Effectiveness of shared decision making strategies for stroke prevention among patients with atrial fibrillation: cluster randomized controlled trial

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ABSTRACT

OBJECTIVE

To evaluate the effectiveness of multiple decision aid strategies in promoting high quality shared decision making for prevention of stroke in patients with non-valvular atrial fibrillation.

DESIGN

Cluster randomized controlled trial.

SETTING

Six academic medical centers in the United States.

PARTICIPANTS

Patient participants were aged ≥18 with a diagnosis of non-valvular atrial fibrillation, at risk for stroke (CHA_2DS_2-VASc ≥1 for men, ≥2 for women), and scheduled for a clinical appointment to discuss stroke prevention strategies. Participating clinicians were those who manage stroke prevention strategies for participating patients.

INTERVENTION

Patients were randomized to use a patient decision aid or usual care; clinicians were randomized to use an encounter decision aid or usual care with all participating patients.

MAIN OUTCOME MEASURES

Primary outcome measures were quality of shared decision making measured by OPTION12, knowledge of atrial fibrillation and its management, and decisional conflict.

RESULTS

1117 participants across six sites were included in the analysis. Compared with usual care, the combined use of both the patient decision aid and the encounter decision aid improved the quality of shared decision making (adjusted mean difference 12.1 (95% confidence interval (CI) 8.0 to 16.2; P<0.001), improved patients' knowledge (odds ratio 1.68 (95% CI 1.35 to 2.09; P<0.001), and reduced patients' decisional conflict (adjusted mean difference −6.3 (95% CI −9.6 to −3.1; P<0.001). Statistically significant improvements were also observed with the encounter decision aid alone versus usual care for all three outcomes and with the patient decision aid alone versus usual care for quality of shared decision making and knowledge. No important differences were observed in treatment choices for stroke prevention or in participants' satisfaction. No statistically significant difference in the length of visit across study groups was detected.

CONCLUSION

Patients who received any decision aid (encounter decision aid, patient decision aid, or both) had lower decisional conflict, better shared decision making, and greater knowledge than those receiving no decision aid, except for the effect of the patient decision aid on decisional conflict, which did not reach statistical significance. The study establishes that use of either pre-visit or in-visit decision aids individually or in combination is advantageous compared with usual care.

TRIAL REGISTRATION

ClinicalTrials.gov NCT04357288.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Several shared decision making tools, or decision aids, have been developed for atrial fibrillation, including patient decision aids and encounter decision aids

Evidence has shown the effectiveness of patient decision aids and encounter decision aids in improving shared decision making outcomes in a clinical setting

No data are available on the comparative effectiveness of these different types of decision aid on supporting shared decision making in practice

WHAT THIS STUDY ADDS

The use of either decision aid individually or in combination yielded better shared decision making outcomes compared with usual care

Introduction

Atrial fibrillation is the most common cardiac dysrhythmia in adults and one of the most common preventable causes of ischemic stroke. Atrial fibrillation affects more than 37 million people worldwide and is projected to affect more than 62 million people by 2050.[1] People with atrial fibrillation are four to five times more likely to have a stroke than those without atrial fibrillation,[2] and atrial fibrillation related strokes are associated with increased morbidity and mortality compared with non-atrial fibrillation related strokes.[3] In patients with non-valvular atrial fibrillation, oral anticoagulants, including warfarin or direct acting oral anticoagulants, can effectively prevent strokes (class I, level of evidence A recommendation).[4 5] Despite their effectiveness, oral anticoagulants are historically underused, with as many as 50% of at risk patients with atrial fibrillation who are given a prescription for an oral anticoagulants do not start therapy, and 30-

50% of those who start therapy discontinue it within one year.[6]

The benefit of oral anticoagulants for prevention of stroke in atrial fibrillation is well established, but so are the harms—namely, major bleeding events.[7-10] Decisions about stroke prevention treatment with oral anticoagulants require understanding and careful consideration of factors such as the risk of thromboembolic events due to inadequate anticoagulation concentrations, the inherent risk of bleeding events, cost considerations, and the necessity for monitoring.

Shared decision making is increasingly recognized as an important part of stroke prevention by prescribing oral anticoagulants in every major clinical practice guideline for atrial fibrillation worldwide.[4 11-14] Shared decision making is a process by which clinicians and patients arrive at a healthcare decision together through discussion of risks and benefits in addition to patients' related preferences and values.[15] Several shared decision making tools, or decision aids, have been developed for atrial fibrillation,[16 17] including patient decision aids designed for use by patients before a clinical encounter and encounter decision aids designed for use by clinicians and patients during a clinical encounter. Evidence has shown the effectiveness of a patient decision aid or encounter decision aid in improving shared decision making outcomes in a clinical setting[18 19]; however, no reliable estimate exists of the comparative effectiveness of these different types of decision aids in supporting shared decision making in practice. The aim of this study was to evaluate the effectiveness of a patient decision aid and an encounter decision aid in promoting high quality shared decision making for stroke prevention in the care of patients with non-valvular atrial fibrillation at risk of stroke.

Methods

Trial design and participants

This four arm, cluster randomized, multicenter clinical trial evaluated the effects of usual care alone (control), usual care with a patient decision aid, usual care with an encounter decision aid, or usual care with both decision aids on shared decision making and clinical outcomes. This study was implemented at six US academic medical centers: University of Utah (Salt Lake City, Utah), Mayo Clinic (Rochester, Minnesota), Northwestern University (Chicago, Illinois), University of Alabama at Birmingham (Birmingham, Alabama), University of Michigan (Ann Arbor, Michigan), and Vanderbilt University Medical Center (Nashville, Tennessee). The trial design and protocol have been published elsewhere,[20] and the only minor deviation from this established protocol throughout the course of the study was the addition of telehealth visits at the start of the covid-19 pandemic.

Eligible patients were at least 18 years old, had a diagnosis of non-valvular atrial fibrillation, had at least one non-sex related risk factor for thromboembolic events (that is, CHA_2DS_2-VASc ≥1 for men, ≥2 for women),[21] and were eligible to receive anticoagulation as judged by their clinician. On the basis of their anticoagulation status at baseline, patients were assembled into two cohorts—those considering starting anticoagulation (initiation) and those considering continuing anticoagulation (monitor). The initiation cohort included patients who had no previous anticoagulation history, were taking daily aspirin instead of an anticoagulant, had discontinued anticoagulation usage (for any reason) more than six months before trial participation, or started anticoagulation ≤60 days from study enrollment. The monitor cohort consisted of patients who had been taking anticoagulation for more than 60 days and who met at least one of the following criteria: had problems with their current anticoagulation therapy, such as labile international normalized ratio control, perceived or actual side effects, or affordability of medication; emerging evidence suggesting re-evaluation of previous relative contraindications to direct acting oral anticoagulants therapy (for example, apixaban use in cases of renal dysfunction, obesity); or changes in medical condition that might affect stroke prevention in atrial fibrillation, such as declining renal function or a coronary stent placement. Clinician participation was open to those who were involved in the management of eligible patients with atrial fibrillation.

