ABSTRACT
Background: Satisfaction with treatment has been identified as an important contributing factor to adherence with oral anticoagulant (OAC) therapy in patients with atrial fibrillation (AF). We aimed to evaluate the satisfaction level of patients with AF regarding OAC use over time, using validated patient-reported outcome instruments, and to identify associated patient characteristics.

Methods: Participants were recruited from specialized AF clinics in Canada. Eligible AF patients who were prescribed OACs were followed for up to 2 years. Participants were interviewed via telephone every 3-4 months using a structured survey. The Treatment Satisfaction Questionnaire for Medication (TSQM II) and the Anti-Clot Treatment Scale (ACTS) were used to measure satisfaction over time.

Atrial fibrillation (AF) is a major risk factor for ischemic stroke, the second leading cause of death worldwide.1,2 Oral anticoagulants (OACs) are a central part of stroke risk reduction in patients with AF.3-5 However, nonadherence to OAC therapy is common and has been significantly associated with poor outcomes such as ischemic stroke, systemic embolism, higher healthcare costs, and a higher mortality rate, compared with those for adherent patients.6-7

Patients’ satisfaction with therapy has been associated with various outcomes in a range of diseases including adherence to
therapy. Studies of patients with AF on OAC therapy have also identified treatment satisfaction as an important psychosocial determinant of adherence to therapy, with a lower level of satisfaction with OAC treatment being a significant predictor of stroke/systemic embolism, mediated by OAC nonadherence and nonpersistence. In patients with AF, vitamin K antagonist therapy was associated with greater global satisfaction than was DOAC treatment. Satisfaction with benefit and burden as measured by the ACTS scale, and global satisfaction on the TSQM II scale, tended to increase over time. Patient factors that were somewhat consistently associated with greater satisfaction were female sex and younger age.

Conclusions: Patients with AF were highly satisfied with their therapy, with few differences among OAC classes and individual OACs. Individual patients may or may not be more satisfied with DOAC than VKA therapy, and regardless of the OAC prescribed, the may require significant support to maintain therapy adherence.

Results: Among the 306 participants, satisfaction scores on the TSQM II and ACTS instruments were high. Unadjusted analyses showed significantly greater satisfaction with the burden of therapy with direct OACs (DOACs) compared to that with warfarin (small-magnitude effect) and greater satisfaction with the convenience of rivaroxaban, compared with that of all other OACs (moderate-magnitude effect). After adjustment for all other variables, vitamin K antagonist therapy was associated with greater global satisfaction than was DOAC treatment. Satisfaction with benefit and burden as measured by the ACTS scale, and global satisfaction on the TSQM II scale, tended to increase over time. Patient factors that were somewhat consistently associated with greater satisfaction were female sex and younger age.

Conclusions: Patients with AF were highly satisfied with their therapy, with few differences among OAC classes and individual OACs. Individual patients may or may not be more satisfied with DOAC than VKA therapy, and regardless of the OAC prescribed, the may require significant support to maintain therapy adherence.

Methods

Design

A multicentre, prospective, longitudinal cohort study was conducted at British Columbia’s 5 specialized AF clinics. Ethics approval was granted by the research ethics boards of the University of British Columbia, Interior Health, Fraser Health, Vancouver Island Health, Providence Health, and Vancouver Coastal Health.

Sampling strategy

Patients with AF attending the study clinics who were prescribed OAC therapy (warfarin, dabigatran, rivaroxaban, or apixaban) for stroke prevention were eligible. Edoxaban was not available in Canada at the time of data collection. Patients were excluded if they declined to provide consent, were unable to participate in study activities due to either cognitive impairment or other reasons identified by the referring clinician, or had a planned temporary course of OAC (eg, for cardioversion). Clinicians identified eligible patients and provided them with the study information sheet. Those interested were referred to the study coordinator, who contacted them either in person or by phone following their clinic visit. Recruitment and data collection were refined through an initial pilot study of 59 participants.

Data collection

Participants’ demographic and clinical data were collected during the baseline visit. Patients were then interviewed every 3-4 months (similar to the normal frequency of clinic follow-ups) for 2 years, until OAC discontinuation or loss to follow-up. Follow-up data were collected by telephone interviews using a structured survey, conducted in English, by trained research assistants who were pharmacists or pharmacists-in-training and were not involved in the participants’ care. The survey included several validated questionnaires and additional questions developed by the study team based on their clinical and research experience with AF patients. All interviewers were trained by the study coordinator (A.K.), observed for their first interview, and given feedback before conducting interviews independently.
Data collection commenced in January 2015 and continued until January 2018. The following were noted in every interview: changes in OAC therapy since the preceding visit, satisfaction level with therapy, and occurrence of clinical events (eg, bleeding, stroke, hospitalization).

