Asia Pacific Heart Rhythm Society (APHRS) scientific statement on stroke prevention strategies in patients with device-detected atrial fibrillation: the 4S-DDAF approach

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Summary

Device-detected atrial fibrillation (DDAF), including atrial high-rate episodes recorded at a cardiovascular implantable electronic device and subclinical atrial fibrillation detected by insertable cardiac monitor and smart wearables, poses an increasing challenge in stroke prevention. Although oral anticoagulants (OACs) are effective in clinical AF, their benefit-risk balance in DDAF remains uncertain. In response, the Asia Pacific Heart Rhythm Society (APHRS) proposes the 4S-DDAF approach (Strip documentation and longest AF duration, Symptoms, Stroke [ischemic] history, and Score) to guide anticoagulation decisions. This approach integrates electrogram review, symptom assessment, history of ischemic stroke or transient ischemic attack (TIA), and CHA_2DS_2-VASc scoring, emphasizing individualized care. OACs are recommended for patients with AF episodes ≥24 h, prior stroke/TIA, CHA_2DS_2-VASc score ≥4, or vascular disease. In patients not meeting these thresholds, close monitoring and risk factor management are advised. The 4S-DDAF approach provides a practical and evidence-informed strategy for clinical decision-making in the management of DDAF.

Keywords: Device-detected atrial fibrillation; Atrial high-rate episodes; Subclinical atrial fibrillation; 4S-DDAF approach; APHRS

Introduction

Atrial fibrillation (AF)-related ischemic stroke can be effectively prevented by oral anticoagulants (OACs), with direct oral anticoagulants (DOACs) being the preferred choice, as recommended by international guidelines.[1–3] However, paroxysmal AF can be difficult to diagnose, especially in patients with a low AF burden, unless long-term continuous monitoring is performed. The atrial lead of a cardiovascular implantable electronic device (CIED) can continuously monitor atrial rhythm, and atrial high-rate episodes (AHREs) are detected in approximately 30% of patients.[4] In the ASSERT trial, AHREs defined as atrial rates >190 bpm lasting >6 min were associated with a 2.52-fold increased risk of ischemic stroke.[5] However, the annual risk of ischemic stroke in patients with AHREs was only 1.69%, which is lower than would be expected in clinically diagnosed AF patients with a mean $CHADS_2$ score of 2.2.[5] Therefore, whether OACs should be prescribed for patients with AHREs but without clinically diagnosed AF remains a clinical

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challenge. Actually, a recent survey conducted among physicians of the European Heart Rhythm Association revealed significant discrepancies in clinical practice regarding the use of OACs for CIED-detected AHREs. Most respondents considered the duration of AF episodes when deciding on OAC initiation: 33% of physicians recommended OACs when the duration exceeded 5–6 min, while 18% would consider anticoagulation only if the episodes lasted more than 24 h.[6] With the increasing use of insertable cardiac monitor (ICM) and smart wearables, the detection of so-called subclinical atrial fibrillation (SCAF) introduces additional clinical complexity. The optimal stroke prevention strategy for device-detected atrial fibrillation (DDAF), including AHREs identified by CIEDs or SCAF captured by ICM or wearables, remains a topic of ongoing debate.[7–9] This highlights the urgent need for a society-endorsed scientific statement to provide clear guidance on this important clinical issue.

In this Asia Pacific Heart Rhythm Society (APHRS) scientific statement, we summarize international guideline recommendations, review high-quality data from randomized trials, and propose a novel algorithm—the **4S-DDAF approach** (**S**trip documentation and longest AF duration; **S**ymptom; **S**troke (ischemic) history; **S**core)—to guide everyday clinical practice. All members of the writing committee agreed with the proposed algorithm.

