates location:  $i=0$  is Tokyo and  $i=1$  is 46 prefectures other than Tokyo

$j$  indicates the regulated status by law:  $j=0$  is unregulated and  $j=1$  is regulated

$y$  indicates survey point in time:  $y=0$  is 2019, and  $y=1$  is 2020

$s$  indicates indoor smoking status:  $s=0$  is no smoking and  $s=1$  is separate smoking or smoking

than in mainly meals establishments. These results might suggest the decision to create a smoke-free environment depended on whether or not the establishment served alcohol. Furthermore, these results suggest that under the current Japanese law that permits establishments to remain unregulated, it is difficult to make progress in making all bars and restaurants “no smoking”.

Previous studies indicated that never or former smoker owners or employees in restaurants and bars were more likely to have a positive attitude towards the smoke-free legislation [12, 13]. Hence, the smoking status of owners would affect with the decision regarding indoor smoking status. The promotion of “no smoking” in unregulated establishments may also be associated

with the owner’s own smoking status or the service category of the establishment.

We found more restaurants and bars which serve mainly alcohol in the “staying separate or smoking” category than in the “changing from separate smoking or smoking to no smoking” in this study. Previous studies have shown that smoking bans were more prevalent in the mainly meals than the mainly alcohol restaurants and bars [14, 15], and the present study found similar results. Indoor smoking is common in bars or pubs, and owners would be concerned about the possible reduction of customers or sales that would result from an indoor smoking ban [16]. In Japan, the mainly alcohol restaurants and bars have traditionally been regarded as places where smoking is socially acceptable [15]. It appears that

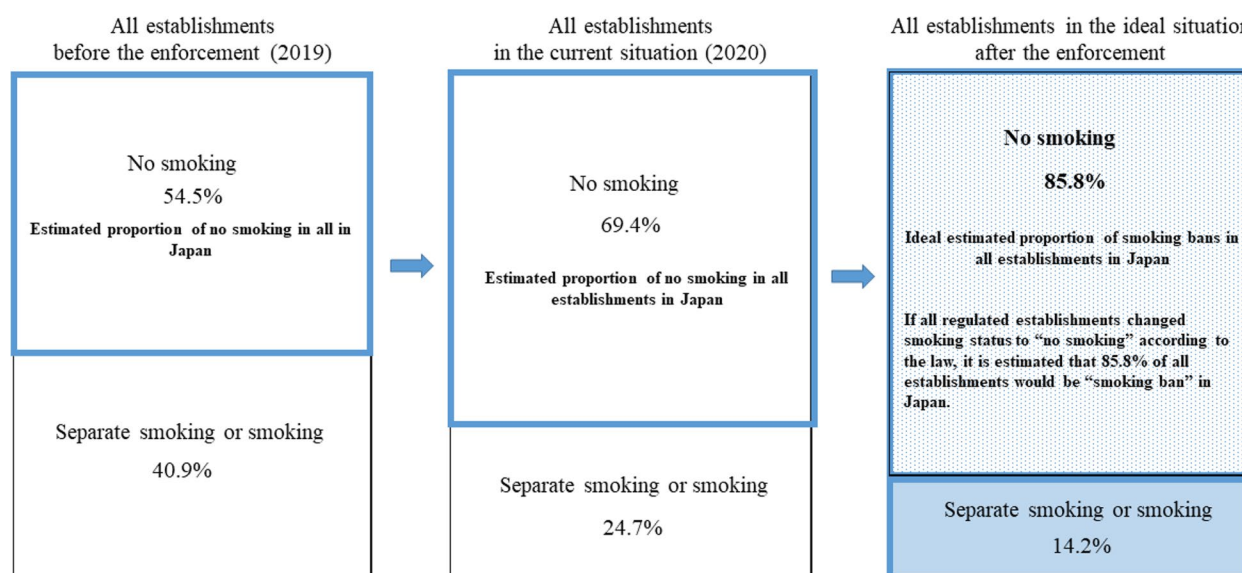


**Fig. 4** National estimate of indoor smoking status in all restaurants and bars before/after the enforcement. Estimated proportion of indoor smoking status before/after the enforcement was calculated by summing up the value of multiplying "Proportion of number of establishments in the Tabelog" by "Proportion of establishments in this study that were observed as no smoking, separated or smoking" before/after the enforcement. Ideal estimated proportion of smoking status in the ideal situation after the enforcement was estimated using the proportion assuming all regulated establishments changed "No smoking" and the national estimated proportion of "No smoking" in the unregulated establishments

voluntary smoking bans in unregulated, mainly alcohol establishments may be less aggressively promoted than other service categories.

