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Targeted screening of atrial fibrillation using automated blood pressure measurement device with atrial fibrillation detection function, in patients with type 2 diabetes mellitus in primary care setting

Yu Man Wong[1*], Pang Fai Chan[1], Kit Ping Loretta Lai[1], Man Hei Matthew Luk[1], Hoi Tik Fung[1] and Sze Wai Yeung[1]

Abstract

Objective The prevalence of atrial fibrillation (AF) in type 2 diabetes mellitus (DM) patients under primary care in Hong Kong was yet to be explored. We aimed to evaluate the prevalence of AF in patients with DM so as to provide evidence-based recommendations to incorporate AF screening as a component in regular diabetic risk and complication assessment. The performance of automated BP machine Microlife WatchBP Office AFIB as a screening tool for the detection of AF was also evaluated.

Method This was a cross-sectional study. Patients with type 2 DM who attended the regular diabetic risk and complication assessment in the participating clinics from 24 August 2021 to 27 January 2022 were recruited. Blood pressure measurement by Microlife WatchBP Office AFIB and 12-lead ECGs were performed for AF screening.

Results Among 2015 DM patients in primary care, the prevalence of AF was found to be 1.9% (95% confidence interval [CI] 1.3–2.6). The prevalence of AF increased with age, from 0.5% in patients aged < 65 years, to 2.2% in patients aged 65–74 years and 4.3% in patients aged ≥ 75 years. The sensitivity and specificity of Microlife WatchBP Office AFIB to detect AF were 80% (95% CI 61.8–92.3) and 97.9%. (95% CI 97.3–98.5), respectively. The positive and negative predictive values were 32.8% (95% CI 21.9–45.1) and 99.7% (95% CI 99.5–99.9) respectively.

Conclusions AF screening with the use of Microlife WatchBP Office AFIB is a simple procedure and can be considered as a standard assessment in the regular comprehensive diabetic risk and complication assessment in primary care setting.

Background

Atrial fibrillation (AF), the most common sustained arrhythmia, has become a global epidemic as a consequence of the ageing population and increased survival of chronic diseases [1]. The prevalence of AF in Hong Kong was 1.8% according to a community-based systematic AF screening programme in 2015. The prevalence increased with age for both men and women [2]. According to the

*Correspondence:
Yu Man Wong
wym010@ha.org.hk
[1] Department of Family Medicine and Primary Health Care, Kowloon East Cluster, Hospital Authority, Hong Kong, China

ATRIA study, the number of patients with AF was estimated to increase 2.5-fold from year 2000 to 2050 [1]. In a nationwide study in Korea, the prevalence of AF increased from 0.73% in year 2006 to 1.53% in 2015 and was expected to reach 5.81% in 2060 [3].

The association between AF and stroke was shown by rigorous studies in the past [4, 5]. However, many patients with AF are asymptomatic and are diagnosed with AF only when presented with acute stroke [6].

Diabetes is an important risk factor for developing AF and is associated with 34% of increased risk [7]. Poor glycaemic control and longer duration of diabetes are associated with increased risk of developing AF and overall risk increases about 3% per year of diabetes mellitus [8, 9]. In a meta-analysis restricted to prospective studies, higher level of HbA1c was associated with an increased risk of AF [10]. AF patients with DM suffer worse AF symptoms, lower quality of life, increased risk of hospitalisations and death [11]. Moreover, DM increases the thromboembolic risk by hyperinsulinemia, coagulation activation and hypofibrinolysis which produce a strong hypercoagulable state [12]. Early detection of AF in DM patients can unquestionably improve clinical outcomes by preventing thromboembolic stroke with the use of oral anticoagulants and strict glycaemic control and hence reduce economic burden on patients and healthcare system.

Higher prevalence of AF in DM patients was demonstrated in different studies worldwide. A study in China showed the prevalence of AF was higher in patients with DM than those without DM. (1.2 vs 0.5%) [13]. A study in Sweden reported age-adjusted prevalence of atrial fibrillation was 2% in patients with hypertension only, 6% in patients with both hypertension and DM, 4% in patients with DM only and 2% in controls, respectively [14]. In UK, the prevalence of AF in patients with DM was 5.5% for men, and 4.4% for women in 2016 [15]. The prevalence of AF in DM patients in Hong Kong is yet to be explored.