Outcome measures

Satisfaction with medication was measured using 2 instruments: the Treatment Satisfaction Questionnaire for Medication Version 2 (TSQM-II) and the Anti-Clot Treatment Scale (ACTS). The TSQM is a validated and widely used instrument measuring satisfaction with medication on 4 subscales: side effects, effectiveness, convenience, and global (score range: 0-100). The ACTS is a validated anticoagulation-specific instrument with 2 subscales that are scored on a 5-point Likert scale: a 12-item burden subscale (score range: 12-60), and a 3-item benefit subscale (score range: 3-15). The burden subscale was reverse-coded per the ACTS coding instructions, so that higher scores indicated greater satisfaction on all scales.

Analysis

Patients were included in the analysis if they completed at least one study follow-up visit and provided complete baseline and follow-up satisfaction data. Univariate analyses of demographic characteristics were reported using means and standard deviations (SDs) for continuous variables, and frequencies and percentages for categorical variables. The mean and SD of patient satisfaction scores over the follow-up period were reported for every subscale and also stratified by OAC. Unadjusted relationships between average satisfaction and OAC were explored using the analysis of variance test followed by post hoc pairwise t-tests with Bonferroni’s correction to explore differences. The standardized mean difference (SMD; Cohen’s d) was calculated for significant differences with effect size values of 0.2-0.5, 0.5-0.8, and > 0.8, deemed to be small, moderate, and large, respectively.

Linear regression models were used to study the relationship between patient factors and therapy satisfaction. Given the repeated data structure, we used a generalized estimating equation (GEE) technique to account for the dependencies among repeated data structure, we used a generalized estimating equation (GEE) technique to account for the dependencies among

The sample size was one of convenience. We originally aimed a larger sample for a comparison of adherence with warfarin vs DOACs, an objective unrelated to the present satisfaction analyses.

Results

The study flow is shown in Figure 1. Characteristics of the participants (N=306; 58.8% males, average age 69 (SD 10) years] included in the analysis are summarized in Table 1. Pilot study participants (N = 59) were excluded because the study procedures were being iteratively refined during that period (Fig. 1). Participants were followed-up for up to 2 years, with a median follow-up time of 14.1 months (inter-quartile range 10.5 months), and an average of 3.2 (SD 1.4) study visits per patient.

Satisfaction with therapy

Distributions of the TSQM and ACTS scores are shown in Figures 2 and 3, respectively. Average unadjusted TSQM
AF, atrial fibrillation; CCS—SAF scale, Canadian Cardiovascular Society Severity of Atrial Fibrillation Scale; CD, Canadian dollars; CHA2DS2-VASc, Congestive Heart Failure History, Hypertension History, Age > 75 Years, Age 65 to 74 Years, Diabetes Mellitus, Stroke History, Vascular Disease History, female sex; HAS-BLED, Hypertension, Abnormal Renal Function, Abnormal Liver Function, Stroke History, Bleeding History or Predisposition, Labile INR, Elderly > 65 Years, Drugs or Alcohol; Index OAC, OAC therapy at enrollment; OAC, oral anticoagulants; SD, standard deviation; VKA, Vitamin-K antagonist.

* Stroke risk score calculated based on the presence of the following: cardiomyopathy (1 score), hypertension (1 score), age > 75 years (2 scores), age 65-74 years (1 score), diabetes (1 score), stroke (2 scores), vascular disease (1 score), sex category female (1 score).

† Bleeding risk score calculated based on presence of the following: hypertension (1 score), abnormal liver/kidney function (1 score each), stroke (1 score), bleeding (1 score), labile INR or International Normalized Ratio (1 score), elderly—age > 75 years (1 score), drugs or alcohol use (1 score each).

scores were (out of 100; higher scores imply greater satisfaction) as follows: global satisfaction: 71.2 (SD 10.1); convenience: 76.5 (SD 7.12); side effects: 97.4 (SD 6.13); and effectiveness: 68.3 (SD 10.5). Average unadjusted ACTS scores were 11 out of 15 (SD 1.76) on the benefit subscale and 57 out of 60 (SD 2.76) on the burden subscale.

