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Original Research Article

Optimising Anticoagulant Therapy Among Patients with Atrial Fibrillation Using the Hosm-AC Tool: A Pilot Study

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ABSTRACT

Introduction: Oral anticoagulants (OACs) are essential for stroke prophylaxis in patients with atrial fibrillation (AF). However, warfarin therapy requires precise dosing and frequent monitoring to ensure optimal effectiveness and safety. The HoSM-AC tool, a single-page smartphone application, was developed to facilitate evidence-based decision-making in selecting appropriate OACs, including direct oral anticoagulants (DOACs), for patients with non-valvular AF (NVAF). **Objective:** This study aimed to evaluate the effectiveness of the HoSM-AC tool in optimising OAC therapy among patients with NVAF. **Methods:** This pre-post quasi-experimental study included NVAF patients receiving OAC therapy between 1 July 2023 and 31 December 2024 (n = 98). The HoSM-AC tool was used to calculate CHA2DS2-VASc, HAS-BLED, and SAMe-TT2R2 scores, after which the most appropriate OAC regimen was recommended based on the tool's algorithm. Patients were followed for six months post HoSM-AC implementation to monitor bleeding events and hospital admissions related to deranged coagulation profiles. McNemar's test was used for statistical analysis. **Results:** Bleeding events significantly decreased following the implementation of the HoSM-AC tool (p=0.021). The proportion of patients receiving optimal OAC therapy increased from 24.5% to 54.1% (p<0.001). No significant reduction was observed in hospital admissions due to deranged coagulation profiles (p=0.375). Key interventions included switching 21.4% of patients to DOACs and discontinuing unnecessary antiplatelet therapy in 9.2% of cases. Time in therapeutic range (TTR) improved significantly, increasing from 55% to 67% (p=0.041). **Conclusion:** The HoSM-AC tool was effective in guiding clinicians towards optimal OAC selection, resulting in reduced bleeding risk and improved anticoagulation control among patients with NVAF. However, some patients may be reluctant to switch from warfarin to DOACs, which could limit real-world implementation of algorithm-driven therapy.

INTRODUCTION

Oral anticoagulants (OACs) are essential for preventing stroke and systemic embolism in patients with atrial fibrillation (AF). The OACs currently available in Malaysia include warfarin and direct oral anticoagulants (DOACs), such as dabigatran, apixaban and rivaroxaban. However, optimising the dosing regimen for patients on warfarin can be challenging due to potential dietary, drug, and herbal interactions. In addition, frequent blood monitoring is required to maintain the target international normalised ratio (INR) for optimal anticoagulation and minimal bleeding risk. The recommended INR range varies depending on the indication for

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anticoagulation, but is typically 2-3 [1]. In recent years, DOACs have gained popularity in many healthcare institutions and have increasingly replaced warfarin as the preferred OAC due to their improved safety profiles and simpler dosing adjustments. Nonetheless, limitations remain, as their use is not approved for patients with valvular AF due to the lack of clinical trial evidence in this population. Therefore, selecting the most appropriate OAC for AF patients continues to be a challenge in many healthcare settings.

For AF, several scoring systems are available to guide clinicians in determining the indication for OAC therapy by balancing stroke prevention and bleeding risk. These include the CHA2DS2-VASc and HAS-BLED scores. The CHA2DS2-VASc score estimates stroke risk in patients with AF, with higher scores indicating increased risk. Male patients with a CHA2DS2-VASc score of ⩾1 and female patients with a score of ⩾ 2 may be considered for anticoagulation therapy. Anticoagulation is recommended for males with a CHA2DS2-VASc score of ⩾2 and females with a score of ⩾3 [2]. The HAS-BLED score estimates the risk of major bleeding in patients on anticoagulation, with higher scores indicating a greater bleeding risk [3]. Time in therapeutic range (TTR) is an established indicator of anticoagulation quality for patients on warfarin, reflecting the proportion of time a patient's INR remains within the target range. A TTR of at least 58% is required to demonstrate a net clinical benefit from OAC therapy [4]. Patients with low TTR may require interventions to their regimen, including switching to a DOAC. The SAMe-TT2R2 score further aids in predicting which patients are likely to achieve good INR control on warfarin (scores 0-1) versus those who may benefit more from DOACs (scores ⩾2) [5].