The reality that we observed was that almost 80% of the regulated restaurants and bars that were required to change to "no smoking" by law did not change. The restaurants and bars that kept "separate smoking" or "smoking" contrary to the law, were more likely to serve alcohol and allow HTPs in their seating areas than those restaurants and bars in "staying no smoking" or "staying separate or smoking". It has been indicated that many owners of restaurants or bars where alcohol can be consumed did not comply with the law regarding smoking bans. Reluctance to comply with the ban has been evident in many countries; in the face of forthcoming smoking bans, bar and restaurant owners in Ireland, Canada, and United States used scaremongering tactics (including fear of breaking the law and loss of employment for hospitality sector workers) to try to prevent the ban [17]. Furthermore, the partial Japanese law allows the establishment of heated tobacco smoking rooms, where eating and drinking are allowed, even in restaurants and bars that are regulated by the law. Therefore, it is possible that these restaurants and bars have chosen not to change to a completely smoke-free environment. We found that establishments meeting regulation criteria are allowed to operate as a "smokers' lounge" if their primary purpose is smoking and face-to-face sales of tobacco products, and

if it is limited to serving light meals and alcohol (Supplementary Fig. 1). Therefore, some regulated establishments may have changed their business designation to smokers' lounge in order to continue operating even if the law requires them to change to an indoor smoking ban. Also, under the law, unregulated establishments can set up smoking rooms/areas [7]. However, regulated establishments may mistakenly believe that their establishments are unregulated by law and choose to have smoking rooms/areas without notifying the government. Second, almost 30% of owners of restaurants and bars reported not fully understanding the revised Health Act or Tokyo Metropolitan Ordinance to prevent SHS exposure in the survey in Tokyo [18] and Osaka prefectures [19]. In this study, almost 30% of all establishments that had to change to "no smoking" were non-compliant with the law, which echoed the results of previous surveys. Previous studies indicated that a lower level of knowledge about the smoke-free legislation was associated with maintaining separate indoor smoking areas in restaurants and bars [20]. Third, it is possible that owners of restaurants and bars are knowingly not complying. Minimal sanctions and inadequate regulation have been considered as impediments to widespread smoking bans in previous studies [21, 22]. In Japan, there are penalties for violation of the anti SHS legislation but these are basically warnings, not immediate business suspensions or fines. In addition, monitoring is carried out only through

reports from the general public, and not by governments. Furthermore, Japan's smoke-free legislation is partial, and this may be associated with the non-compliance. It has been reported that the prevalence of illegal in-bar smoking was higher in countries with partial smoke-free legislation than in countries with comprehensive legislation [23]. If the competing restaurants and bars that were not regulated by legislation continue to allow indoor smoking, the regulated establishments may not change their indoor smoking status, for fear of losing custom and sales [22].

Enforcement of the law in Japan coincided with the COVID-19 pandemic. Therefore, restaurants and bars that were negatively affected by the economic impact of COVID-19 may have been concerned that the smoking ban would further drive away customers. However, it is already clear that the implementation of the smoke-free law does not have any economic impact on restaurants and bars [24–26]. Therefore, now that four years have passed since the pandemic, it is necessary to communicate again with the regulated restaurants and bars and take action to allay their concerns about economic impact.

Under the partial law in Japan, it may be difficult to achieve total smoking bans in restaurants and bars. It has been pointed out that the exceptions to legal regulations may cause confusion in understanding and complying with the law, which may eventually lead to noncompliance [27, 28]. Additionally, voluntary smoke-free policies based on the self-judgement of restaurants and bars that are exceptions to the law are not effective and the adoption of effective legislative, executive or administrative measures is necessary [6, 29]. Furthermore, the establishment of smoking rooms permitted by the law also prevents total smoking bans in restaurants and bars. The elimination of tobacco smoke must be absolute to create a comprehensively smoke-free environment. The smoking rooms, ventilation or air filtration advocated by the tobacco industry have not been effective, and have reduced the effectiveness of smoke-free areas in restaurants and bars. Japanese law has hampered the achievement of completely smoke-free restaurants and bars and in some cases allowed HTPs use in the same room as eating and drinking customers.

It has been reported that second-hand aerosol exposure from HTPs is associated with both asthma attacks/asthma-like symptoms and persistent cough in non-smokers [30]. It has further been suggested that HTPs may cause health hazards similar to those of tobacco. The current Japanese law permitting the establishment of HTPs smoking rooms in restaurants and bars is unlikely to protect the health of employees, and strong regulation of HTPs use is needed. It has also been reported that

countries with partial laws are less likely to achieve adult smoking cessation than those with comprehensive laws [24, 29, 31]. The fact that smoking rates have not declined may suggest lower support for, and compliance with, the law among smokers in Japan than in countries with comprehensive laws.

It is already clear worldwide that the comprehensive law maximizes the effectiveness of smoking bans. Enforcement of the law has improved respiratory symptoms and lung function among bartenders, a job category vulnerable to SHS exposure [2]. While the observed nicotine concentration decreased in establishments that were made smoke-free by law, the observed concentration in bars and restaurants that were exempt from legal regulation was very high, indicating a very high risk of SHS exposure for those who work in these restaurants and bars [27]. A previous study conducted in six European countries revealed that SHS exposure in public places, including restaurants was lower in countries with comprehensive laws than in countries with partial laws [29].

It has been suggested that there are two approaches to the successful enforcement of such comprehensive laws: the first is to build voluntary compliance, which involves awareness-raising strategies such as educational campaigns; the second is a proactive approach, which involves monitoring compliance and imposing penalties and sanctions on violators [28, 32].