Table 2 shows participants' satisfaction on the TSQM and ACTS subscales, stratified by OAC. The unadjusted ACTS satisfaction with burden score was significantly higher for DOACs than for warfarin (57.28 vs 56.41, P < 0.05; SMD 0.33; small effect size). Unadjusted satisfaction regarding convenience with rivaroxaban was greater than that with all other OACs (SMD 0.74; moderate effect size). Overall, patients reported a high satisfaction level with OAC therapy.

Factors associated with satisfaction

Figure 4 summarizes the factors associated with anticoagulation therapy satisfaction in patients with AF based on the repeated-measures regression analyses.

On the TSQM II effectiveness subscale, factors significantly associated with increased patient satisfaction were younger age, female sex, and higher income (Fig. 5). For every year increase in age, the score for satisfaction with the effectiveness of OAC decreased by 0.23 units (2.3 units per 10-year increment of age). Female sex was associated with an approximately 4-unit higher satisfaction-with-effectiveness score than male sex. Patients in the high-income band were about 4 units higher on their satisfaction-with-effectiveness score than those in the low- and medium-income bands.

No factors were found to be significantly associated with satisfaction with side effects or satisfaction with convenience on the TSQM II side effects and convenience subscale in our regression analysis.

Factors significantly associated with higher global satisfaction with OAC on the TSQM II were lower stroke risk, female sex, vitamin K antagonist (VKA) therapy (vs DOAC therapy), and not experiencing bleeding (Fig. 5). Patients with a CHA2DS2-VASc score of < 2 had a 3-unit higher global satisfaction score than did patients with higher stroke risk. Being female was associated with an approximately 4-unit higher global satisfaction score, compared with being male. Not experiencing a bleed was associated with an approximately 4-unit higher global satisfaction score than that of patients who bled. Patients on VKA therapy had an approximately 4-unit higher global satisfaction score than did patients on DOACs. Patients’ global satisfaction with their therapy also increased significantly over time. On average, the global satisfaction score increased by 0.93 units every 3 months, corresponding to an approximately 4-unit higher level of global satisfaction per year of therapy.

Regression analysis of the ACTS burden subscale results showed younger age and no bleeding experience to be associated with higher satisfaction with medication burden (Fig. 6). For each year increase in age, the satisfaction with burden of OAC score decreased by 0.05 units, corresponding to a 0.5-unit decrease in satisfaction per 10 years of age progression. Not experiencing bleeding was associated with an approximately 0.5-unit higher satisfaction-with-burden score than that for patients who bled. The score for satisfaction with medication burden increased significantly over time. On average, the score for satisfaction with OAC burden increased by 0.29 units every 3 months, corresponding to an approximately 1.2-unit higher score per year of therapy.

On the ACTS benefits subscale, female sex and a lower AF symptom score were significantly associated with higher satisfaction with OAC benefits (Fig. 6). Being female was associated with a 0.69-unit higher score for satisfaction with benefits than being male. The score for satisfaction with
beneﬁts was approximately 0.23 units higher per unit decrease in the AF symptom severity score. Satisfaction with beneﬁts increased signiﬁcantly over time. On average, the score for satisfaction with OAC beneﬁts increased by 0.10 units every 3 months, corresponding to 0.4-unit increase per year of therapy.

Discussion
In this study of patients with AF taking OACs, patient-reported satisfaction levels on the TSQM II and ACTS were high. Unadjusted analyses showed signiﬁcantly greater satisfaction with the burden of therapy with DOACs, compared with that with warfarin (a small-magnitude effect) and greater satisfaction with the convenience of rivaroxaban, the only once-daily DOAC in the study, compared with all other OACs (a moderate-magnitude effect). After adjustment for all other variables, VKA therapy was associated with a higher level of global satisfaction than DOAC treatment. No other signiﬁcant differences among OAC classes or individual OACs were found. Our exploration of patient factors associated with satisfaction revealed a few patterns. Satisfaction with the beneﬁts and burden of oral anticoagulants on the ACTS scale, and global satisfaction on the TSQM II scale, tended to increase over time. The patient factors somewhat consistently associated with higher satisfaction on multiple scales were female sex and younger age; experiencing no bleeding was associated with a higher satisfaction level on some scales.