In clinical practice, these scores are often calculated using separate medical calculators, which can be time-consuming. OAC selection is also influenced by medication availability and prescriber preference. To streamline this process, the HoSM-AC tool, a single-page interface smartphone application, was developed by creating an algorithm to integrate current treatment guidelines and standardise OAC therapy decision-making for patients with non-valvular AF (NVAF). The HoSM-AC algorithm consolidates the CHA2DS2-VASc, HAS-BLED, and SAMe-TT2R2 scores with renal function parameters, such as creatinine clearance and estimated glomerular filtration rate (eGFR), to provide rapid, patient-specific anticoagulant recommendations. This tool enables physicians and pharmacists to promptly assess renal function and identify the most appropriate OAC (warfarin or a specific DOAC) based on individual clinical characteristics. To support its implementation in routine clinical practice, this study aimed to evaluate the effectiveness of the HoSM-AC tool in optimising oral anticoagulant therapy among patients with NVAF.

METHOD

Study design

This pre-post quasi-experimental study was conducted among adult patients with NVAF who were prescribed an OAC and had active follow-up at Hospital Sultanah Maliha in Langkawi, Kedah, Malaysia (a 110-bed district hospital), between 1st July 2023 and 31st Dec 2024. All recruited patients were followed for up to six months post-intervention. Interventions were carried out by both study and non-study physicians and pharmacists (unblinded). Patients who did not require any intervention continued their follow-up as per usual care. Universal sampling was applied, whereby all patients meeting the inclusion and exclusion criteria were included. Patients were excluded if they defaulted on OAC treatment, underwent heart valve repair or replacement, or were transferred from or to other healthcare facilities.

The HoSM-AC tool was developed based on published clinical studies [6–10] to generate an algorithm for selecting the most appropriate oral anticoagulant. It is a single-page interface smartphone application (for Android users) developed using Android Studio (Figure I), and is also accessible via Google Sheets (for iOS users). The tool was designed by the study investigator. Additional features included options for self-purchase, eligibility for Jabatan Perkhidmatan Awam (JPA) reimbursement, and pensioner status with corresponding codes to enhance local applicability. The algorithm also incorporates information on whether the patient is on a nasogastric tube to determine the suitability of crushable OAC formulations. Before implementation, the usability of the HoSM-AC tool was evaluated by physicians and pharmacists using a validated assessment instrument for rating healthcare smartphone applications [11].

Sample size

A minimum sample size of 55 participants per group was required for this pilot study to detect small to medium standardised effect sizes [12]. After accounting for a 10% dropout rate, the final required sample size was 60 participants per group for both the pre- and post-HoSM-AC tool implementation phases.

Statistical analyses

All statistical analyses were performed using IBM SPSS Statistics version 29. Categorical variables were presented as

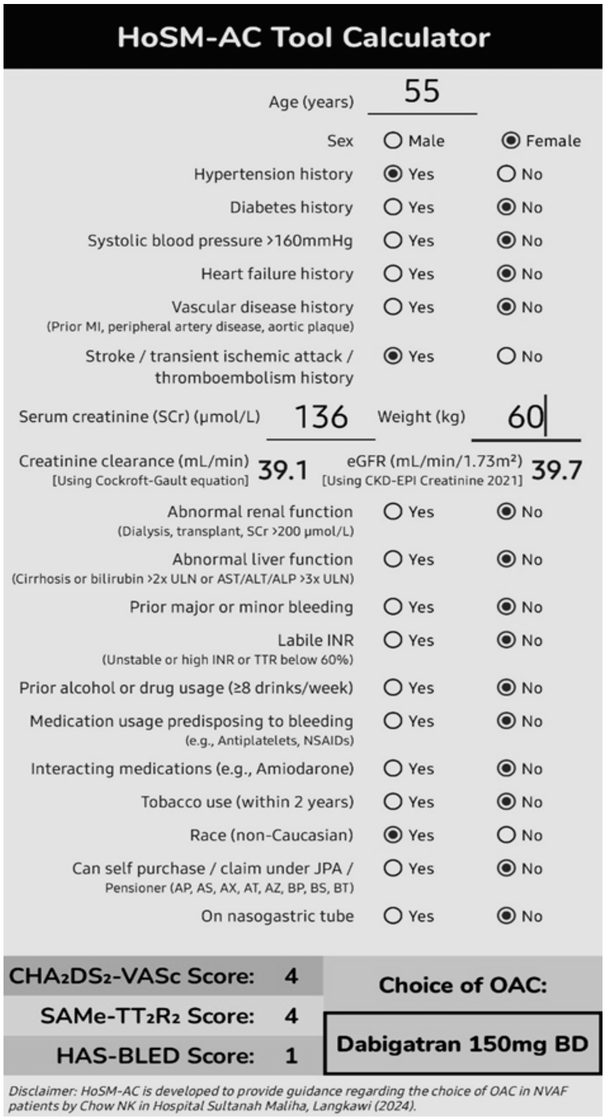

Figure I. A screenshot of the HoSM-AC tool interface

frequencies and percentages, while continuous variables were reported as medians with interquartile ranges (IQRs) due to non-normal data distribution. McNemar's test was used to compare paired proportions, including the occurrence of haemorrhagic events, hospitalisations due to deranged coagulation profiles, and the proportion of patients achieving a target TTR of ≥58% before and after implementation of the HoSM-AC tool. Differences in TTR values pre- and post-intervention were assessed using the Wilcoxon signed-rank test. A p-value <0.05 was considered statistically significant.