Japanese law, which has approaches such as the creation of smoking rooms, is unlikely to prevent SHS exposure and smoking-related disease among employees, as shown in previous studies in other countries; as long as the law is partial, it is expected that it would be difficult to make progress in creating entirely smoke-free restaurants and bars. Following the example of Spain, where a comprehensive law was enforced sometime after a partial law which allowed smoking rooms in restaurants and bars, Japan needs to revise its law as soon as possible, to end legal exemptions which make it possible for restaurants and bars to allow indoor smoking. In addition, it is necessary not only to simply improve the law, but also to conduct awareness-raising activities, to monitor compliance, strengthen penalties by administrative intervention, and to enhance communication to gain policy support so that the law can be fully enforced and the compliance rate increased, as indicated as a strategy."

### Strengths and limitations

We have reported the impact of the revised Health Promotion Act or the Tokyo Metropolitan Ordinance to prevent SHS exposure on smoking bans in restaurants and bars in Japan for the first time. The revised law will be reviewed by the government in 2025. The results of this study indicate problems of smoking bans in restaurants

and bars due to the limited regulation by the current law and provide important evidence for discussion with policy makers for a review of the law.

However, there are several limitations to this study. First, the survey response rate was only 14.3% before the enforcement and 23.2% after. This may indicate that the responses came primarily from owners who were interested in smoking bans. If so, among the establishments that did not answer, there may be a considerable number of restaurants and bars that will continue to allow indoor smoking. Thus, the proportion of “no smoking” in unregulated restaurants and bars may be lower than found in this study. Second, there were potential errors due to the self-completion of the questionnaire which could affect the validity and reliability of the results, especially for indoor smoking status. Third, the revised laws or ordinances were implemented during the COVID-19 pandemic era. The impact of this pandemic on the determination of indoor smoking status in restaurants and bars would be difficult to examine, as it requires comparison with a hypothetical situation in which there was no COVID-19 pandemic. Fourth, the present study was based on self-administered questionnaire survey responses by owners only. The opinions of employees or customers regarding smoking bans in restaurants and bars could not be ascertained. Moreover, there is no objective assessment of the extent to which owners, employees, or customers are actually exposed to SHS such as levels of nicotine and particulates in the breath, and cotinine in saliva, urine, and hair. In order to clarify the impact of the partial law on people’s support for smoking bans and on the health on employees and others, it is necessary to conduct further surveys with a wide range of subjects and to evaluate SHS exposure from both subjective and objective perspectives in the future.

## Conclusion

The current implementation of indoor smoking bans in restaurants and bars is progressing in a higher proportion of establishments than planned before the enforcement. On the other hand, we observed restaurants and bars that have not implemented a ban despite being legally required to do so. These findings indicate that the details of the law may not have been adequately communicated to restaurants and bars and that the legislation is inadequate and its enforcement insufficient. In order to progress the indoor smoking bans in all restaurants and bars, it may be important to communicate the details of the legislation more insistently and in easily understood language. Also, further examination of the detailed factors that advance or hinder indoor smoking bans in restaurants and bars is necessary. We need to continue to monitor indoor smoking status, and to discuss the necessity

of implementing comprehensive regulation in Japan with policy makers, researchers, owners and employees in restaurants and bars. This approach will enable us to share the issues related to understanding or complying with the current legislation, and to consider effective revisions to the law or ordinance regarding SHS exposure in restaurants and bars with policy makers.

## Abbreviations

|          |                                                                   |
|----------|-------------------------------------------------------------------|
| SHS      | Secondhand smoke                                                  |
| WHO FCTC | World Health Organization Framework Convention on Tobacco Control |
| HTPs     | Heated tobacco products                                           |

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12889-024-20765-6>.

Additional file 1: Appendix 1. Survey on the Impact on Restaurants or Bars of Strengthened Passive Smoking Countermeasures. This file was the questionnaire used in the first survey conducted in February–March 2020.

Additional file 2: Appendix 2. Survey on stores management and environmental improvements associated with COVID-19 pandemic. This file was the questionnaire that was used in the second survey conducted in March 2021. These questionnaires were sent to 809 restaurants and bars that responded to the first survey and were still running in 2021.

Additional file 3: Appendix 3. Survey on stores management and environmental improvements associated with COVID-19 pandemic. This file was the questionnaire used in the second survey conducted in March 2021. These questionnaires were sent to 2,800 restaurants and bars that were still in operation in 38 cities in Tokyo, Osaka, and Aomori prefectures, which were newly added to the second survey conducted in March 2021.

Additional file 4: Appendix 4. How did we estimate national indoor smoking status in restaurants and bars? In this file, we describe the detailed method of the estimation of national indoor smoking status in restaurants and bars in Japan.

Additional file 5: Supplementary Fig. 1. Signs explaining indoor smoking status, especially establishments that do not choose to be completely smoke-free indoors. This figure explains signs about indoor smoking status that restaurants and bars post on their storefronts.

Additional file 6: Supplementary Fig. 2. Changes in indoor smoking status for all restaurants and bars before and after the enforcement of the smoke-free legislation. This figure shows the changing indoor smoking status in all restaurants and bars in this survey before and after the enforcement.