Guideline recommendations from American to European Societies

Table 1 summarizes guideline recommendations for the use of OACs in patients with DDAF.[2,3] Neither the 2023 ACC/AHA nor the 2024 ESC AF guidelines issued Class I recommendations on this issue, reflecting the ongoing uncertainty. The ACC/AHA guidelines suggest that initiating OACs is reasonable for patients with AHREs lasting ≥24 h and a CHA_2DS_2-VASc score ≥2, within a shared decision-making framework (Class IIa).[2] Notably, 2023 ACC/AHA AF guidelines were published before results from the NOAH-AFNET 6 and ARTESiA trials became available.[10,11] In contrast, the ESC guidelines announced after these 2 trials were even more conservative, offering only a Class IIb recommendation that DOACs may be considered for patients with asymptomatic DDAF and high thromboembolic risk, excluding those with high bleeding risk.[3]

	2023 ACC/AHA[2]	2024 ESC[3]
Class I recommendation	None	None
Class IIa recommendation	For patients with a device-detected AHRE lasting ≥24 h and with a CHA_2DS_2-VASc score ≥2 or equivalent stroke risk, it is reasonable to initiate oral anticoagulation within a SDM framework that considers episode duration and individual patient risk.	None
Class IIb recommendation	For patients with a device-detected AHRE lasting between 5 min and 24 h and with a CHA_2DS_2-VASc score ≥3 or equivalent stroke risk, it may be reasonable to initiate anticoagulation within a SDM framework that considers episode duration and individual patient risk.	Direct oral anticoagulant therapy may be considered in patients with asymptomatic device-detected subclinical AF and elevated thromboembolic risk to prevent ischaemic stroke and thromboembolism, excluding patients at high risk of bleeding.
Class III recommendation	Patients with a device-detected AHRE lasting <5 min and without another indication for oral anticoagulation should not receive oral anticoagulation	None

ACC/AHA, American College of Cardiology/American Heart Association; AHRE, atrial high-rate episode; ESC, European Society of Cardiology; SDM, shared decision-making.

Table 1: **Recommendations of guidelines for oral anticoagulation for patients with device-detected atrial fibrillation.**

Evidence-based insights from the randomized controlled trials: NOAH-AFNET 6 and ARTESiA

Two prospective clinical trials have evaluated DOACs in patients with DDAF, the NOAH-AFNET 6 (edoxaban) and ARTESiA (apixaban), comparing them to non-anticoagulation strategies (antiplatelets or placebo).[10,11] A study level meta-analysis of these trials showed a 32% reduction in ischemic stroke risk with DOACs but a 62% increase in major bleeding, with no significant heterogeneity between trials.[12] The annual stroke risk without DOACs was 1.02% in ARTESiA and 1.1% in NOAH-AFNET 6—slightly above the 'tipping point' 0.9% threshold often used for considering DOAC therapy.[13] An analysis of benefit and harm timing suggested that stroke prevention benefits from DOACs are delayed and modest, while bleeding risks appear earlier.[14] Although this study was limited by the reconstruction of patient data from the numbers at risk and the Kaplan–Meier graphs of published trials, rather than from "real" patient-level data, the difference between the time to benefit (2.67 years) to prevent one stroke and the time to harm (1.67 years) to observe one major bleeding event was evident.[14] These findings indicate that decision-making for DOACs in DDAF may differ from clinical AF and necessitate a more structured approach.

The 4S-DDAF approach to guide DOACs use in AHREs

We propose the "**4S-DDAF approach (S**trip documentation and longest AF duration; **S**ymptoms; **S**troke (ischemic) history; **S**core**)"** as a practical framework to guide DOAC use in DDAF (AHREs identified by CIEDs or SCAF captured by ICM or wearables) (Fig. 1).