Randomization and blinding

Patients were randomly assigned with equal allocation to either the use of the patient decision aid or usual care. Clinicians were randomly assigned with equal allocation to either use the encounter decision aid with all study participants or a usual care arm in which they did not use the encounter decision aid for any study participants. Randomization of patients was stratified by CHA_2DS_2-VASc score (≥2 or <2 in men; ≥3 or <3 in women) and cohort (initiation or monitor). Randomization was also stratified by study site for both patients and clinicians. A study coordinator allocated all participants by using the REDCap randomization function. Participants could not be blinded to allocation owing to the nature of the intervention.

Interventions

The development of the decision aids used in the study has been described previously[22]; it is briefly described below. Figure 1 shows screenshots of each decision aid.

Patient decision aid

Patients randomized to use the patient decision aid were asked to view it before arriving for their clinic visit or at the clinic immediately before their appointment. The patient decision aid includes an explanation of atrial fibrillation and how it affects a patient's life and features the CHA_2DS_2-VASc and HAS-BLED calculators to illustrate individualized risks of stroke and bleeding events, respectively. It also provided comparisons between warfarin and direct acting oral anticoagulants, covering aspects such as bleeding

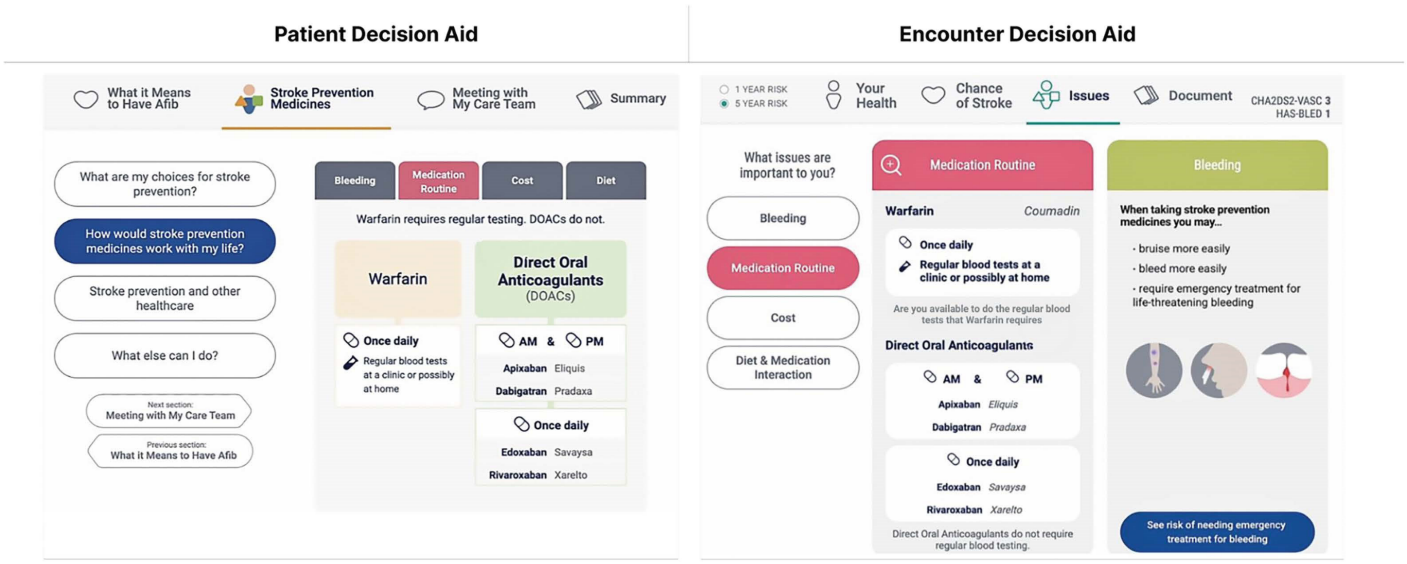

Fig 1 | Screenshots of the patient decision aid (left) and encounter decision aid (right). These examples show how details of medication routine are described for each tool

risks, medication routines, costs, and drug and dietary interactions. The patient decision aid was designed as an interactive, non-linear online tool, enabling patients to explore topics of interest in the order they prefer, with two distinct pathways for the initiation and monitor cohorts.

Encounter decision aid

Clinicians randomized to the encounter decision aid used the tool with study patients during their encounters. The encounter decision aid served as an interactive online tool designed to support clinical conversations about stroke prevention. The content and framework of the encounter decision aid mirrored that of the patient decision aid. After the clinicians received training on its use, they used the encounter decision aid with patients during in-person appointments and telehealth consultations (via screen sharing).

Outcomes

The primary outcome measures assessed three co-primary outcome domains: quality of shared decision making measured using the OPTION12 scale, an observer based score derived from the clinical encounter, transformed to a value between 0 and 100, with higher scores representing greater shared decision making[23]; patient's knowledge of atrial fibrillation and its management measured using a seven item true/false survey adapted from a previous study,[24] with scores representing the proportion of correct answers; and patient decision making measured using the Decisional Conflict Scale, a 16 item Likert-type scale transformed to a score of 0-100, with lower scores representing lower levels of decisional conflict.[25] Additional process and outcome measures included agreement between patient and clinician on treatment choice, length of visit, clinician's recommendation regarding the method used in the consultation (encounter decision aid versus no encounter decision aid), clinician's satisfaction with the anticoagulation discussion, and patient's satisfaction with the encounter decision aid/patient decision aid to which they were exposed. Outcomes were collected from patients and clinicians through surveys administered immediately post-encounter.

Sample size

We assumed that the number of study patients seen per clinician would follow the distribution seen in a previous trial,[26] with an average of 5.18 patients per clinician. We assumed intraclass correlations of 0.25 for the OPTION12 score and 0.10 for the knowledge and decisional conflict scores,[27-30] and that at least 95% of randomized patients would have non-missing measurements on each of these outcomes. Under these assumptions, the sample size of 1200 would provide 80% power with a two sided α of 0.05 to detect mean differences, expressed as fractions of one standard deviation, of 0.40, 0.33, and 0.33 for the OPTION12, knowledge, and decisional conflict scores, respectively, for the primary comparison of patient decision aid and encounter decision aid combined versus usual care. The minimum detectable effect sizes were 0.41, 0.34, and 0.34, respectively, for encounter decision aid versus usual care and 0.29, 0.29, and 0.29, respectively, for patient decision aid versus usual care, using the α levels described below. These minimum detectable effect sizes were smaller than or very close to average treatment effects on each of these outcomes estimated in a review of previous studies (0.94, 0.33, and 0.42, respectively).[31]

Statistical analyses

Before any formal analyses, the statisticians and research team at the University of Utah developed a statistical analysis plan; the primary investigator

at each site approved this plan. Each investigator remained blinded to results until after our statistical analysis plan was fully executed and the initial data collection was complete.