Various screening tools have been studied for their effectiveness in AF screening. In a systemic review and meta-analysis including 21 studies, pulse palpation was shown to have the lowest diagnostic accuracy as shown by its lowest specificity (82%; 95% CI 0.76–0.88) when compared to other tools, which included non-12-lead ECG (95%; 95% CI 0.92–0.97), automated blood pressure monitors (BPM) (92%; 95% CI 0.88–0.95) and smartphone applications (95%; 95% CI 0.88–0.98). The sensitivities of all above methods were similar [16]. Microlife WatchBP Office AFIB and Home A, the automated oscillometric blood pressure monitor devices, were developed and implemented with a specific algorithm for AF detection. NICE Medical Technologies Guidance recommended their use in primary care for opportunistic screening of AF during office BP measurement since 2013 [17].

A large-scale prospective study in Hong Kong showed results supporting Microlife WatchBP Home A use as an effective screening tool in patents with a history of hypertension and/or DM or age ≥ 65, with reasonable sensitivity of 80.6% and high negative predictive value of 99.8% [18]. Another prospective AF screening study which compared an interpretable smartphone single-lead ECG, AliveCor detector, with Microlife WatchBP Office AFIB and Microlife AG showed that Microlife devices had higher sensitivity than AliveCor detector, (83.3%, 95% CI 62.6–95.3) vs (66.7%, 95% CI 44.7–84.4), regardless of patient age and hypertension or diabetes mellitus status. Both devices showed high specificity (> 98%) [19].

In Hong Kong, most diabetic patients are under primary care in public sector with regular comprehensive diabetic risk and complication assessment. Primary care setting provides a structured management pathway for newly diagnosed AF cases. These cases will be referred directly to cardiologists for further cardiac assessment and to the family medicine specialists under primary care for evaluation and initiation of oral anticoagulants. AF screening during the comprehensive diabetic risk and complication assessment by using automated BPM can be an practical alternative for its high accuracy, convenience of use and availability.

To date, there was no study on targeted screening of AF in DM patient group locally. This study aimed to evaluate the prevalence of AF in DM patients so as to provide evidence-based recommendations to incorporate AF screening as a component in regular comprehensive diabetic risk and complication assessment. The diagnostic performance of automated BPM Microlife WatchBP Office AFIB was also evaluated in order to advocate its use as a AF screening tool in diabetic patients in primary care.

Methodology

Study design

This was a cross-sectional study carried out in three public primary care out-patient clinics which provided regular comprehensive diabetic risk and complication assessment for around 28,000 diabetic patients in year 2020 in Hong Kong. The clinics are run by Hospital Authority, which is a statutory body that provides public healthcare services to Hong Kong citizens through hospitals, specialist clinics, primary care out-patient clinics, and community out-reach services. All adult diabetic patients aged ≥ 18 years who attended for the diabetic risk and complication assessment in the participating

clinics from 24 August 2021 and 27 January 2022 were recruited.

The flowchart in Fig. 1 illustrated the inclusion and exclusion criteria of the study.

Procedure

Recruited subjects first had blood pressure measurement by Microlife WatchBP Office AFIB using routine mode. The BP readings were obtained on the preferred arm in sitting position with the measuring cuff at heart level, using appropriate cuff sizes. Three consecutive measurements with one- minute interval in between measurements were taken. The Afib icon would be displayed if AF rhythm was detected. Immediately after BP measurement, full 12-lead ECG was done in all subjects. Nurses who performed the ECGs would screen the ECG reports for rhythm abnormalities. Patients with AF detected by Microlife WatchBP Office AFIB and/or 12-lead ECG were assessed immediately by clinic family medicine specialists to confirm the diagnosis of AF. Cases of newly diagnosed AF were referred to cardiologist for further cardiac assessment and to the AF Clinics in the three study clinics for evaluation and initiation of oral anticoagulants. Abnormal ECG findings other than AF that required immediate medical attention were also assessed immediately by respective clinic family medicine specialists for further clinical evaluation. For normal ECG or ECG with abnormalities that did not require immediate medical attention, the ECG handling followed the local clinic workflow and would be reviewed during next routine visits.