Additional file 7: Supplementary Fig. 3. Changes in indoor smoking status for the unregulated restaurants and bars before and after the enforcement of the smoke-free legislation. This figure shows the more detailed changing indoor smoking status in the unregulated restaurants and bars in this survey before and after the enforcement than Fig. 2.

Additional file 8: Supplementary Fig. 4. Indoor smoking status of planned before the enforcement and of actual status after the enforcement. This figure shows the indoor smoking status that the separated or smoking restaurants and bars were considering before the enforcement of smoke-free legislation and the indoor smoking status that they actually implemented after the enforcement.

Additional file 9: Supplementary Fig. 5. Changes in indoor smoking status for the regulated restaurants and bars before and after the enforcement of the smoke-free legislation. This figure shows the more detailed changing indoor smoking status in the regulated restaurants and bars in this survey before and after the enforcement than Fig. 3.

Additional file 10: Supplementary Fig. 6. National estimate of indoor smoking status in all restaurants and bars by regulation status before/after the

enforcement. This figure shows the national estimation of indoor smoking status in both the regulated and unregulated restaurants and bars before and after the enforcement in Japan.

Additional file 11: Supplementary Fig. 7-A. National estimate of indoor smoking status in restaurants and bars that mainly served meals before/after the enforcement. Supplementary Fig. 7-B. National estimate of indoor smoking status in all restaurants and bars that mainly served meals by regulation status before/after the enforcement. Supplementary Fig. 7-C. National estimate of indoor smoking status in restaurants and bars that mainly served alcohol before/after the enforcement. Supplementary Fig. 7-D. National estimate of indoor smoking status in all restaurants and bars that mainly served alcohol by regulation status before/after the enforcement. These figures represent the national estimation of indoor smoking status in restaurants or bars, based on the service categories and the regulated or unregulated by law.

Additional file 12: Supplementary Table 1-A. Proportion of no smoking in restaurants and bars observed in the present study and calculated in the sensitivity analysis. Supplementary Table 1-B. Proportion of changing indoor smoking status in restaurants and bars observed in the present study and calculated in the sensitivity analysis. This table shows the proportion of "no smoking" and the proportion of changing indoor smoking status in restaurants and bars observed in this study and calculated in the sensitivity analysis.

Additional file 13: Supplementary Table 2. Differences in characteristics of the unregulated restaurants and bars regarding changes in indoor. This table shows the detailed characteristics of the unregulated restaurants and bars.

Additional file 14: Supplementary Table 3 (xlsx): Differences in characteristics of the regulated restaurants and bars regarding changes in indoor.

This table shows the detailed characteristics of the regulated restaurants and bars based on the changing indoor smoking status.

Additional file 15: Supplementary Table 4. Smoking status of owners before the enforcement and changing indoor smoking status before and after the enforcement in the unregulated restaurants and bars. This table shows the smoking status of owners in the unregulated restaurants and bars before the enforcement of the law based on the changing indoor smoking status.

Additional file 16: Supplementary Table 5-A. National estimate of no smoking (%) and separate smoking or smoking (%) by regulation before the enforcement (2019). Supplementary Table 5-B. National estimate of no smoking (%) and separate smoking or smoking (%) by regulation before the enforcement (2020). These tables show the results of national estimation of indoor smoking status in Japan before and after the enforcement of the law.

Additional file 17: Supplementary Table 6-A. National estimate of no smoking (%) and separate smoking or smoking (%) by service category before/after the enforcement. Supplementary Table 6-B. National estimate of no smoking (%) and separate smoking or smoking (%) by service category and regulation by law before/after the enforcement. These tables show the results of national estimation of indoor smoking status in Japan based on the service category and the regulated or unregulated by law.

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## Authors' contributions

AK, IM, and YI conceived the study and collected the data, and MN supervised the project. AK analyzed the data and all authors contributed to the interpretation of the results. AK wrote the report supported by all authors, and all authors read and approved the final manuscript.

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## Data availability

The datasets used during the current study are available from the corresponding author on reasonable request.

## Declarations

### Ethics approval and consent to participate

The "Ethical Guidelines for Medical and Health Research Involving Human Subjects" were not applicable to this study as the subjects were restaurants and bars not human subjects, and ethics approval and informed consent was waived by institutional review board of Osaka University: Ethical Review Board Osaka University Hospital.

In the first page of the questionnaire, we explained the purpose of this study, stated that cooperation in the survey was voluntary and considered as agreement to participate of the survey. In addition, we included the contact information so that we could respond to inquiries and refusals to respond. Information on each restaurant and bar was handled on personal computers with appropriate security measures such as setting passwords and installing security software, so that no disadvantage would arise from this study.

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.