Strategy for comparing co-primary outcomes

Because the three co-primary outcomes assessed conceptually distinct outcome domains, we analyzed each outcome on a comparison-wise basis without multiple comparison adjustment. However, for each co-primary outcome, we used a gatekeeping strategy to preserve a study-wise type 1 error of 0.05 for that outcome. In this strategy, the comparison of the combination of patient decision aid and encounter decision aid together versus usual care was treated as the primary comparison. The gatekeeping rule specified that if the primary treatment group comparison was statistically significant (two sided α=0.05), the comparisons of patient decision aid alone versus usual care and of encounter decision aid alone versus usual care would be done as secondary comparisons, using two sided α levels of 0.01 and 0.04, respectively. If the primary comparison was not significant, the patient decision aid versus usual care and the encounter decision aid versus usual care comparisons would be interpreted as exploratory. A higher α was assigned to the encounter decision aid versus usual care comparison to account for the effects of clustering by clinician on statistical power. Additional pairwise comparisons of patient decision aid versus encounter decision aid, the combination of patient decision aid and encounter decision aid versus patient decision aid alone, and the combination of patient decision aid and encounter decision aid versus encounter decision aid alone were prespecified exploratory comparisons.

Analysis of co-primary outcomes

Analyses of all outcomes were done in the full analysis cohort, which comprised randomized participants who were confirmed to be eligible and attended the index study visit at which the decision aids were administered. Using an intention-to-treat strategy, we imputed missing outcome measurements by using fully sequential multiple imputation (details provided in the supplementary material). We did the co-primary statistical analyses for the OPTION12 scale and Decisional Conflict Scale by using separate analyses of linear mixed effects models to relate these outcomes to the four randomized treatment groups.[32] The six clinical sites as well as the CHA_2DS_2-VASc score group, patient's sex, and cohort (initiation or monitor), which defined the randomization stratification factors, were fixed effect covariates in the model. The treating clinician was included as a random effect to account for clustering of outcomes by clinician. We did the co-primary statistical analysis for the knowledge outcome by using a generalized linear mixed effects model for a binomial outcome with a logistic link function, with the binomial outcome defined by the number of items answered correctly on the scale. The model included a treatment group and the same covariates described above for the OPTION12 and Decisional Conflict Scale analyses, with the clinician again treated as a random effect. For each outcome, we used linear contrasts to estimate the primary, secondary, and exploratory treatment comparisons defined above.

Subgroup analysis

We did subgroup analyses for six baseline subgroup factors that we defined a priori: patient's cohort (initiation versus monitor), patient's age (≤65, 65-74, ≥75 years), patient's sex at birth (male, female), patient's education (less than college degree, college/graduate degree), patient's digital literacy[33] (very confident versus other), and clinician's training (MD/DO/MBBS versus other).

For each subgroup factor, we extended the mixed effects models described above for the three co-primary outcomes by adding interaction terms between that factor and the four cells of the two-by-two factorial design. We estimated the results of the primary and secondary treatment comparisons (three comparisons in all) within each subgroup and displayed the results as a forest plot with P values for the associated treatment by subgroup interactions.

Other process and outcome measures

We compared agreement on treatment choice between patient and clinician, clinician's treatment choice, length of visit, clinician's recommendation for the method used in consultations (encounter decision aid versus no encounter decision aid; clinicians could respond "yes," "no," or "not sure"), and clinician's satisfaction with anticoagulation discussion (five point Likert scale from 1, "not at all satisfied," to 5, "extremely satisfied") between treatment groups by using linear mixed models for continuous outcomes and generalized linear mixed models for binary or ordered categorical outcomes, as appropriate, using the same fixed and random effects as in the analyses of the primary and secondary outcomes. We summarized patients' recommendation of encounter decision aid/patient decision aid usage (five point Likert scale from 1, "not at all likely," to 5, "extremely likely"). Details of the analysis of the clinician's treatment choice categorical outcome are provided in the supplementary materials.

Patient and public involvement

Relevant stakeholders were involved in the design, conduct, and analysis of the research study. Stakeholders included clinicians, patients, and other content based experts involved in the study's conceptualization, design, conduct, and analysis. We held regular meetings with stakeholders to gather input and feedback. In response to this feedback, we made changes in the outcome measures used, recruitment scripts and strategies, and length of survey measures. Furthermore, significant stakeholder feedback was used in the development of the decision aids used in this study.[22]

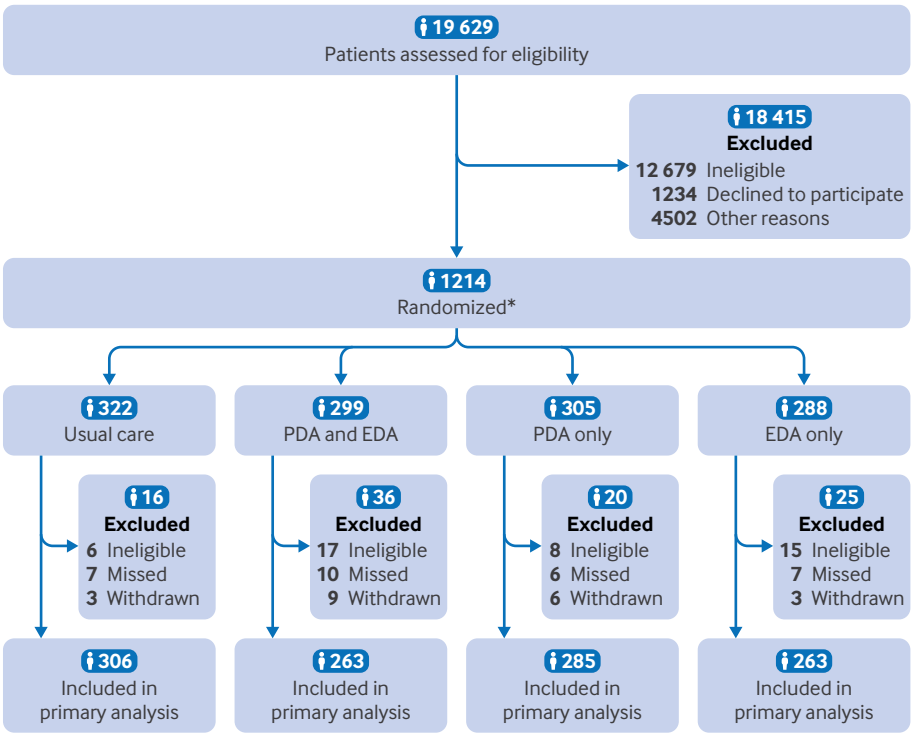

Fig 2 | CONSORT (Consolidated Standards of Reporting Trials) diagram. Patients were excluded after randomization for the following primary reasons: patient discovered to be ineligible (eg, no diagnosis of atrial fibrillation, contraindication to oral anticoagulants), missed or cancelled appointments, patient withdrew from study. EDA=encounter decision aid; PDA=patient decision aid

Results

Between 14 December 2020 and 3 July 2023, we enrolled 1214 patient participants across the six sites; 604 (50%) were randomized to the patient decision aid and 610 (50%) to usual care. Our analysis cohort consisted of 1117 participants, as 97 participants were later found to be ineligible or withdrew from the study encounter visit (usual care, n=16; encounter decision aid/patient decision aid, n=36; patient decision aid only, n=20; encounter decision aid only, n=25). Figure 2 shows the number of participants enrolled, excluded, and included in the analysis in each arm. We enrolled 107 clinicians, of whom 51 (48%) were randomized to the encounter decision aid and 56 (52%) to usual care. The mean age of the patients was 69 (standard deviation 9) years, with most patients reporting as male, white non-Hispanic, and at least a college graduate (table 1). Most (831; 74%) patients' CHA_2DS_2-VASc score was ≥2 for men and ≥3 for women, and most were in the monitor cohort (797; 71%). Clinicians from the six sites were mostly male and non-Hispanic white; the vast majority were cardiologists (see supplementary materials).