Our results can be interpreted in the context of 2 recent systematic reviews examining patient satisfaction with OACs. Katerenchuk et al. meta-analyzed 20 studies of various designs in which satisfaction with OACs for AF or venous thromboembolism were measured.35 The ACTS burden score was signiﬁcantly higher with DOACs than VKAs, and the ACTS beneﬁt score was marginally higher with DOACs than VKAs, both with high heterogeneity. The TSQM results favored DOACs over VKAs on all the subscales, also with high heterogeneity.35 All results were graded as having “very low” or “low” certainty, except for the TSQM effectiveness score, which was deemed to have “moderate” certainty.35 Patient factors associated with satisfaction were not reported.35

Afzal et al. performed a narrative systematic review including 7 studies of patients with AF, measuring OAC satisfaction using both the TSQM and ACTS scales.36 The results were mixed, with most showing satisfaction scores favoring DOACs or no difference, and a small number showing higher satisfaction with VKAs.36 A small number of studies showed that patients on rivaroxaban, compared to those on other ACs, were more satisﬁed in one or more domains of the scales.36 Patient factors associated with satisfaction were not reported.36

As in our study, others have also found greater patient satisfaction with the convenience of rivaroxaban compared to that of VKAs.37,38 The SAKURA AF registry substudy, however, showed a higher convenience score for rivaroxaban vs other DOACs, but no signiﬁcant difference compared to
warfarin. Non-AF-specific literature has identified a complex medication dosing regimen as being negatively associated with satisfaction, and a qualitative study in patients with AF identified that more patients were satisfied with the reduced complexity of their therapy when they switched from VKA to DOAC therapy. The SAKURA AF registry substudy also showed greater satisfaction with DOACs on the ACTS burden subscale, and no difference on the ACTS benefits subscale, as we also observed. The same investigators showed that lower satisfaction with DOAC benefit was independently associated with increased risk of stroke or systemic embolism, further pointing to the relationship between OAC satisfaction and patient outcomes.

Few studies have examined factors associated with patient satisfaction with OACs, and a couple of these studies have found an association of being female with higher satisfaction with OAC therapy, as in our study. One study, albeit small, found that being female was associated with higher satisfaction with OAC convenience, and the SAKURA AF registry found an association of being female with greater satisfaction with OAC side effects. An association of younger age with a higher satisfaction level was found in our study; others have

![Image: Violin plots of the distributions of the Anti-Clot Treatment Scale (ACTS) satisfaction scores. Higher scores mean greater satisfaction.]

**Figure 3.** Violin plots of the distributions of the Anti-Clot Treatment Scale (ACTS) satisfaction scores. Higher scores mean greater satisfaction.

**Table 2.** Average satisfaction scores over follow-up, stratified by index oral anticoagulant; higher scores mean greater satisfaction

| Satisfaction measure | All DOACs | Warfarin | Dabigatran | Apixaban | Rivaroxaban |
|----------------------|----------|----------|------------|----------|-------------|
| TSQM II              |          |          |            |          |             |
| Effectiveness        | 68.10    | 68.72    | 71.45      | 67.00    | 68.03       |
| Side effects         | 97.27    | 97.65    | 98.98      | 97.08    | 96.93       |
| Convenience          | 76.87    | 75.38    | 73.29      | 74.54    | 79.62       |
| Global               | 71.09    | 71.35    | 73.11      | 69.45    | 71.77       |
| ACTS                 | 57.28*   | 56.41    | 57.22      | 56.91    | 57.58       |
| Burden (of 60)       | 11.01    | 11.03    | 10.98      | 10.81    | 11.15       |

DOACs, direct oral anticoagulants; TSQM II, Treatment Satisfaction Questionnaire for Medication version 2; ACTS, Anti-Clot Treatment Scale.

* $P = 0.029$ all DOACs vs warfarin, assessed by $t$ test.

$^*$Analysis of variance test: $P < 0.05$; post hoc pairwise $t$ test with Bonferroni’s correction: rivaroxaban vs warfarin $P = 0.0007$; rivaroxaban vs dabigatran $P = 0.0058$; rivaroxaban vs apixaban $P = 0.0003$. 
# Subscales

| Patient variables |
|-------------------|
| Female sex |
| Younger age |
| Severity of AF |
| No bleed |
| VKA as index OAC |
| High income |
| White race |
| Low bleeding risk* |
| Low stroke risk† |
| AF type |

## Satisfaction with burden

## Satisfaction with benefit

## Satisfaction with effectiveness

## Satisfaction with side effects

## Satisfaction with convenience

## Global satisfaction

| Statistically significant (P < 0.05) |
|------------------------------------|
| Marginally significant (0.05 ≤ P < 0.1) |

**Figure 4.** Factors associated with anticoagulation satisfaction at a glance. AF, atrial fibrillation; OAC, oral anticoagulant; VKA, vitamin K antagonist.