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## 資 料

## 加熱式タバコの喫煙者の尿中コチニン値の評価：ELISA 法の有効性

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**目的** 尿中コチニン濃度は、喫煙者の喫煙状況を客観的に評価するための信頼性の高いバイオマーカーとして広く利用されている。その測定には、液体クロマトグラフィー質量分析法（LC-MS 法）やガスクロマトグラフィー質量分析法（GC-MS 法）といった高精度な手法が主に使用されているが、高額な機器や専門的な分析技術を要するため大規模調査には不向きである。一方、LC-MS 法と GC-MS 法に匹敵する精度を持つ、簡便かつ低コストの酵素免疫測定法（ELISA 法）が注目されている。ELISA 法は紙巻タバコの喫煙者の尿中コチニン値の評価で有用性が示されているが、加熱式タバコへの適用については検討されていない。本研究は、加熱式タバコ使用者の尿中コチニン濃度を測定し、ELISA 法が LC-MS 法と同等に有効であるかを検証することを目的とした。

**方法** 某事業場で勤務する労働者を対象に、平日の昼休み中に尿を採取した。「非喫煙者」11人、「紙巻タバコのみ喫煙者」13人、「加熱式タバコのみ喫煙者」9人の計33人を解析対象とし、尿中コチニン濃度を LC-MS 法および ELISA 法で測定した。両手法の測定値の相関をピアソン相関係数で評価し、一致性をブランド・アルトマンプロットで検討した。

**結果** ELISA 法と LC-MS 法の測定結果は高い相関を示し（紙巻タバコのみ喫煙者： $r = 0.84$ ,  $P < 0.001$ ；加熱式タバコのみ喫煙者： $r = 0.96$ ,  $P < 0.001$ ），ブランド・アルトマンプロットでは概ね高い一致性が得られ、両手法間のデータの90.9%は一致限界内に収まった。

**結論** ELISA 法は、紙巻タバコのみならず加熱式タバコ使用者の尿中コチニン値の評価においても有用であることが示された。その簡便性と低コスト性より、大規模疫学調査や職場での喫煙対策における応用が期待される。

**Key words**：加熱式タバコ，尿中コチニン，酵素免疫測定法(ELISA法)，液体クロマトグラフィー質量分析法（LC-MS 法）

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## I 緒 言

タバコの使用は、喫煙者本人だけでなく、その周囲の人々にも深刻な健康リスクをもたらすことが広く知られている。従来の紙巻きタバコの喫煙は、肺がんや心血管疾患、呼吸器疾患など多くの疾患の主要な原因であり、また受動喫煙による健康被害も大

きな社会問題となっている。

近年では、加熱式タバコ（Heated Tobacco Products；HTPs）などの新たなタバコ製品が市場に急速に普及している。令和4年国民健康・栄養調査結果によると、現在喫煙している者の男性の30.1%、女性の34.4%が加熱式タバコを使用している<sup>1)</sup>。とくに20代の女性喫煙者の85.7%は加熱式タバコを使用していることが分かった。メーカーは、加熱式タバコについて、紙巻きタバコと比べ、発生する有害性成分の量が平均で90～95%低減されていると主張している<sup>2)</sup>。しかしながら、加熱式タバコ的主流煙中のニコチン濃度はレギュラーで $1.1 \pm 0.1$  mg/cig, メンソールで $1.2 \pm 0.1$  mg/cig で、紙巻きタバコは高タールで $1.7 \pm 0.1$  mg/cig, 低タールで

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1.0 ± 0.1 mg/cig とほぼ同じである<sup>3)</sup>。また、タバコ産業の調査において、ヒトが実際に加熱式タバコと紙巻きタバコを1回使用した際、血中ニコチン濃度の最大値はそれぞれ8.4 (95% CI: 6.8, 10.3) ng/mL と11.9 (95% CI: 9.5, 14.9) ng/mL で、最大値に達するまでの時間はどちらも約8分で、顕著な差はなかったことが示されている<sup>4)</sup>。さらに、加熱式タバコの主流煙には、多くの種類の有害化学物質が含まれることから<sup>5)</sup>、加熱式タバコの利用者やその周囲の人々への健康リスクが懸念されている。

コチニンはタバコに含まれるニコチンが体内で代謝された後に生じる物質であり、その濃度はタバコ煙への曝露量を反映するとされている。そのため、尿中コチニン濃度は喫煙者の喫煙状況を客観的に評価するための信頼性の高いバイオマーカーとして広く利用されてきた<sup>6)</sup>。尿中コチニン濃度を測定するための分析手法としては、液体クロマトグラフィー質量分析法 (LC-MS 法) やガスクロマトグラフィー質量分析法 (GC-MS 法) といった高精度な技術が標準的に用いられている<sup>7,8)</sup>。これらの手法は、コチニンを高感度かつ高特異的に検出することが可能であり、精密な評価を行う上で欠かせない手段である。しかし、これらの手法には高額な機器を必要とし、分析には専門的な技術が求められるため、利用可能な施設に限られる。また、試料の前処理に約15時間を必要とすること、1検体あたりの測定費用が高額であることが課題である<sup>9-11)</sup>。とくに、大規模調査における使用には不向きであるとの指摘もある。

これらの背景から、簡便かつ低コストで測定が可能な手法として、酵素免疫測定法 (ELISA 法) が注目されている。ELISA 法は、簡易的な設備で測定が可能であり、大規模な集団調査や臨床現場での使用に適しているとされている<sup>12)</sup>。先行研究では、ELISA 法が GC-MS 法に匹敵する精度を持つことが示されており、紙巻きタバコの喫煙者の尿中コチニンの評価においてその有用性が認められている<sup>13)</sup>。しかし、加熱式タバコによる曝露評価については研究がまだ行われていない。