OPTION12, knowledge, and decisional conflict

Table 2 shows unadjusted and adjusted means and standard deviations for the three co-primary outcomes of quality of shared decision making (OPTION12), knowledge, and decisional conflict by treatment group. In the first step of the gatekeeping strategy outlined above, patients randomized to the combination of encounter decision aid and patient decision aid showed significantly improved quality of shared decision making (OPTION12) scores (estimated difference 12.1, 95% confidence interval (CI) 8.0 to 16.2; P<0.001), knowledge scores (adjusted odds ratio comparing the proportion of correct responses on the knowledge score 1.68, 95% CI 1.35 to 2.09; P<0.001), and decisional conflict scores (estimated difference −6.3, 95% CI −9.6 to −3.1, P<0.001), compared with patients randomized to control (table 3).

In the secondary comparisons of the individual decision aids versus control, both the encounter decision aid alone and the patient decision aid alone had significantly better results for each of the shared decision making outcomes, except for the effect of the patient decision aid on decisional conflict which did not reach statistical significance. In exploratory comparisons between the two decision aids directly, knowledge scores were similar between the encounter decision aid and patient decision aid groups (estimated difference 0.84, 95% CI 0.64 to 1.10; P=0.20), the quality of shared decision making (OPTION12) score was greater in the encounter decision aid group (estimated difference 9.1, 5.0 to 13.2; P<0.001), and the modest difference in decisional conflict scores did not achieve statistical significance (estimated difference −3.2, −6.6 to 0.1; P=0.06). Lastly, we examined the

Table 1 | Baseline characteristics of patients overall and by treatment group. Values are numbers (percentages) unless stated otherwise

Characteristic	Usual care (n=306)	EDA and PDA (n=263)		PDA only (n=285)		EDA only (n=263)	
		Value	SMD*	Value	SMD*	Value	SMD*
Mean (SD) age, years	68.7 (9.5)	68.7 (9.4)	0.00	68.9 (9.0)	0.02	69.9 (9.5)	0.13
Age categories, years:							
<65	82/293 (28)	64/257 (25)	−0.07	63/275 (23)	−0.12	56/258 (22)	−0.15
65-74	126/293 (43)	124/257 (48)	0.11	144/275 (52)	0.19	120/258 (47)	0.07
≥75	85/293 (29)	69/257 (27)	−0.05	68/275 (25)	−0.10	82/258 (32)	0.06
Sex assigned at birth:							
Female	103/298 (35)	98/255 (38)	0.08	95/276 (34)	0.00	105/261 (40)	0.12
Male	195/298 (65)	157/255 (62)	−0.08	181/276 (66)	0.00	156/261 (60)	−0.12
Race/ethnicity:							
White non-Hispanic	269 (88)	230 (87)	−0.01	249 (87)	−0.02	233 (89)	0.02
White Hispanic	5 (2)	2 (1)	−0.08	5 (2)	0.01	2 (1)	−0.08
Black	10 (3)	8 (3)	−0.01	9 (3)	−0.01	13 (5)	0.08
Asian	0 (0)	1 (<1)	0.09	3 (1)	0.15	3 (1)	0.15
American Indian/Alaskan	1 (<1)	1 (<1)	0.01	1 (<1)	0.00	0 (0)	−0.08
Multirace	6 (2)	3 (1)	−0.07	3 (1)	−0.07	5 (2)	0.00
Other	3 (1)	2 (1)	−0.02	3 (1)	0.01	3 (1)	0.02
Prefer not to answer	12 (4)	16 (6)	0.10	12 (4)	0.01	4 (2)	−0.15
Education:							
Less than college	107/291 (37)	86/252 (34)	−0.06	99/272 (36)	−0.01	101/256 (39)	0.06
College graduate (bachelor's degree)	81/291 (28)	68/252 (27)	−0.02	83/272 (31)	0.06	70/256 (27)	−0.01
Graduate or professional school degree	103/291 (35)	98/252 (39)	0.07	90/272 (33)	−0.05	85/256 (33)	−0.05
Health insurance:							
No, I do not have health insurance at this time	4/291 (1)	2/254 (1)	−0.06	1/271 (<1)	−0.11	1/256 (<0.1)	−0.11
Yes, I am now covered by a form of health insurance or health plan	287/291 (99)	252/254 (99)	0.06	269/271 (99)	0.06	255/256 (>99)	0.11
Don't know	0/291 (0)	0/254 (0)	NA	1/271 (<1)	0.09	0/256 (0)	NA
CHA_2DS_2-VASc score:							
≥2 for men; ≥3 for women	231 (75)	193 (73)	−0.05	212 (74)	−0.03	195 (74)	−0.03
<2 for men; <3 for women	75 (25)	70 (27)	0.05	73 (26)	0.03	68 (26)	0.03
Positive for limited reading ability[34]	31/291 (11)	16/253 (6)	−0.16	19/273 (7)	−0.13	19/254 (7)	−0.11
Digital literacy:							
Very confident	165/291 (57)	153/253 (60)	0.08	150/271 (55)	−0.03	134/254 (53)	−0.08
Other	126/291 (43)	100/253 (40)	−0.08	121/271 (45)	0.03	120/254 (47)	0.08

Each patient is weighted equally irrespective of number of patients seen by each clinician.
EDA=encounter decision aid; PDA=patient decision aid; SD=standard deviation; SMD=standardized mean difference.
*SMDs provide differences in means or in percentages between each active treatment group and control (usual care) divided by SD of variable being summarized.

effect of both decision aids together, compared with each decision aid alone. We observed similar results for each co-primary outcome between the encounter decision aid and patient decision aid group and the encounter decision aid alone group. However, when we compared the encounter decision aid and patient decision aid together with the patient decision aid alone, the combined decision aid group showed significantly greater OPTION12 scores (estimated difference 8.3, 95% CI 4.3 to 12.4; P<0.001), as well as lower decisional conflict (estimated difference −3.7, −7.1 to −0.4; P=0.03) compared with the patient decision aid alone.

We also did subgroup analyses for the primary comparisons between encounter decision aid and patient decision aid versus control by age, patient cohort, digital literacy, provider training, education, and sex assigned at birth (fig 3). In general, the estimated treatment effects were similar across these subgroups.