Step 1: strip documentation and longest AF duration

In patients with DDAF, it is important to review atrial electrograms to exclude false positives, which (for example) in the ASSERT trial accounted for 17.3% of

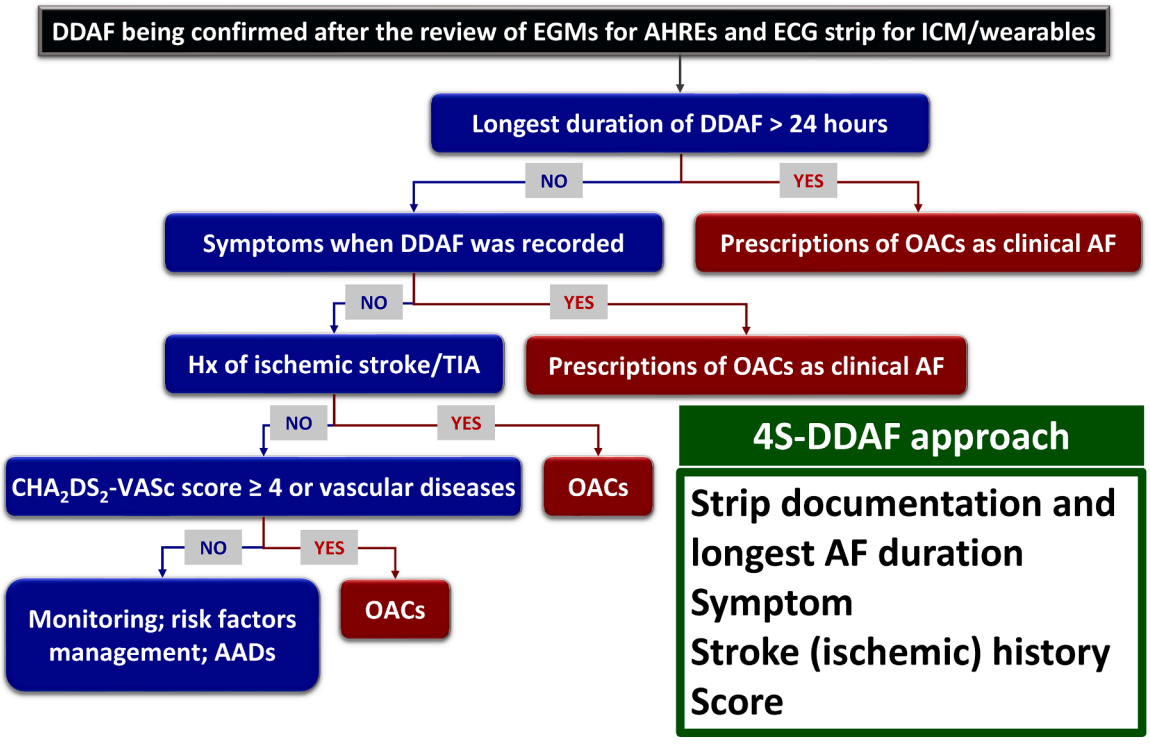

Fig. 1: The 4S-DDAF approach to guide OAC use in DDAF. AAD, antiarrhythmic drug; AF, atrial fibrillation; AHREs, atrial high-rate episodes; DDAF, device-detected AF; ECG, electrocardiogram; EGM, electrogram; ICM, insertable cardiac monitor; OACs, oral anticoagulants; TIA, transient ischemic attack.

5769 AHREs.[15] In CIEDs, common false-positive causes include far-field oversensing (T or R waves), myopotentials, electromagnetic interference, and other supraventricular tachycardias. If AHREs are confirmed, assess the longest episode duration. Even with wearables and ICM, artifacts may be present, and any recorded electrocardiogram (ECG) strips should be reviewed.

AF burden in clinical practice, research, and technology development has been the topic of a clinical consensus statement of the European Society of Cardiology Council on Stroke and the European Heart Rhythm Association.[16] In this document, a consensus definition of AF burden is proposed, stating that "AF burden is the proportion of time in AF (%) during a specified (near-) continuous monitoring period of at least 28 days during a total specified and reported observation period. The longest episode of AF (LEAF), expressed as a time duration, should also be reported when appropriate". The recommendation of "at least 28 days" is based on the prior study demonstrating that serial long-term (7–14 day) intermittent monitors accumulating at least 28 days of annual monitoring provide estimates of AF burden comparable with ICM.[17] Although both the percentage of time in AF and the LEAF are important components about "AF burden" and can be readily assessed by CIEDs or ICMs without long-term ECG monitoring, LEAF has been more commonly used as an enrollment criterion and as a basis for patient categorization in clinical trials comparing the risks of adverse clinical outcomes.[16] In the ASSERT trial, only patients whose the longest durations of AHREs exceeded 24 h demonstrated a statistically significant increase in the risk of ischemic stroke or systemic embolism compared to those without AHREs.[18]