本研究の目的は、加熱式タバコ利用者の尿中コチニン濃度を測定し、ELISA 法が LC-MS 法と同様に有効であるかを検証することである。これにより、従来の紙巻きタバコだけでなく、加熱式タバコの曝露を評価する際に、より簡便かつコスト効率の高い測定法を確立することを目指している。加熱式タバコの普及が進む中で、大規模調査にも応用可能なタバコ煙への曝露評価の手法を開発することは、今後の公衆衛生政策や喫煙対策の推進において極めて重要であると考えられる。

## Ⅱ 方 法

### 1. 対象者

某事業場で勤務する日本人労働者549人を対象とし、研究の趣旨を説明し、同意を得た労働者60人を対象とした。平日の昼休み中に尿を採取し、普段の喫煙状況 (非喫煙、元喫煙、現喫煙) をグーグルフォームを用いた自記式質問票への記入を依頼した。また、尿中コチニンの半減期は約20時間とされているため<sup>14)</sup>、尿採取の直前24時間以内の喫煙状況も調べた。先行研究<sup>13)</sup> で報告された相関係数 ( $r=0.63$ ) を参考に、検出力0.8、有意水準0.05で相関係数  $r=0.7$  を検出するには約13人が必要と算出された。研究協力者の確保 (手上げ方式の依頼) や、LC-MS 法による設備、測定技術、時間と費用などの制約から、「非喫煙者」11人、「紙巻きタバコ喫煙者」13人、「加熱式タバコ利用者」9人、の計33人を解析対象とした。

### 2. 尿中コチニン値の測定方法

ニコチンは肝臓で代謝されてコチニンや他の代謝物 (trans-3'-ヒドロキシコチニン (3-HC)、3-HC グルクロン酸抱合体等) に変換され、これらが尿中に排泄される。ニコチンの主要代謝経路は図1で示している。

対象者から採取した尿検体を2つに分割し、それぞれ LC-MS 法と ELISA 法で測定を行った。ELISA 法はコチニン測定 ELISA キット (株式会社コスミックコーポレーション、東京、日本) を用いた。LC-MS 法の測定には、超高速液体クロマトグラフ (UHPLC) UltiMate 3000 (Thermo Fisher Scientific、横浜、日本) とハイブリッド四重極オービトラップ質量分析計 Q Exactive Focus (Thermo Fisher Scientific、横浜、日本) を使用し、LC-MS/MS モードで測定した<sup>9-11)</sup>。ELISA 法で用いられる抗体は、尿中コチニンに加えて 3-HC、3-HC グルクロン酸抱合体とも反応することが知られている<sup>13)</sup> ことから、LC-MS 法で測定されたコチニン、3-HC、3-HC グルクロン酸抱合体の値を用いて、以下の式でニコチン代謝物濃度を算出した<sup>13)</sup>。

ニコチン代謝物濃度

$$= \text{コチニン} + 1.013 \times (3\text{-HC}) + 2.218 \times (3\text{-HC グルクロン酸抱合体})$$

以下、ELISA 法の結果と、LC-MS 法の結果から算出したコチニン代謝物濃度を尿中コチニン値として比較し、両手法の一致性を評価した。

### 3. データの分析

尿中コチニン濃度を喫煙状況「非喫煙者」「紙巻きタバコ喫煙者」「加熱式タバコ利用者」で分類

図1 ニコチンの主要代謝経路

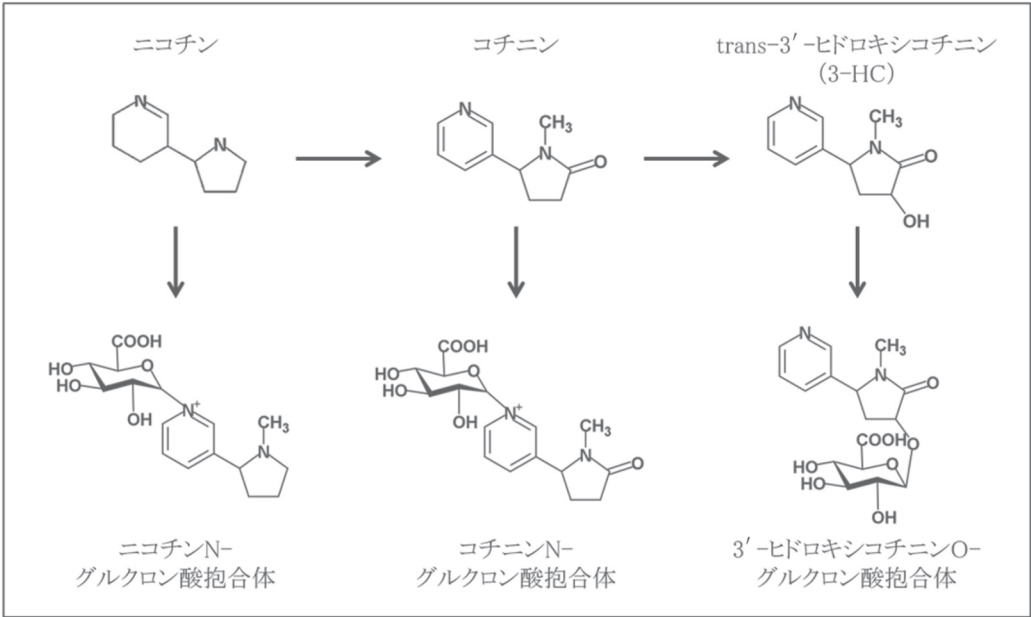


表1 喫煙状況別の ELISA 法と LC-MS 法による尿中コチニン値 (ng/mL)