Experience outcomes

Patient and clinician satisfaction

We examined the experience and satisfaction of both the clinicians' and patients' usage of the decision aids as secondary outcomes (table 4). Most clinicians

Table 2 | Co-primary outcomes by randomized treatment

Group	Unadjusted estimates						Adjusted estimates—mean (SE)		
	OPTION12 score		Knowledge score		Decisional conflict score				
	No	Mean (SD)	No	Mean* (SD)	No	Mean (SD)	OPTION12 score	Knowledge score	Decisional conflict score
Usual care	255	30.7 (12.36)	292	0.75 (0.19)	291	25.8 (20.51)	31.6 (1.45)	0.76 (0.01)	25.8 (1.14)
EDA and PDA	231	42.5 (15.74)	255	0.84 (0.17)	255	19.4 (16.23)	43.7 (1.52)	0.84 (0.01)	19.5 (1.23)
PDA only	229	34.5 (13.57)	273	0.83 (0.16)	273	23.4 (20.02)	35.4 (1.46)	0.84 (0.01)	23.2 (1.18)
EDA only	235	43.7 (16.20)	256	0.81 (0.20)	255	20.0 (19.91)	44.5 (1.51)	0.82 (0.01)	20.0 (1.24)

EDA=encounter decision aid; PDA=patient decision aid; SD=standard deviation; SE=standard error.
*Proportion of questions answered correctly.

Table 3 | Group comparisons for co-primary outcomes

	OPTION12 score			Knowledge score		Decisional conflict score		
Comparison*	Estimated difference (CI)	SE	P value	Odds ratio (CI)	P value	Estimated difference (CI)	SE	P value
Primary comparison†								
EDA and PDA *v* control	12.1 (8.0 to 16.2)	2.09	<0.001	1.68 (1.35 to 2.09)	<0.001	-6.3 (−9.6 to −3.1)	1.67	<0.001
Secondary comparisons								
EDA *v* control‡	12.9 (8.6 to 17.1)	2.07	<0.001	1.41 (1.11 to 1.79)	0.003	−5.8 (−9.3 to −2.4)	1.68	<0.001
PDA *v* control§	3.8 (1.1 to 6.4)	1.02	<0.001	1.68 (1.24 to 2.28)	<0.001	−2.6 (−6.8 to 1.6)	1.63	0.11
Exploratory comparisons¶								
EDA *v* PDA	9.1 (5.0 to 13.2)	2.07	<0.001	0.84 (0.64 to 1.10)	0.20	−3.2 (−6.6 to 0.1)	1.72	0.06
EDA and PDA *v* EDA	−0.8 (−3.0 to 1.4)	1.12	0.48	1.19 (0.95 to 1.49)	0.14	−0.5 (−3.9 to 2.9)	1.72	0.76
EDA and PDA *v* PDA	8.3 (4.3 to 12.4)	2.07	<0.001	1.00 (0.77 to 1.29)	0.99	−3.7 (−7.1 to −0.4)	1.72	0.03

CI=confidence interval; EDA=encounter decision aid; PDA=patient decision aid; SE=standard error.
*Treatment comparisons under linear mixed effects model (for decisional conflict and OPTION12) or generalized linear mixed effects model (for knowledge score).
†Statistical significance indicated by P<0.05; 95% CI given.
‡Statistical significance indicated by P<0.04; 96% CI given.
§Statistical significance indicated by P<0.01; 99% CI given.
¶95% CI given.

recommended the consultation method used in their respective treatment group (85.9-90.7% per group), and we found no statistically significant differences between the treatment groups when comparing clinicians' recommendation of the method used in visit (encounter decision aid versus no encounter decision aid) or clinicians' satisfaction. Patients who were exposed to either or both of the decision aids also recommended usage of the decision aid(s) they received.

Treatment choice

Direct acting oral anticoagulants were the most commonly prescribed treatment for each of the groups (63.7-70.0% per group). When we compared the concordance between clinician reported and patient reported treatment choice, 76.2-77.9% of responses between patients and clinicians agreed. We found no statistically significant differences when comparing clinician-patient agreement on treatment choice by group (table 5 and supplementary materials).

Appointment length

When comparing the length of visit across study groups, we observed no statistically significant differences. The mean length of visit ranged from 20.3 minutes to 21.6 minutes across the different decision aid use groups (see supplementary materials).

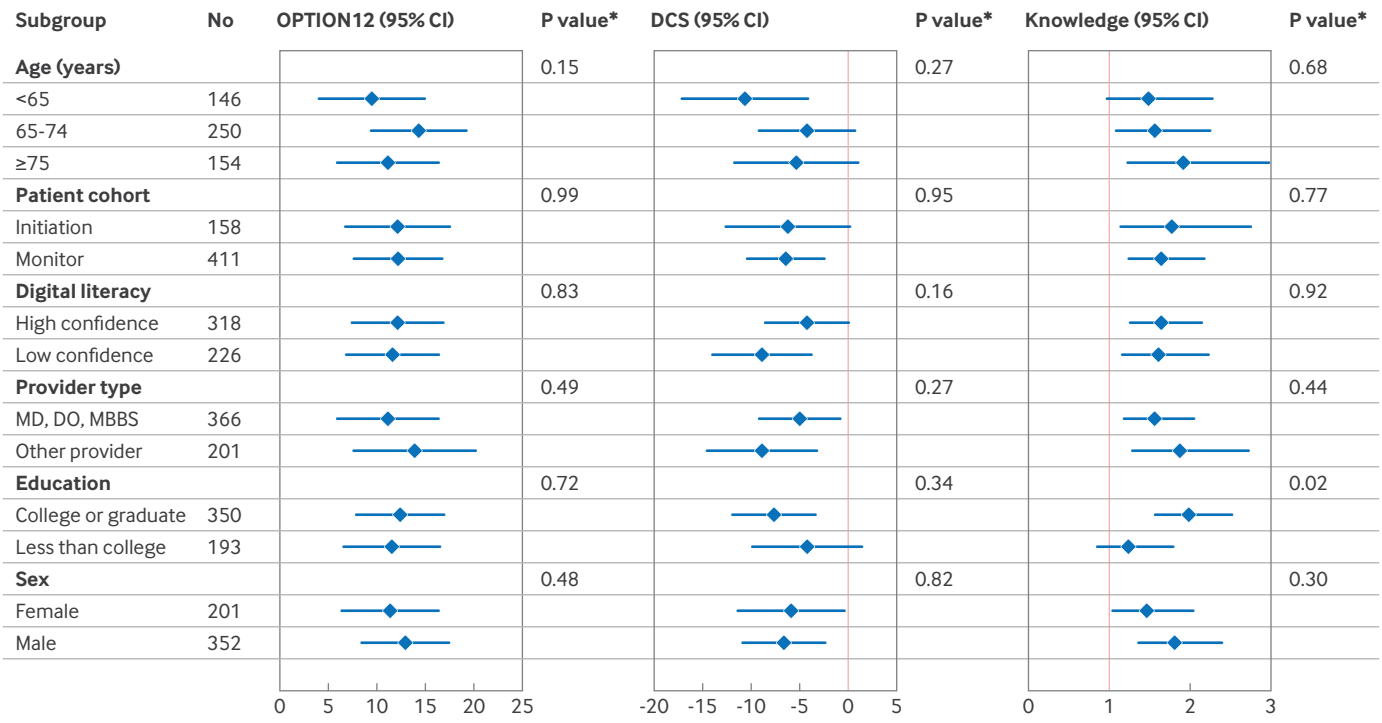

Fig 3 | Subgroup analyses for primary comparisons between encounter decision aid (EDA) and patient decision aid (PDA) versus control. Mean difference and 95% confidence interval (CI) for both EDA and PDA versus control group are presented for OPTION12 and Decisional Conflict Score (DCS). Odds ratio and 95% CI for both EDA and PDA versus control group are presented for knowledge. *P value for comparison between subgroups