Patients' demographic data including age, gender, body mass index (BMI), current smoking status, duration of diabetes, history of hypertension, latest serum glycated haemoglobin level (HbA1c) and previous AF diagnosis were ascertained from computerised record. For patients who had history of AF or newly diagnosed AF, CHA_2DS_2-VASc scores were calculated. All data were documented in an Excel data collection form for further data analysis.

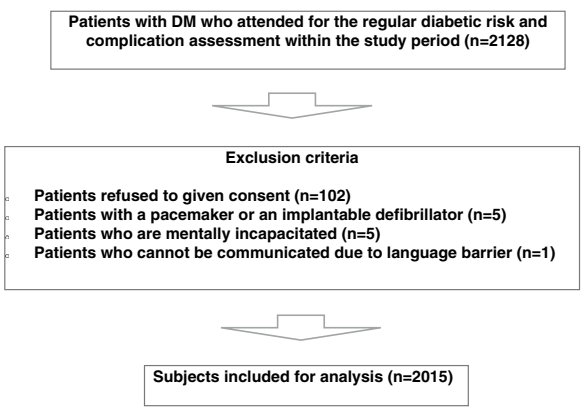

Fig. 1 Flowchart on subject selection

The diagnosis of AF was established by characteristics on an ECG which included (1) irregular R-R intervals (when atrioventricular (AV) conduction was present), (2) absence of distinct repeating P waves, and (3) irregular atrial activity [20]. Since multi focal atrial tachycardia and frequent premature beats could have irregular R–R interval, these abnormal rhythms might be misinterpreted as AF by the Microlife WatchBP Office AFIB machine. On the other hand, AF with complete atrioventricular block could have a regular R–R interval and thus missed by the machine. Previous AF diagnosis included history of paroxysmal, persistent or permanent AF under primary care or cardiologist care.

Sample size calculation

The prevalence of AF in DM patients in our locality was unknown. Hence, we opted to employ the data from a study carried out in China where the population was ethnically the same as our population. According to the study, the prevalence of AF in DM patients was 1.2% [13]. The minimum sample size to obtain 0.5% absolute precision with 95% level of significance was 1822 [21].

Outcomes

Primary outcome was the prevalence of AF in DM patients under primary care. Secondary outcome was the diagnostic performance of Microlife WatchBP Office AFIB in AF detection in terms of sensitivity, specificity, positive and negative predictive values.

Statistical analysis

Continuous variables with symmetrical distribution were presented as means and standard deviations (SD). Skewed continuous variables were presented as median and first/third quartiles. Categorical variables were presented as percentages. Prevalence was presented as percentage with 95% confidence interval. The 95% confidence interval was based on exact binomial distribution calculation method. Statistical analysis was conducted with SPSS statistical software version 21 and R Project for statistical computing version 4.0.5.

Results

Study population

Between 24 August 2021 and 27 January 2022, a total of 2128 DM patients were screened, 2015 patients fulfilled our inclusion criteria and were recruited in our study as shown in Fig. 1. Table 1 summarises the patients' characteristics.

Table 1 Characteristics of recruited patients

	Total ($n=2015$)
Age, mean ± SD, years	66.4 ± 10.6
Female sex—no. (%)	1082 (53.7)
Body mass index, mean ± SD	25.5 ± 4.06
Smoker—no. (%)	169 (8.4)
Hypertension—no. (%)	1698 (84.3)
Duration of DM, mean ± SD, years	8.7 ± 7.9
Latest HbA1c level, mean ± SD (%)	6.9 ± 0.9
Congestive heart failure—no. (%)	15 (0.7)
Prior stroke or transient ischaemic attack—no. (%)	126 (6.3)
History of vascular disease (prior MI/PVD/aortic plague)—no. (%)	28 (1.4)
Previous history of AF—no. (%)	33 (1.6)
CHA_2DS_2-VASc score mean ± SD	3.3 ± 1.3

CHA_2DS_2-VASc score (C: congestive heart failure [1 point]; H: hypertension [1 point]; A2: age 65–74 years [1 point] and age ≥ 75 years [2 points]; D: diabetes mellitus [1 point]; S: prior stroke or transient ischaemic attack [2 points]; VA: vascular disease [1 point]; and Sc: sex category [female] [1 point])

The mean age was 66.4 ± 10.6 years. 1082 patients were female (53.7%). Most patients were non-smokers (91.6%). Hypertension was present in 1698 patients (84.3%). The mean duration of DM was 8.7 ± 7.9 years. The mean latest HbA1c level was 6.9 ± 0.9%. A total of 126 patients (6.3%) had history of ischaemic stroke or transient ischaemic attack. Fifteen patients (0.7%) had history of congestive heart failure, and 28 patients (1.4%) had history of vascular disease (prior MI/ PVD/ aortic plague). The mean CHA_2DS_2-VASc score was 3.3 ± 1.3.