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki and the Malaysian Good Clinical Practice Guideline. Ethical approval was obtained from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (NMRR ID-24-02265-RDW).

RESULT

During the study period, 201 patients receiving OAC therapy were identified. Of these, 103 were excluded due to death, valvular AF, treatment for thromboembolism only, or loss to follow-up. As a result, 98 patients with NVAF were recruited for this study.

.Table I. Patients' demographic data and medical history (n = 98).

Variables	n (%)	Median (IQR)
Sex		
Male	51 (52.0)	
Female	47 (48.0)	
Ethnic		
Malay	91 (92.9)	
Chinese	5 (5.1)	
Others	2 (2.0)	
Age, years		66.5 (11.0)
Hypertension		
Yes	93 (94.9)	
No	5 (5.1)	
Diabetes		
Yes	46 (53.1)	
No	52 (46.9)	
History of stroke/TIA/thromboembolism		
Yes	6 (6.1)	
No	92 (93.9)	
Cardiovascular diseases		
Yes	31 (31.6)	
No	67 (68.4)	
Heart failure		
Yes	29 (29.6)	
No	69 (70.4)	
Serum creatinine, µmol/L		83.0 (37.0)
eGFR, mL/min/1.73 m^2 (using 2021 CKD-EPI equations)		70.3 (22.2)
Duration on OAC from initiation until end of study (months)		54.0 (40.0)
Type of OAC (before HoSM-AC)		
Warfarin	64 (65.3)	
DOAC	34 (34.7)	
Type of OAC (after HoSM-AC)		
Warfarin	44 (44.9)	
DOAC	54 (55.1)	

DOAC: direct oral anticoagulant; eGFR: estimated glomerular filtration rate; IQR: interquartile range; OAC: oral anticoagulant; TIA: transient ischemic attack.

The median CHA2DS2-VASc score among participants was 3 (IQR: 1), while the median HAS-BLED score was 1 (IQR: 1). Meanwhile, the median SAMe-TT2R2 score was 3 (IQR: 2). A comprehensive summary of patient demographics and clinical characteristics is presented in Table I.Ten healthcare professionals evaluated the usability of the HoSM-AC tool, yielding an average total score of 55.8 out of 60, indicating a satisfactory user experience regarding both the application content and interface.

For patients with suboptimal TTR, several interventions were implemented, as illustrated in Figure II. Among those who remained on the same OAC, dose adjustments, management of drug interactions, and dietary counselling were provided. A total of 21 patients (21.4%) were switched from warfarin to a DOAC.

Table II presents the comparison of clinical outcomes before and after implementation of the HoSM-AC tool. Bleeding events include haematuria, gum bleeding, and epistaxis. Hospitalisations with deranged coagulation profiles occurred with or without bleeding. Inappropriate OAC therapy includes incorrect OAC selection or incorrect dosing.

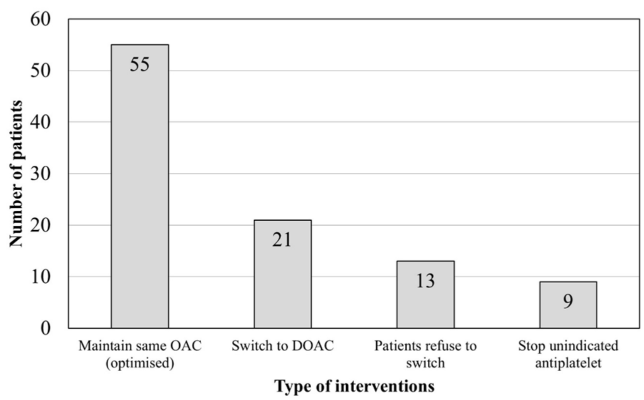

Figure II. A screenshot of the HoSM-AC tool interface.

Table II. Comparison of outcome before and after HoSM-AC implementation (n = 98).

Treatment Outcomes	Pre n (%)	Post n (%)	P value*
No bleeding event	88 (89.8%)	96 (98.0%)	p = 0.021
Any bleeding event	10 (10.2%)	2 (2.0%)	
No hospitalisations with deranged coagulation	94 (95.9%)	97 (99.0%)	p = 0.375
Hospitalisations with deranged coagulation profiles	4 (4.1%)	1 (1.0%)	
Inappropriate OAC therapy	74 (75.5%)	45 (45.9%)	p < 0.001
Appropriate OAC therapy	24 (24.5%)	53(54.1%)	

Note: *McNemar's test. OAC: oral anticoagulant.