Table 4 | Summary statistics of secondary outcomes. Values are numbers (percentages)

	Control	EDA and PDA	PDA only	EDA only
Clinician satisfaction*				
Would recommend method used in consultation to decide about anticoagulation (EDA, no EDA):				
Yes	238 (85.9)	225 (90.0)	229 (86.7)	224 (90.7)
No	9 (3.2)	6 (2.4)	5 (1.9)	5 (2.0)
Not sure	30 (10.8)	19 (7.6)	30 (11.4)	18 (7.3)
Satisfied with the discussion about anticoagulation:				
1-2	6 (2.2)	3 (1.2)	7 (2.7)	3 (1.2)
3	19 (6.9)	34 (13.7)	19 (7.2)	35 (14.2)
4-5	251 (90.9)	212 (85.1)	237 (90.1)	209 (84.6)
Patient would recommend PDA†				
1-2	NA	14 (8.0)	22 (10.1)	NA
3	NA	32 (18.3)	34 (15.5)	NA
4-5	NA	129 (73.7)	163 (74.4)	NA
Patient would recommend EDA†				
1-2	NA	13 (7.4)	NA	12 (6.5)
3	NA	31 (17.6)	NA	30 (16.3)
4-5	NA	132 (75.0)	NA	142 (77.2)
Clinician reported treatment choice				
Use of warfarin	27 (8.8)	22 (8.4)	21 (7.4)	22 (8.4)
Use of apixaban, dabigatran, edoxaban, or rivaroxaban (DOAC):	195 (63.7)	184 (70.0)	187 (65.6)	180 (68.4)
To not take a stroke prevention drug or to make the decision at another time‡	39 (12.8)	34 (12.9)	42 (14.7)	40 (15.2)
No discussion about stroke prevention drugs took place, other, or missing	45 (14.7)	23 (8.8)	35 (12.3)	21 (8.0)

Sample sizes and percentages weight each patient encounter equally irrespective of number of patients seen by each clinician.
EDA=encounter decision aid; DOAC=direct oral anticoagulant; PDA=patient decision aid.
*Measured on 5 point Likert scale with categories 1="Not at all satisfied;" 2, 3="Somewhat satisfied;" 4, 5="Completely satisfied." Clinicians could also select "NA no discussion" where appropriate.
†Measured on 5 point Likert scale with categories: 1="Not at all;" 2, 3, 4, 5="Extremely."
‡Contains 10 patients for whom clinician had chosen "use of aspirin or other antiplatelet agent."

Discussion

Our study found that the use of either the patient decision aid or the encounter decision aid tool among patients with non-valvular atrial fibrillation was more advantageous than usual care. Patients who received both the encounter decision aid and the patient decision aid had improved observer assessed quality of shared decision making, objectively assessed patient knowledge, and patient reported decisional conflict compared with usual care. In addition to the overall benefit seen with the combined use of the patient decision aid and encounter decision aid tools, use of the encounter decision aid alone showed similarly improved outcomes compared with usual care, whereas the patient decision aid alone improved shared decision making and knowledge, but not decisional conflict, compared with usual care.

Meaning of results

The magnitude of improvement in quality of shared decision making (OPTION12) was greatest for the encounter decision aid only group when we compared each strategy with usual care, although the encounter decision aid alone and the combined use of the encounter decision aid and patient decision aid performed similarly, both showing almost a full

Table 5 | Group comparisons for secondary outcomes

	Agreement of patient and clinician reported treatment choice*		Clinician recommends method used in visit†		Clinician satisfaction with discussion†	
Comparison	Odds ratio (CI)	P value	Odds ratio (CI)	P value	Odds ratio (CI)	P value
Primary comparison						
EDA and PDA *v* control	0.95 (0.58 to 1.55)	0.84	1.20 (0.46 to 3.14)	0.71	0.59 (0.28 to 1.24)	0.16
Secondary comparisons						
EDA *v* control‡	0.99 (0.61 to 1.61)	0.96	1.17 (0.42 to 3.24)	0.76	0.61 (0.27 to 1.37)	0.21
PDA *v* control§	0.87 (0.48 to 1.58)	0.56	1.04 (0.50 to 2.20)	0.88	0.72 (0.43 to 1.22)	0.11
Exploratory comparisons						
EDA *v* PDA	1.13 (0.70 to 1.83)	0.62	1.12 (0.42 to 2.98)	0.82	0.85 (0.40 to 1.83)	0.68
EDA and PDA *v* EDA	0.96 (0.63 to 1.47)	0.86	1.03 (0.52 to 2.02)	0.94	0.95 (0.62 to 1.46)	0.83
EDA and PDA *v* PDA	1.09 (0.65 to 1.81)	0.75	1.15 (0.43 to 3.03)	0.78	0.81 (0.39 to 1.71)	0.59

Treatment comparisons under generalized linear mixed effects model.
CI=confidence interval; EDA=encounter decision aid; PDA=patient decision aid.
*Odds ratios indicate ratio of odds of agreement between indicated treatment groups for this binary outcome.
†Odds ratios indicate ratio of odds between treatment groups for higher (more favorable) score for these ordinal outcomes (three ordered categories for clinician recommendation and five ordered categories for clinician satisfaction).
‡96% confidence intervals given for this treatment comparison.
§99% confidence intervals given for this treatment comparison.

standard deviation improvement. The encounter decision aid alone and combined encounter decision aid and patient decision aid groups markedly outperformed the patient decision aid alone group on the OPTION12 score. Because OPTION12 is an observer based encounter measure designed to identify changes in behaviors during the clinical encounter, the finding that the encounter decision aid groups outperformed non-encounter decision aid study groups is not surprising.

By contrast, study arms with the patient decision aid (the patient decision aid only arm and the combined encounter decision aid and patient decision aid arm) showed the greatest, and equivalent, improvement in knowledge compared with usual care. The encounter decision aid only arm also showed improvements in knowledge compared with usual care, although this improvement was less than was seen in the combined encounter decision aid and patient decision aid group. This could indicate that patients were able to incorporate more knowledge when using the patient decision aid independently outside of the clinical encounter than when the encounter decision aid was used by the clinician during a clinical encounter.