Prevalence of AF in DM patients

Among the recruited patients, the prevalence of AF was 1.9% (95% confidence interval [CI] 1.3–2.6), based on clinical history of confirmed diagnosis of AF or AF detected on 12-lead ECG during the study. There were in total 38 patients with diagnosis of AF, including 33 patients who had known history of AF based on clinical history and 5 patients who were newly diagnosed AF by 12-lead ECG during the study. Of these 5 newly diagnosed AF patients by 12-lead ECG, 4 of them were detected by Microlife WatchBP Office AFIB. Of these 33 cases with known history of AF based on clinical history, 20 patients showed AF rhythm on ECG and 13 showed rhythms other than AF (Fig. 2). The prevalence of AF increased with age in patents with DM, from 0.5% (95% CI 0.1–1.2) in patients aged < 65 years, to 2.2% (95% CI 1.3–3.6) in patients aged 65–74 years and 4.3% (95% CI 2.5–6.7) in patients aged ≥ 75 years (Table 2). The prevalence of AF in patients with HbA1c < 7% and HbA1c ≥ 7% was 2% (95% CI 1.3–2.9) and 1.8% (95% CI 0.9–3), respectively (Table 3).

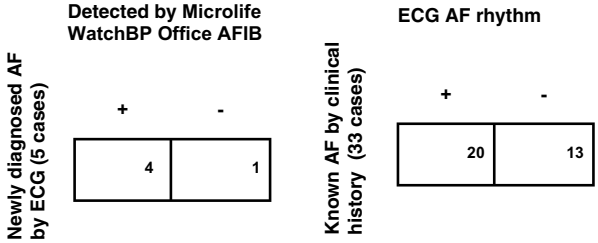

Fig. 2 Clinical findings in known and newly diagnosed AF cases

Diagnostic accuracy of Microlife WatchBP Office AFIB

Microlife WatchBP Office AFIB correctly identified AF in 20 out of 25 patients who had AF rhythm confirmed with 12-lead ECG during the study. There were 41 false positive results with Microlife WatchBP Office AFIB detected AF yet ECG showing rhythms other than AF, including 1 case of atrial flutter. There were 5 false negative results in patients with AF rhythm being shown on 12-lead ECG but not detected by Microlife WatchBP Office AFIB. The corresponding sensitivity and specificity to detect AF by Microlife WatchBP Office AFIB were 80% (95% Cl 61.8–92.3) and 97.9% (95% CI 97.3–98.5), respectively. The positive and negative predictive values of the Microlife WatchBP Office AFIB to identify AF were 32.8% (95% CI 21.9–45.1) and 99.7 (95% CI 99.5–99.9) respectively. The positive and negative likelihood ratio were 38.8 (95% CI 27.1–55.7) and 0.2 (95% CI 0.09–0.45), respectively.

Figure 3 summarises the number of true positive, true negative, false positive and false negative results and the ECG rhythm of the false positive results. The sensitivities, specificities, positive predictive values, negative predictive values, positive and negative likelihood ratio in different age groups and in well-controlled and suboptimally controlled DM groups are shown in Tables 4 and 5, respectively.