Based on these findings, we suggest that the decision to initiate OACs in patients with DDAF whose LEAF exceeds 24 h could be approached similarly to that in patients with clinical AF. However, the tipping threshold of AF burden (percentage of time in AF) for initiating OACs in patients whose LEAF is less than 24 h remains uncertain due to the lack of high-quality data. Furthermore, progression of LEAF from <24 h to >24 h occurred in >9% of patients annually in the ARTESiA trial. This progression was associated with a doubling of the risk of all-cause mortality, driven by increases in both heart failure-related and arrhythmic deaths.[19] This finding highlights that we are dealing with a rhythm that is dynamic in nature and arrhythmia burden is not 'static'. Therefore, we do not propose any specific recommendations on this issue.

Step 2: symptoms at the time of DDAF

If patients clearly recall symptoms during recorded DDAF, these may be classified as "clinical AF" in a similar way for OAC prescriptions, since such symptoms might have led to a clinical AF diagnosis if medical attention had been sought. Nonetheless, it has been well recognized that even clinical AF is often asymptomatic, and only 1 in 12 episodes of paroxysmal AF are actually symptomatic.[20] In patients who have undergone catheter ablation, previously symptomatic paroxysmal AF is more likely to become asymptomatic.[21] Importantly, clinical risks associated with asymptomatic clinical AF are the same or even worse than the risks associated with symptomatic AF, as recently highlighted among hospitalized Chinese AF patients.[22] Therefore, more extensive monitoring and closer, more frequent follow-up are necessary, even when patients do not associate the recorded DDAF episodes with any symptoms. On the other hand, patients' reports of "symptoms" should also be interpreted with caution, as recall bias may arise during history taking.

Step 3: stroke (ischemic) history

Previous randomized trials showed a higher detection rate of AF with ICM compared to external ECG monitoring in patients with ischemic stroke.[23,24] A recent meta-analysis demonstrated that, compared to non-ICM strategies, ICMs were associated with a more than threefold increase in the detection of incident AF in patients with a history of stroke or those at high risk of developing stroke.[25] Although several studies have demonstrated that AF detected after stroke or transient ischemic attack (TIA) may represent a distinct clinical entity with a lower risk of recurrent stroke than known AF,[26–28] the ARTESiA trial showed that the risk of stroke or systemic embolism was higher among patients with a history of ischemic stroke or TIA than those without such a history (apixaban arm: 1.20%/year vs 0.74%/year; aspirin arm: 3.14%/year vs 1.07%/year).[29] Given the high risk of recurrence in patients with a prior stroke, prescribing OACs for secondary prevention appears to be a reasonable clinical decision. In ARTESiA, 8.6% of participants had a history of ischemic stroke or TIA, and apixaban reduced the risk of stroke or systemic embolism by 7% in these patients, compared to a 1% reduction in those without such a history over a 3.5-year follow-up period.[29] The corresponding increases in major bleeding were 3% and 1%, respectively (Fig. 2). Therefore, we recommend initiations of OACs for secondary stroke prevention in patients with DDAF having a history of stroke or TIA. However, for patients with competing etiologies of ischemic stroke, such as severe carotid stenosis or intracranial atherosclerotic stenosis, the optimal stroke prevention strategy should be based on shared decision-making, and clinical discretion remains essential.