When we examined performance on the decisional conflict score, we observed significant improvements only in the combined encounter decision aid and patient decision aid group and the encounter decision aid alone group compared with usual care. Scores lower than 25 on the decisional conflict score have been associated with implementing decisions,[35] and the adjusted mean scores for all study groups were below this threshold, except for the usual care group. However, the usual care group's score was slightly above this threshold (25.8), suggesting limited decisional conflict among study participants as a whole. This is not surprising considering that fewer than a third (29%) of participants had a new diagnosis of atrial fibrillation, and most had been living with atrial fibrillation for some time.

When directly comparing the encounter decision aid and patient decision aid in secondary analyses, the only significant difference we found was on the assessment of shared decision making quality using the OPTION12 score, which is to be expected given the nature of this observer based encounter measure. Lastly, we observed no differences between the combined encounter decision aid and patient decision aid groups and the encounter decision aid alone group, suggesting that when an encounter decision aid is already in use, adding a patient decision aid may provide limited benefit. However, the combined encounter decision aid and patient decision aid group had decreased decisional conflict and increased shared decision making compared with the patient decision aid alone group, suggesting that when a patient decision aid is already in use, adding an encounter decision aid may provide additional benefit.

Overall, the use of both decision aids was favorably recommended by patients. Clinicians also recommended the use of the encounter decision aid, which added only about a minute to the consultation or clinic visit time. We found no significant differences between groups in relation to anticoagulant treatment choice.

Implications of findings

Taking these results together, we can draw several conclusions: the use of either decision aid yielded better shared decision making outcomes than usual care; the relative value of the encounter decision aid and patient decision aid depends on which outcomes are prioritized (for example, quality of shared decision making versus patient's knowledge); and a combined approach (encounter decision aid and patient decision aid) may yield more benefits over the use of a patient decision aid alone.

The findings from this trial are timely, given the increasing importance of shared decision making for prescribing of oral anticoagulants in atrial fibrillation clinical guidelines.[4 11-14] Existing guidelines suggest that shared decision making should be part of decision making on atrial fibrillation related stroke prevention; however, little guidance is provided on how shared decision making can or should be achieved. This study implies that using either a patient decision aid or an encounter decision aid is effective in achieving shared decision making when making decisions about atrial fibrillation.

Comparison with other studies

Our findings are consistent with a recent systematic review on the use of digital patient support tools in atrial fibrillation treatment decisions, which reported decreased decisional conflict and increased knowledge for patients exposed to a digital support tool, compared with usual care.[17] Our results are also consistent with the results of two recent studies examining decision support in the care of patients with atrial fibrillation. A 2020 study by Kunneman and colleagues examined the effect of an encounter decision aid versus usual care for patients with atrial fibrillation.[24] They found that the encounter decision aid had similar favorable effects on shared decision making outcomes to those that we found in our trial, including clinicians expressing greater satisfaction with its use. A 2023 study by Wang and colleagues examined the effect of a digital decision toolkit for atrial fibrillation compared with usual care and found that it decreased decisional conflict.[36] Our study adds to the extant literature by examining the effect of an encounter decision aid and a patient decision aid alone and in combination compared with usual care and shows the relative value of each decision aid strategy. This result is a particularly novel and meaningful contribution to decision science, increasing understanding of the relative advantages and disadvantages of each type of decision aid.

To our knowledge, this is the largest randomized controlled trial of decision aids and the first to directly compare the use of a complementary patient decision aid and encounter decision aid. These results suggest that the use of either the patient decision aid or the

encounter decision aid will improve decision making outcomes, and that the use of these methods seems to be feasible within the flow of clinical care. However, when choosing which tool to use for clinical decisions, considering both the differential performance of each tool on the primary outcomes and the varying cost or burden of using these tools in a clinical environment is important. For example, a patient decision aid may be more effective for decisions that are laden with information that patients must digest and interpret. By contrast, decision making situations that require more clinician-patient engagement during the encounter may benefit more from an encounter decision aid. The efforts needed for the use of each tool may include engaging and training clinicians to use an encounter decision aid and the availability of resources to provide a patient decision aid to patients before the encounter.

Limitations of study

Although this study has important strengths, it also has a few limitations. Observers assessing the OPTION12 outcome measure on video recorded encounters cannot be blinded to allocation; their unblinded assessments could be biased in favor of decision aids, in particular the encounter decision aid. In addition, participants less adept at using digital tools may have been more reluctant to enroll in a trial using web based decision aids, limiting the applicability of our findings. The post-randomization exclusions by clinicians could have introduced bias. Although these numbers were small, they were higher in the study arms that included the encounter decision aid and patient decision aid. Finally, the decision aids, particularly the encounter decision aid, extended the duration of consultations, although this difference was not statistically significant. Nevertheless, this finding may have effects on healthcare utilization and quality.[37]

Future research

The findings from this multicenter randomized trial suggest that both patient decision aids and encounter decision aids will be effective across a variety of clinical settings. How best to implement them and how their routine use will affect access to and utilization of healthcare remain unclear. In addition, as time for clinical encounters becomes increasingly limited, understanding longer term effects of decision aids on total number of visits and downstream clinical encounters, including communications that occur outside of the visit encounter, is important. The use of decision aids may result in an enriched conversation and increased patient engagement, and these outcomes may translate to better adherence to treatment plans and/or fewer follow-up visits or less post-visit messaging. Although the primary goal of shared decision making is to ensure that decisions made are aligned with the values and goals of informed patients,[15] additional outcomes might benefit, such as adherence to treatment plans, subsequent clinical outcomes, patients' experience, and efficiencies in healthcare delivery.

Conclusion

Use of either a patient decision aid or an encounter decision aid in patients with atrial fibrillation who were scheduled for a clinical appointment to discuss stroke prevention strategies for atrial fibrillation increased shared decision making and patients' knowledge and decreased decisional conflict. Use of these tools was perceived to be acceptable to both patients and clinicians, the tools did not seem to influence the treatment decisions made, and their use only modestly increased the duration of clinical encounters. This trial provides evidence about the relative value of supporting shared decision making with an encounter decision aid, a patient decision aid, or a combination of these tools.

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Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned (and, if relevant, registered) have been explained.