On the other hand, the median TTR significantly improved from 55% (IQR: 33) to 66.7% (IQR: 49; p = 0.041). The proportion of patients achieving the target TTR of ⩾58% increased from 48.4% to 56.8%, although this increment did not reach statistical significance (p = 0.629).

DISCUSSION

The HoSM-AC tool facilitated a more systematic treatment protocol for patients with NVAF, allowing those with higher bleeding risk and subtherapeutic anticoagulation to receive closer medical attention during interventions. Specifically, these patients were prioritised for switching from warfarin to a DOAC when indicated. However, the proportion of patients switching to DOACs following the implementation of the HoSM-AC tool remained relatively low at 21.4%. This phenomenon may be attributed to patients' anxiety about new therapies and the higher costs associated with DOACs. As the study participants were predominantly older adults, with a median age of 66.5 years, these factors likely contributed to their reluctance to switch therapies, as many were comfortable with their current warfarin therapy despite the need for frequent monitoring. These findings are consistent with previous literature on OAC treatment acceptance [13].

The 2% bleeding risk observed among our study participants aligns closely with the 1.5% bleeding incidence reported in the literature [3]. As the concomitant use of antiplatelet therapy with OAC is often unnecessary [14], our study identified nine (9.2%) patients who successfully discontinued inappropriate antiplatelet therapy in cases of concurrent antiplatelet-OAC use. Most of these patients had a history of ischaemic cardiovascular events or stroke. This intervention may have contributed indirectly to the significant reduction in bleeding events [15]. Although the proportion of patients with hospitalisations did not differ significantly before and after the tool implementation, this may be because minor bleeding events, such as gum bleeding, can occur even with a normal INR and may not require hospitalisation. Additionally, the small number of hospitalisations in our cohort may have limited the ability to detect significant differences.

In this study, the traditional method of calculating TTR was used, which corresponds to the context of outpatient visits (i.e., the proportion of outpatient visits with INR values within the target range divided by the total number of visits). Although TTR remains a widely used measure of OAC treatment quality, studies have suggested that it may have limited applicability in clinical practice, possibly due to non-standardised intervals for coagulation profile monitoring [16]. Despite the significant increase in median TTR among our patients, the proportion achieving the target TTR ⩾58% did not change significantly post-intervention, which may be partly explained by a subgroup of patients (n = 13, 13.3%) who refused to switch therapies. Close monitoring of clinical outcomes, such as bleeding and thromboembolic events, along with dietary counselling, management of potential drug-drug interactions, and reinforcement of medication adherence, remains crucial in clinical practice. As no thromboembolic events occurred following the implementation of the HoSM-AC tool, statistical analysis for this outcome was not performed.

There have been disagreements regarding the use of the SAMe-TT2R2 score in Asian populations due to the inclusion of race (non-Caucasian) in the score calculation, which might not accurately represent the indication for switching therapy to DOACs. This issue is particularly relevant in the Malaysian context, which comprises a multiracial population, as a local study has reported significant differences in TTR among different ethnic groups [17]. Nevertheless, the SAMe-TT2R2 score was incorporated in the HoSM-AC algorithm because no validated alternative tool is available for the Malaysian population. In our cohort, the median SAMe-TT2R2 score was 3, suggesting that most patients had suboptimal anticoagulation control with warfarin. A sub-analysis using the Korean Modified SA2Me-TTR score [18] produced contrasting results, with a median score of 1 (IQR: 1), indicating that modification of warfarin therapy might be unnecessary. This discrepancy arises because the modified method, developed for the Korean population, replaces the race component with eGFR <50 mL/min/1.73 m^2, and our cohort had higher median eGFR values (70.3 mL/min/1.73 m^2). Consequently, applying this method to our cohort yielded lower scores. Therefore, the Modified SA2Me-TTR score was not adopted in the development of the HoSM-AC algorithm.

CONCLUSION

The HoSM-AC tool effectively guided clinicians in the appropriate selection of OACs, leading to reduced bleeding risks, optimised OAC therapy and improved TTR among NVAF patients. A potential limitation in translating the algorithm-driven therapy to routine practice is that some patients may be reluctant to switch therapies, influenced by familiarity with their current regimen and concerns about cost or new medications. The HoSM-AC algorithm could be further improved in the future by integrating new OACs along with additional practical considerations, such as dosing convenience, real-world contraindications, and cost-effectiveness, to support more robust and clinically applicable decision-making.

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CONFLICT OF INTEREST

No funding was received for this study. All authors declare that they have no conflicts of interest or financial relationships relevant to this article to disclose.

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