Discussion

Our prospective cross-sectional study found that among the 2,015 DM patients included, the prevalence of AF was 1.9%. The prevalence of AF increased with age in patents with DM and up to 4.3% in patients aged ≥ 75 years. The prevalence was comparable to various studies conducted previously in Chinese population [2, 22]. As we know the prevalence of AF is lower in non-Caucasian than in Caucasian as shown by a cohort study [23], our study also demonstrated a lower prevalence rate of AF in DM patients when compared to other population including Sweden [14] and UK [15], which were 6% and 5%, respectively. Prevalence of AF in all age groups in this study was 1.9% compared with 1.8% in general population [2]. Higher prevalence was shown in patients aged 65–74 and ≥ 75 years compared to general population (2.2% and

Table 2 Prevalence of AF in DM patients

Age (years)	All (*n* = 2015)	Age < 65 (*n* = 857)	Age 65–74 (*n* = 759)	Age ≥ 75 (*n* = 399)
No. of participants with AF	38	4	17	17
Prevalence rate (%) 95% CI (%)	1.9 (1.3–2.6)	0.5 (0.1–1.2)	2.2 (1.3–3.6)	4.3 (2.5–6.7)

Table 3 Prevalence of AF in patients with well-controlled and suboptimally controlled DM

HbA1c (%)	< 7	≥ 7
No. of participants with AF	25	13
No. of participants without AF	1256	721
Prevalence rate (%) 95% CI (%)	2.0 (1.3–2.9)	1.8 (0.9–3.0)

4.3% vs 1.9%, respectively). The prevalence of AF in well-controlled and suboptimally controlled DM patients was comparable. Glycemic control was not shown to have an impact on prevalence of AF in our study.

The Microlife WatchBP Office AFIB showed a reasonable overall sensitivity of 80%, specificity of 97.9% and negative predictive value of 99.7%. The study showed a positive predictive value of only 32.8% which could be explained by the relatively low prevalence of AF in DM patients in our locality. The diagnostic performance of Microlife WatchBP Office AFIB was generally consistent across all pre-specified age groups and patients with hypertension. Microlife WatchBP Office AFIB showed a high specificity of 97.9%, by correctly ruling in most patients who had undiagnosed AF with few false positives and demonstrated its value as a screening tool for AF detection.

The targeted screening population of DM patients are high risk group of thromboembolism in AF as reflected by the mean CHA_2DS_2-VASc score (3.33 ± 1.26). These patients are most likely to be benefited by use of oral anticoagulants for prevention of stroke and thromboembolism. As recommended by ESC guideline [20], a structured referral platform should be organised for screen-positive cases for further physician-led clinical evaluation to confirm the diagnosis of AF and provide optimal management. The public primary care setting in Hong Kong provides a platform for referral of newly

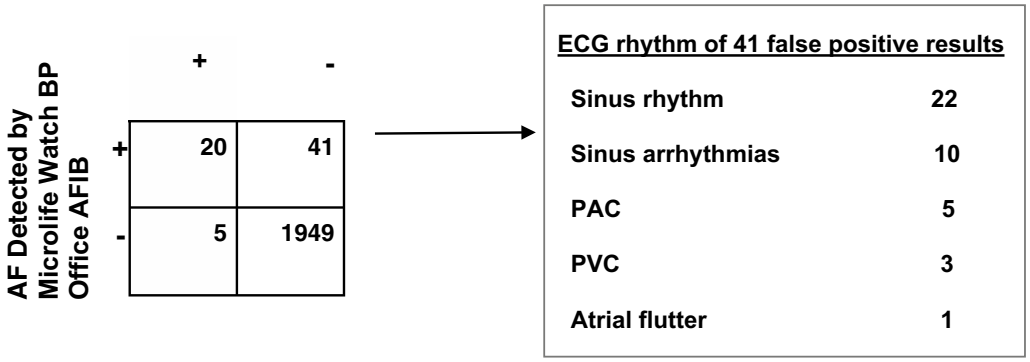

Fig. 3 Diagnostic performance of Microlife WatchBP Office AFIB

Table 4 Diagnostic accuracy of Microlife WatchBP AFIB in DM patients of different age groups