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1 Lippi G, Sanchis-Gomar F, Cervellin G. Global epidemiology of atrial fibrillation: An increasing epidemic and public health challenge. *Int J Stroke* 2021;16:217-21. doi:10.1177/1747493019897870
2 Benjamin EJ, Blaha MJ, Chiuve SE, et al, American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2017 Update: A Report From the American Heart Association. *Circulation* 2017;135:e146-603. doi:10.1161/CIR.0000000000000485
3 Reiffel JA. Atrial fibrillation and stroke: epidemiology. *Am J Med* 2014;127:e15-6.
4 Hindricks G, Potpara T, Dagres N, et al, ESC Scientific Document Group. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. *Eur Heart J* 2021;42:373-498. doi:10.1093/eurheartj/ehaa612
5 January CT, Wann LS, Alpert JS, et al, American College of Cardiology/American Heart Association Task Force on Practice Guidelines. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol* 2014;64:e1-76. doi:10.1016/j.jacc.2014.03.022
6 Ogilvie IM, Newton N, Welner SA, Cowell W, Lip GY. Underuse of oral anticoagulants in atrial fibrillation: a systematic review. *Am J Med* 2010;123:638-645.e4. doi:10.1016/j.amjmed.2009.11.025
7 Giugliano RP, Ruff CT, Braunwald E, et al, ENGAGE AF-TIMI 48 Investigators. Edoxaban versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2013;369:2093-104. doi:10.1056/NEJMoa1310907
8 Connolly SJ, Ezekowitz MD, Yusuf S, et al, RE-LY Steering Committee and Investigators. Dabigatran versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2009;361:1139-51. doi:10.1056/NEJMoa0905561
9 Granger CB, Alexander JH, McMurray JJ, et al, ARISTOTLE Committees and Investigators. Apixaban versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2011;365:981-92. doi:10.1056/NEJMoa1107039
10 Patel MR, Mahaffey KW, Garg J, et al, ROCKET AF Investigators. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med* 2011;365:883-91. doi:10.1056/NEJMoa1009638
11 January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol* 2019;74:104-32. doi:10.1016/j.jacc.2019.01.011
12 Lip GYH, Banerjee A, Boriani G, et al. Antithrombotic Therapy for Atrial Fibrillation: CHEST Guideline and Expert Panel Report. *Chest* 2018;154:1121-201. doi:10.1016/j.chest.2018.07.040
13 Andrade JG, Aguilar M, Atzema C, et al, Members of the Secondary Panel. The 2020 Canadian Cardiovascular Society/Canadian Heart Rhythm Society Comprehensive Guidelines for the Management of Atrial Fibrillation. *Can J Cardiol* 2020;36:1847-948. doi:10.1016/j.cjca.2020.09.001
14 Hauk L. Newly Detected Atrial Fibrillation: AAFP Updates Guideline on Pharmacologic Management. *Am Fam Physician* 2017;96:332-3.
15 Charles C, Gafni A, Whelan T. Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. *Soc Sci Med* 1999;49:651-61. doi:10.1016/S0277-9536(99)00145-8
16 Torres Roldan VD, Brand-McCarthy SR, Ponce OJ, et al. Shared Decision Making Tools for People Facing Stroke Prevention Strategies in Atrial Fibrillation: A Systematic Review and Environmental Scan. *Med Decis Making* 2021;41:540-9. doi:10.1177/0272989X211005655
17 Zeng A, Tang Q, O'Hagan E, et al. Use of digital patient decision-support tools for atrial fibrillation treatments: a systematic review and meta-analysis. *BMJ Evid Based Med* 2024;bmjebm-2023-112820. doi:10.1136/bmjebm-2023-112820
18 Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;4:CD001431. doi:10.1002/14651858.CD001431.pub5
19 Stacey D, Lewis KB, Smith M, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2024;1:CD001431.
20 Jones AE, McCarty MM, Brito JP, et al, STEP-UP AFIB Writing Group. Randomized evaluation of decision support interventions for atrial fibrillation: Rationale and design of the RED-AF study. *Am Heart J* 2022;248:42-52. doi:10.1016/j.ahj.2022.02.010
21 Lip GY, Nieuwlaat R, Pisters R, Lane DA, Crijns HJ. Refining clinical risk stratification for predicting stroke and thromboembolism in atrial fibrillation using a novel risk factor-based approach: the euro heart survey on atrial fibrillation. *Chest* 2010;137:263-72. doi:10.1378/chest.09-1584
22 Jones AE, McCarty MM, Cameron KA, et al. Development of Complementary Encounter and Patient Decision Aids for Shared Decision Making about Stroke Prevention in Atrial Fibrillation. *MDM Policy Pract* 2023;8:23814683231178033. doi:10.1177/23814683231178033
23 Elwyn G, Hutchings H, Edwards A, et al. The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. *Health Expect* 2005;8:34-42. doi:10.1111/j.1369-7625.2004.00311.x
24 Kunneman M, Branda ME, Noseworthy PA, et al. Shared decision making for stroke prevention in atrial fibrillation: study protocol for a randomized controlled trial. *Trials* 2017;18:443. doi:10.1186/s13063-017-2178-y
25 O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making* 1995;15:25-30. doi:10.1177/0272989X9501500105
26 Kunneman M, Branda ME, Hargraves IG, et al, Shared Decision Making for Atrial Fibrillation (SDM4AFib) Trial Investigators. Assessment of Shared Decision-making for Stroke Prevention in Patients With Atrial Fibrillation: A Randomized Clinical Trial. *JAMA Intern Med* 2020;180:1215-24. doi:10.1001/jamainternmed.2020.2908
27 Branda ME, LeBlanc A, Shah ND, et al. Shared decision making for patients with type 2 diabetes: a randomized trial in primary care. *BMC Health Serv Res* 2013;13:301. doi:10.1186/1472-6963-13-301

28 Metz M, Elfeddali I, Veerbeek M, de Beurs E, Beekman A, van der Feltz-Cornelis C. Effectiveness of a multi-facetted blended eHealth intervention during intake supporting patients and clinicians in Shared Decision Making: A cluster randomised controlled trial in a specialist mental health outpatient setting. *PLoS One* 2018;13:e0199795. doi:10.1371/journal.pone.0199795
29 Krones T, Keller H, Sönnichsen A, et al. Absolute cardiovascular disease risk and shared decision making in primary care: a randomized controlled trial. *Ann Fam Med* 2008;6:218-27. doi:10.1370/afm.854
30 Elwyn G, Edwards A, Hood K, et al, Study Steering Group. Achieving involvement: process outcomes from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice. *Fam Pract* 2004;21:337-46. doi:10.1093/fampra/cmh401
31 Scalia P, Durand MA, Berkowitz JL, et al. The impact and utility of encounter patient decision aids: Systematic review, meta-analysis and narrative synthesis. *Patient Educ Couns* 2019;102:817-41. doi:10.1016/j.pec.2018.12.020
32 Verbeke G, Molenberghs G. *Linear Mixed Models for Longitudinal Data*. Springer, 2000.
33 Horrigan JB. *Digital Readiness Gaps*. Pew Research Center, 2016.
34 Morris NS, MacLean CD, Chew LD, Littenberg B. The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. *BMC Fam Pract* 2006;7:21. doi:10.1186/1471-2296-7-21
35 O'Connor AM. User Manual - Decisional Conflict Scale. 2010. https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_decisional_conflict.pdf
36 Wang PJ, Lu Y, Mahaffey KW, et al. Randomized Clinical Trial to Evaluate an Atrial Fibrillation Stroke Prevention Shared Decision-Making Pathway. *J Am Heart Assoc* 2023;12:e028562. doi:10.1161/JAHA.122.028562
37 León-García M, Wieringa TH, Espinoza Suárez NR, et al. Does the duration of ambulatory consultations affect the quality of healthcare? A systematic review. *BMJ Open Qual* 2023;12:e002311. doi:10.1136/bmjoq-2023-002311

Web appendix: Supplementary materials