Step 4: scoring for stroke risk with the CHA_2DS_2-VASc score

The intrinsic stroke risk will guide decision-making. The 2024 ESC guidelines recommend the non-sex CHA_2DS_2-VASc (ie. CHA_2DS_2-VA) score a Level of Evidence C (ie. consensus) as '*the inclusion of gender complicates clinical practice both for healthcare*

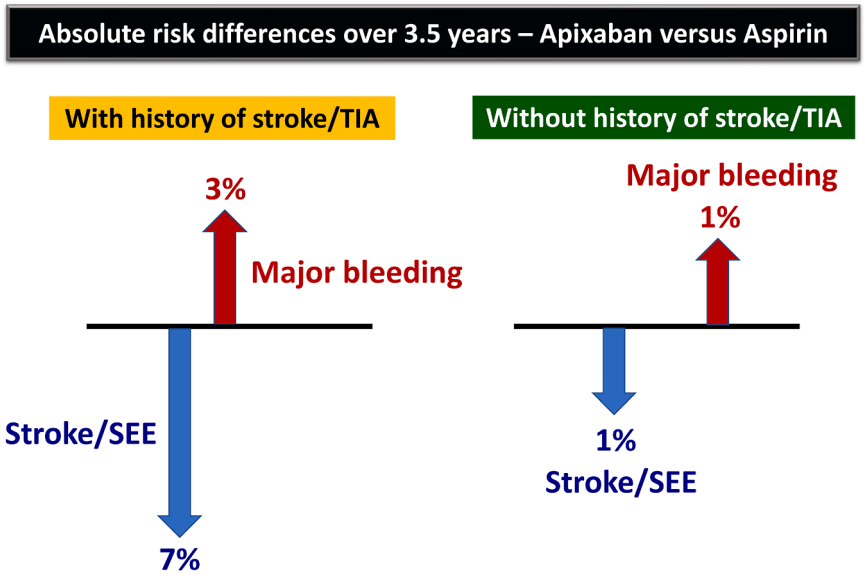

Fig. 2: The risk/benefit of Apixaban versus Aspirin in patients with or without history of stroke/TIA in the ARTESiA trial. SEE, systemic embolic events; TIA, transient ischemic attack. (Data adopted to draw this figure was based on the paper by Shoamanesh et al.[29])

professionals and patients' and '*omits individuals who identify as non-binary, transgender, or are undergoing sex hormone therapy*'.[3] Female sex alone does not justify the initiations of OACs, and the CHA_2DS_2-VA score has been well validated in European cohorts, demonstrating similar performance to the CHA_2DS_2-VASc score in recent years when the female-male difference in stroke risk is non-significant.[30,31] Another study from the UK demonstrated that removing female sex from the CHA_2DS_2-VASc score does not affect its ability to discriminate thromboembolic events in the AF population, and the use of CHA_2DS_2-VA may simplify initial decision-making for thromboprophylaxis.[32] Nevertheless, this equivalence may not be consistent globally, particularly in Asian populations where females with AF remain at a higher risk of stroke than males, and the CHA_2DS_2-VASc score offers superior stroke risk reclassification.[33,34] Therefore, the CHA_2DS_2-VASc score may remain more appropriate for Asian patients with AF, and this issue warrants further region-specific investigation and validation.

Given the generally lower risk of ischemic stroke observed in patients with DDAF,[10,11] the CHA_2DS_2-VASc score threshold for initiating OACs may possibly need to be higher than that used for patients with clinical AF. In the ARTESiA trial, 25% of patients had a CHA_2DS_2-VASc score >4, with an annual stroke/systemic embolism rate of 2.2%.[35] For these patients, stroke prevention benefits outweigh bleeding risks. For CHA_2DS_2-VASc = 4, apixaban prevented 0.32 strokes/systemic embolisms and caused 0.28 major bleeds per 100 patient-years.[35] In addition to the benefits of DOACs over aspirin for secondary prevention demonstrated in ARTESiA (as mentioned in Step 3 above), patients with vascular disease (defined as prior stroke/TIA, coronary or peripheral artery disease) may also derive benefit from DOACs compared to aspirin or placebo, as shown in a pooled analysis of the NOAH-AF and ARTESiA trials.[36]