	All	Age < 65	Age 65–74	Age ≥ 75
Sensitivity (%) (95% CI)	80.0 (61.8–92.3)	33.3 (23.0–83.9)	83.3 (56.9–97.0)	90.0 (62.8–99.4)
Specificity (%) (95% CI)	97.9 (97.3–98.5)	98.6 (97.7–99.2)	97.7 (96.5–98.6)	96.9 (94.9–98.3)
PPV (%) (95% CI)	32.8 (21.9–45.1)	7.7 (5.0–29.7)	37.0 (20.6–55.8)	42.9 (23.4–63.9)
NPV (%) (95% CI)	99.7 (99.5–99.9)	99.8 (99.3–100)	99.7 (99.2–100)	99.7 (98.8–100)
Positive LR (95% CI)	38.8 (27.1–55.7)	23.7 (4.4–29.3)	36.6(21.4–62.4)	29.2 (16.1–52.8)
Negative LR (95% CI)	0.2 (0.1–0.5)	0.7 (0.3–1.5)	0.2 (0.05–0.6)	0.1 (0.02–0.66)

Table 5 Diagnostic accuracy of Microlife WatchBP AFIB in DM patients according to the HbA1c control

	HbA1c < 7%	HbA1c ≥ 7%
Sensitivity (%) (95% CI)	83.3 (62.3–95.6)	71.4 (35–94.6)
Specificity (%) (95% CI)	97.9 (97–98.6)	98.1 (96.9–98.9)
PPV (%) (95% CI)	35.7 (22.4–50.7)	26.3 (10.3–48.3)
NPV (%) (95% CI)	99.8 (99.4–99.9)	99.7 (99.1–1)
Positive LR (95% CI)	38.981(25.446–59.716)	37.092 (18.437–74.62)
Negative LR (95% CI)	0.17 (0.061–0.478)	0.291 (0.09–0.94)

diagnosed AF cases to cardiologists for further cardiac investigation and AF specialist clinics organised by family physicians for evaluation and initiation of anticoagulation therapy. Family physicians play important roles in patient education and discussion with patents in major treatment decisions. The effectiveness of a AF screening programme will be enhanced with such a structured management pathway.

Previous studies on AF screening mostly used single-lead ECG for diagnostic comparison. It is important to note that the diagnosis of AF should only be established by standard 12-lead ECG or a single-lead ECG tracing of minimum 30 s showing rhythm of AF [20]. In order to improve the diagnostic accuracy, our study used standard 12-lead ECG for comparison with Microlife WatchBP Office AFIB for evaluation of its diagnostic performance.

Our study included patients with DM aged < 65 years. This age group was not included in most of other local AF screening studies, as most guidelines recommended screening in patients aged ≥ 65 years [20]. Despite the low prevalence rate (0.5%) in this age group, Microlife WatchBP Office AFIB was still able to demonstrate high specificity and negative predictive value in identifying AF. Further studies are needed to study the effectiveness of AF screening in this age group.

A drawback of applying Microlife WatchBP Office AFIB as a screening tool was the longer duration of BP measurement than usual standard automated BP machines. It required three consecutive measurements with one-minute interval in between measurements in order to improve the diagnostic accuracy for pulse irregularities or AF. The estimated time used for each patient in the study was around five minutes. It may create a burden in face of large patient load during assessment. As Microlife WatchBP Office AFIB would have some false positive findings which included normal rhythm and clinically insignificant abnormal rhythm, the need for ECG to confirm diagnosis would also induce more workload.

Moreover, AF screening may create false reassurance as it is unable to detect paroxysmal AF. Nevertheless, the sensitivity can be improved with regular screening at interval. Future research can also focus on cost-effectiveness of repeated screening of AF with use of automatic BP machines during comprehensive diabetic risk and complication assessment, in detection of AF and prevention of thromboembolism.

As a limitation, our data were obtained from DM patents under primary care provided by three general out-patient clinics in Hong Kong, which limited the generalisability of our results to the whole DM population of Hong Kong. The diagnostic performance of Microlife WatchBP Office AFIB may differ in other clinical settings due to differences in prevalence and patient population.

Conclusion

AF screening with the use of Microlife WatchBP Office AFIB is a simple procedure and can be considered as a standard assessment in the regular comprehensive diabetic risk and complication assessment in primary care setting.

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Author contributions
The authors confirm contribution to the paper as follows: WYM was the principal investigator who wrote the manuscript. CPF and LKPL both contributed to the protocol development of the study, the analysis and interpretation of the data. They also edited the manuscript and made a significant contribution that improved the content of the manuscript. FHT and YSW contributed to data collection. LMHM contributed to the design of the study, and the analysis and interpretation of the data. All authors reviewed the results and approved the final version of the manuscript.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
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Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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