|           | 人数 | ELISA 法        |               | LC-MS 法        |               |
|-----------|----|----------------|---------------|----------------|---------------|
|           |    | 平均±標準偏差 (値の範囲) |               | 平均±標準偏差 (値の範囲) |               |
| 非喫煙者      | 11 | 1.82±0.40      | (1.30～2.50)   | 0.82±0.79      | (0.13～2.62)   |
| 紙巻きタバコ喫煙者 | 13 | 6,084±3,514    | (884～11,746)  | 4,344±1,527    | (1,540～6,228) |
| 加熱式タバコ使用者 | 9  | 4,626±3,244    | (1,040～8,843) | 3,369±1,634    | (1,200～5,326) |

し、各群ごとに分析を行った。ELISA 法および LC-MS 法による測定結果間の相関をピアソン相関係数を用いて解析した。さらに、両測定法間の一致性をブランド・アルトマン分析を用いて評価した。統計解析には JMP Pro 18 (SAS Institute 社) を使用し、有意水準は 5 % とした。

4. 倫理的配慮

本研究は、産業医科大学倫理審査委員会の承認を得て実施し（承認番号 ER23-027号，承認日：2023 年 9 月 26 日；承認番号 R1-037号，承認日：2019 年 11 月 1 日），すべての参加者から文書で研究参加の同意を得て実施した。

Ⅲ 報告内容

非喫煙者11人の平均尿中コチニン値は、ELISA 法で1.82 ng/mL，LC-MS 法で0.82 ng/mLであった。紙巻きタバコの喫煙者13人では、ELISA 法で6,084 ng/mL，LC-MS 法で4,344 ng/mLであった。加熱式タバコの喫煙者 9 人では、ELISA 法で4,626 ng/mL，LC-MS 法で3,369 ng/mLであった（表 1）。紙巻きタバコのみ喫煙者および加熱式タバコのみ喫煙者での ELISA 法と LC-MS 法による尿中コチニン値の相関を図 2 で示した。ピアソン相関係数は、紙巻きタバコのみ喫煙者で0.84，加熱式タバコのみ喫煙者で0.96，両方ともに高い相関を示した（ $P<0.001$ ）。両測定法間の一致性を評価したブランド・アルトマンプロットを図 3 に示した。両測定法の平均差（バイアス）は1,029 ng/mLであり、一致限界は、−2,619 ng/mL から4,677 ng/mL の範囲で、データの90.9% が一致限界内に含まれていた。

Ⅳ 考 察

ELISA 法と LC-MS 法の測定値は高い相関を示し、とくに加熱式タバコの喫煙者での相関係数が0.96と非常に高かった。また、ブランド・アルトマンプロットによる一致性評価の結果、両手法は概ね高い一致性を示したことから、ELISA 法は従来の紙巻きタバコのみならず、加熱式タバコにおいても有効な曝露評価法であることが示された。ELISA 法の低コスト性と簡便性は、加熱式タバコの大規模調査や職場での喫煙者の評価において重要な手法であることが分かった。ELISA 法はコチニン以外のニコチン代謝物（3-