As shown in Table 2, the number needed to treat (NNT) to prevent one stroke or systemic embolism was lower than the number needed to harm (NNH) to cause one major bleeding event among patients with vascular disease—indicating a net clinical benefit favoring DOACs over non-anticoagulation.[36] In contrast, among those without vascular disease, the NNT exceeded the NNH, suggesting a less favorable risk–benefit profile for DOAC therapy. Thus, we recommend OAC therapy for patients with DDAF and a CHA_2DS_2-VASc score $\geq$4, or in the presence of vascular disease regardless of the score.

(a) Patients with vascular diseases

	Stroke/Systemic embolism (%/yr)	Major bleeding (%/yr)
NOAH-AFNET 6 trial		
Edoxaban	1.24	2.13
Placebo	2.19	1.28
	NNT (95% CI) = 105 (102–109)	**NNH (95% CI) = 118 (114–122)**
	NNT < NNH	
ARTESiA trial		
Apixaban	0.96	1.71
Aspirin	1.78	1.14
	NNT (95% CI) = 121 (118–124)	**NNH (95% CI) = 174 (169–180)**
	NNT < NNH	

(b) Patients without vascular diseases

	Stroke/Systemic embolism (%/yr)	Major bleeding (%/yr)
NOAH-AFNET 6 trial		
Edoxaban	0.99	2.19
Placebo	0.82	0.64
	NA	**NNH (95% CI) = 64 (63–65)**
	No benefits with DOACs	
ARTESiA trial		
Apixaban	0.64	1.38
Aspirin	0.82	1.11
	NNT (95% CI) = 540 (507–578)	**NNH (95% CI) = 368 (348–391)**
	NNT > NNH	

CI, confidence interval; DOACs, direct oral anticoagulants; NA, not applicable; NNH, number needed to harm; NNT, number needed to treat. Data in this table were adopted and derived from the paper by Schnabel et al.[36]

Table 2: **NNT and NNH of DOACs versus non-anticoagulation in NOAH-AFNET 6 and ARTESiA trials.[36]**

Management of patients not recommended to receive DOACs

The annual incidence of clinical AF among patients with DDAF ranges from 6.3% to 8.7% (Table 3).[5,10–12,37]

Aggressive detection with ECG monitoring and regular follow-up is essential. The sub-analysis of ASSERT trial demonstrated that the progression of DDAF was strongly associated with heart failure hospitalization.[38] In addition, progression to LEAF lasting more than 24 h or to clinical AF is associated with an increased risk of stroke when OACs are not prescribed.[19] Antiarrhythmic drugs may reduce DDAF burden and slow disease progression, even though the available evidence is largely derived from studies in patients with clinical

	ASSERT[5] (CIEDs)	NOAH-AFNET 6[10,12,37] (CIEDs or ICM [1%])	ARTESiA[11,12] (CIEDs or ICM [5.2%])
Age, mean	77 yrs	77.5 yrs	76.8 yrs
$CHADS_2$ score	2.2 (mean)	NR	NR
CHA_2DS_2-VASc score	NR	4 (median)	3.9 (mean)
Definition of AHREs at CIEDs	atrial rate $\geq$190 bpm lasting >6 min	atrial rate $\geq$180 bpm lasting $\geq$6 min	atrial rate >175 bpm lasting $\geq$6 min, but $\leq$24 h
Incidence of clinical AF	6.29%/yr	8.7%/yr	6.3%/yr

AF, atrial fibrillation; AHRE, atrial high-rate episode; CIED, cardiovascular implantable electronic device; ICM, insertable cardiac monitor; NR, not reported.