**Figure 5.** Forest plots of the estimates of the effects of factors associated with satisfaction on the Treatment Satisfaction Questionnaire for Medication (TSQM II; see Supplemental Table S1 for more details). Age, Canadian Cardiovascular Society Severity of Atrial Fibrillation Scale (CCS-SAF) scale, support, and visit number were continuous variables. AF, atrial fibrillation; CHA2DS2-VASc, Congestive Heart Failure, Hypertension, Age ≥ 75 Years, Age 65 to 74 Years, Diabetes Mellitus, Stroke, Vascular Disease, Sex Category; HASBLED, Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly (> 65 Years), Drugs or Alcohol; VKA, vitamin K antagonist.
found varying directions of association for these factors.17,18,24,26 Ours is the first long-term study to use repeated-measures regression analysis and to show increasing overall satisfaction with OAC therapy over time, increasing satisfaction with its benefits over time, and an increase in patients finding therapy less burdensome over time. Using a different regression technique, the SAKURA AF registry found an association between longer duration of therapy and higher satisfaction level.17

Clinical significance

Our results have some potentially clinically applicable implications. Patients with AF can take OACs and be highly satisfied with them, which might lower clinicians’ reluctance to prescribe OACs in some cases where there is concern about the burdens exceeding the potential benefits. If patients can be supported to continue with therapy, they may be reassured to know that their overall satisfaction may get better with time. Patients may be moderately more satisfied with rivaroxaban than with other OACs from a convenience viewpoint, possibly because of its single—daily dose regimen and lack of International Normalized Ratio testing (notably, edoxaban, another single—daily dose OAC, which was not included in our study). Female patients and younger patients may be more likely to be satisfied with therapy, and hence may be particularly ideal OAC therapy candidates when it is otherwise indicated, whereas older and male patients may require additional education and support to sustain their satisfaction so they remain adherent and persist with therapy.

Our results and those of other studies indicate that individual patients may or may not be more satisfied with DOAC than VKA therapy. Regardless of the OAC prescribed, patients require significant support (eg, tailored education, shared decision-making, frequent follow-up, behavioural strategies, clarifying misconceptions) to maintain adherence and persistence with therapy.17

Limitations

Our results should be interpreted in light of the study’s limitations. Like all observational studies, ours is susceptible to selection biases (eg, nonresponse bias, survival bias, and incidence—prevalence bias). For example, those who discontinued their participation may have been more or less satisfied with their therapy than those who continued. Hence, our results should not be extrapolated beyond patients who are continuing to take OACs. Also, our study, like most in this area, is hindered by the fact that patients had limited experience on which to base their satisfaction perceptions. Ideally, patients would experience taking both a VKA and a DOAC to inform their satisfaction responses. Lastly, we may not have included some variables that could be associated with satisfaction in our analyses, such as insurance coverage status or a measure of comorbidity.

Conclusions

Overall, patients with AF were highly satisfied with their anticoagulation therapy, with a few differences of small magnitude among OAC classes and individual OACs. Participants’ overall satisfaction with benefit, and global satisfaction, increased with time, and they found OAC therapy to be less burdensome over time. DOACs were found to be slightly less burdensome than warfarin, and rivaroxaban was

Figure 6. Forest plots of the estimates of the effects of factors associated with satisfaction on the Anti-Clot Treatment Scale (ACTS; see Supplementary Table S2 for more details). Age, Canadian Cardiovascular Society Severity of Atrial Fibrillation Scale (CCSS-SAF) scale, support, and visit number were continuous variables. Refer to Table 1 for abbreviations and definitions. AF, atrial fibrillation; CHA2DS2-VASc, Congestive Heart Failure, Hypertension, Age ≥ 75 Years, Diabetes Mellitus, Stroke, Vascular Disease, Age 65 to 74 Years, Sex Category; HASBLED, Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly (> 65 Years), Drugs/Alcohol Concomitantly; VKA, vitamin K antagonist.
perceived as being modestly more convenient than all other OACs. Significant and consistent predictors of greater satisfaction were female sex and younger age.

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Disclosures
The authors have no conflicts of interest to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit CJC Open at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2021.06.015.