図2 ELISA法とLC-MS法による尿中コチニン値の相関  
紙巻きタバコ喫煙者（13人） 加熱式タバコ使用者（9人）

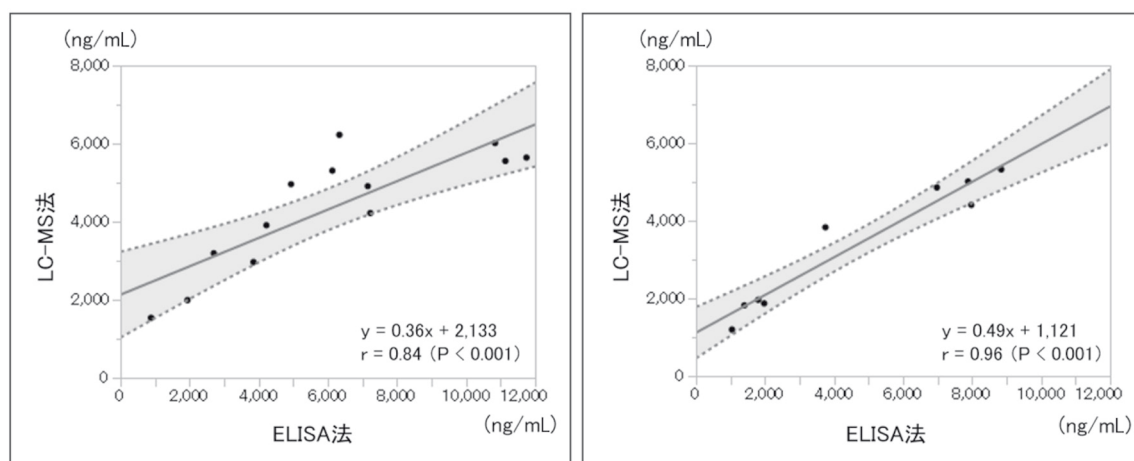
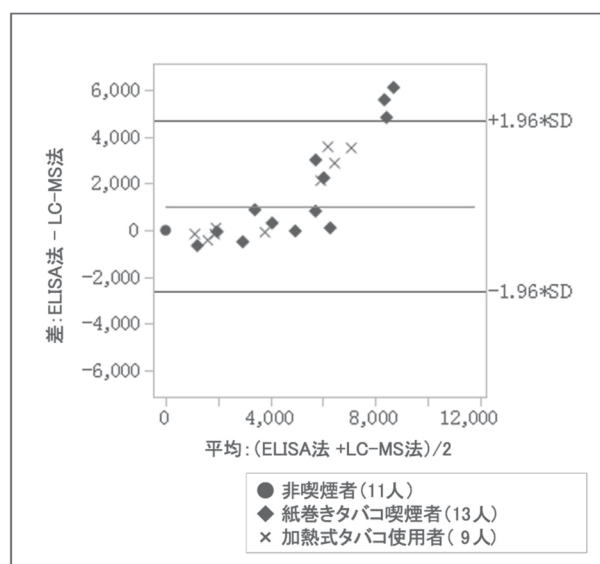


図3 ブランド・アルトマンプロット（ELISA法とLC-MS法の一致性）



HC, 3-HC グルクロン酸抱合体など）との交差反応や夾雑物との反応により高値になるため<sup>13)</sup>、この特性を理解した上で ELISA 法を活用することが必要であり、LC-MS 法の結果と比較する際には補正を行う必要があると考えられる。また、ブランド・アルトマンプロットで紙巻きタバコの喫煙者 3 人の尿中コチニン値が高値領域において一致限界を超えていたことが観察された。これら 3 人は、尿採取の直前 24 時間以内に、1 人は 15 本、2 人は 20 本の紙巻きタバコを喫煙したことを確認している。そのため、重喫煙者の ELISA 法による尿中コチニン濃度は過大評価になる可能性があることを考慮する必要がある。

ELISA 法で測定した非喫煙者の尿中コチニン値は LC-MS 法と同様に喫煙者より低い値を示し、今

後、受動喫煙者における低値の評価が必要と考えられる。

## V 結 語

本研究では、ELISA 法と LC-MS 法による尿中コチニン濃度測定と比較を行い、ELISA 法が紙巻きタバコのみならず、加熱式タバコの曝露評価にも有用であることを示した。ELISA 法は簡便で低コストの手法であり、公衆衛生分野における加熱式タバコの大規模な調査や職場での喫煙対策への応用が期待される。

本調査の実施にあたり、研究に協力いただいた事業所担当者の石井千代様に感謝いたします。また、本研究において開示すべき利益相反はない。

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## Assessment of urinary cotinine levels in heated tobacco product (HTP) users: Effectiveness of enzyme-linked immunosorbent assay (ELISA)

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**Key words** : heated tobacco products, urinary cotinine, enzyme-linked immunosorbent assay, liquid chromatography-mass spectrometry

**Objectives** Urinary cotinine concentration is widely used as a reliable biomarker to objectively evaluate smoking status. High-precision methods, such as liquid chromatography-mass spectrometry (LC-MS) and gas chromatography-mass spectrometry (GC-MS), are mainly used for measuring cotinine concentrations. However, these techniques require expensive equipment and specialized analytical techniques; therefore, they are not suitable for large-scale surveys. Conversely, enzyme-linked immunosorbent assay (ELISA), which is simple and low-cost and has a precision comparable to that of LC-MS and GC-MS, has attracted attention. ELISA has been shown to be useful for evaluating urinary cotinine levels in combustible cigarette smokers; however, its application to heated tobacco product (HTP) users has not yet been examined. Thus, in this study, we aimed to measure urinary cotinine concentrations in HTP users and ascertain whether ELISA is as effective as LC-MS for such measurements.

**Methods** Urine samples were collected from workers at a certain workplace during lunch breaks on weekdays. In total, 33 participants were analyzed: 11 nonsmokers, 13 cigarette-only smokers, and 9 HTP-only users. Urinary cotinine concentrations were measured using LC-MS and ELISA. The correlation between the measurements obtained using these methods was evaluated using Pearson's correlation coefficient; the agreement was examined using the Bland–Altman analysis.

**Results** The ELISA and LC-MS results showed a high correlation (cigarette-only smokers:  $r = 0.84$ ,  $P < 0.001$ ; HTP-only users:  $r = 0.96$ ,  $P < 0.001$ ). The Bland–Altman plot showed a high degree of agreement, with 90.9% of the data between both methods falling within the limits of agreement.

**Conclusion** ELISA was useful for evaluating urinary cotinine levels in cigarette smokers and HTP users. Because of its convenience and low cost, ELISA is expected to be utilized for large-scale epidemiological surveys and promoting smoking control in workplaces.

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