Table 3: **Incidence of clinical AF in 3 trials of device-detected AF.**

AF.[39,40] Maintenance of sinus rhythm may also help reverse atrial cardiomyopathy, which has been associated with the progression of DDAF and an increased risk of cardioembolic stroke.[41,42] Comprehensive management of comorbidities and risk factors is also crucial. Indeed, a holistic or integrated care based on the evidence-based Atrial Fibrillation Better Care (ABC) pathway is essential, regardless of whether patients meet the suggested criteria for initiating OACs. This structured approach has consistently been associated with improved clinical outcomes in patients with AF, including many studies (including 2 randomized trials) from the Asia–Pacific region.[43–47]

Limitation

In this scientific statement, the evidence supporting the 4S-DDAF approach is primarily derived from studies involving CIEDs, with limited data from ICM—only 1% in NOAH-AFNET 6 and 5.2% in ARTESiA. Randomized trials comparing OACs versus no OACs for SCAF detected by wearable devices are currently lacking. However, the central concept of "continuous AF monitoring" via CIEDs, ICMs, and wearables remains fundamentally similar. Therefore, we recommend applying the 4S-DDAF approach to guide OAC use in patients with DDAF, including AHREs detected by CIEDs and SCAF identified by ICMs or wearables. However, further high-quality studies are needed to determine whether the findings from CIED trials are generalizable to ICMs and wearable technologies. Furthermore, although we proposed a 24-h threshold for LEAF, the use of this cutoff to guide OAC strategies has not been evaluated in randomized trials. Future studies are warranted to define clinically meaningful thresholds.

Conclusion

Whether OACs should be prescribed for patients with DDAF remains an important yet unresolved clinical question. We present the APHRS perspective on this issue and propose the 4S approach, grounded in current data and expert consensus, as a practical framework to guide clinical decision-making. Further studies are warranted to assess its feasibility, and additional practical guidance from other international societies will be essential.

Contributors

Tze-Fan Chao: figures, writing; **Chu-Pak Lau:** data interpretation; **Eue-Keun Choi**: literature search, data interpretation; **Chi-Keong Ching**: literature search; **Ngai-Yin Chan**: literature search, data interpretation; **Chung-Lieh Hung**: literature search; **Boyoung Joung**: literature search; **Rungroj Krittayaphong**: data interpretation; **Hung-Fat Tse**: literature search, data interpretation; **Gregory Y.H. Lip**: data interpretation, writing.

Declaration of Interests

Tze-Fan Chao: Speaking fees from Daiichi-Sankyo, Boehringer Ingelheim, Pfizer and Bayer. **Chu-Pak Lau**: Speaking fee from Abbott, Boehringer Ingelheim; Bayer; Medtronic and Sanofi. **Eue-Keun Choi**: Research grants or speaking fees from Abbott, Bayer, BMS/Pfizer, Biosense Webster, Chong Kun Dang, Daewoong Pharmaceutical Co., Daiichi-Sankyo, DeepQure, Dreamtech Co., Ltd., Jeil Pharmaceutical Co. Ltd, Medtronic, Samjinpharm, Samsung Electronics Co., Ltd., Seers Technology, and Skylabs. **Chi-Keong Ching**: None. **Ngai-Yin Chan**: None. **Chung-Lieh Hung**: None. **Boyoung Joung**: Dr B. Joung has served as a speaker for Bayer, BMS/Pfizer, Medtronic, and Daiichi-Sankyo and received research funds from Samjin, Yuhan, Medtronic, Boston Scientifics and Abbott Korea. **Rungroj Krittayaphong**: Consultant and speaker for Daiichi-Sankyo and Pfizer. **Hung-Fat Tse**: Research grants, consultant and speaking fee from Abbott; Amgen; AstraZeneca; Bayer; Boehringer Ingelheim; Boston Scientific; Daiichi Sankyo; Medtronic; Novartis; Pfizer; Sanofi. **Gregory Y.H. Lip**: Consultant and speaker for BMS/Pfizer, Boehringer Ingelheim, Daiichi-Sankyo, Anthos. No fees are received personally. He is a National Institute for Health and Care Research (NIHR) Senior Investigator.

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