Use of digital patient decision-support tools for atrial fibrillation treatments: a systematic review and meta-analysis

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Abstract

Objectives To assess the effects of digital patient decision-support tools for atrial fibrillation (AF) treatment decisions in adults with AF.

Study design Systematic review and meta-analysis.

Eligibility criteria Eligible randomised controlled trials (RCTs) evaluated digital patient decision-support tools for AF treatment decisions in adults with AF.

Information sources We searched MEDLINE, EMBASE and Scopus from 2005 to 2023. Risk-of-bias (RoB) assessment: We assessed RoB using the Cochrane Risk of Bias Tool 2 for RCTs and cluster RCT and the ROBINS-I tool for quasi-experimental studies.

Synthesis of results We used random effects meta-analysis to synthesise decisional conflict and patient knowledge outcomes reported in RCTs. We performed narrative synthesis for all outcomes. The main outcomes of interest were decisional conflict and patient knowledge.

Results 13 articles, reporting on 11 studies (4 RCTs, 1 cluster RCT and 6 quasi-experimental) met the inclusion criteria. There were 2714 participants across all studies (2372 in RCTs), of which 26% were women and the mean age was 71 years. Socioeconomically disadvantaged groups were poorly represented in the included studies. Seven studies (n=2508) focused on non-valvular AF and the mean CHAD2DS2-VASc across studies was 3.2 and for HAS-BLED 1.9. All tools focused on decisions regarding thromboembolic stroke prevention and most enabled calculation of individualised stroke risk. Tools were heterogeneous in features and functions; four tools were patient decision aids. The readability of content was reported in one study. Meta-analyses showed a reduction in decisional conflict (4 RCTs (n=2167); standardised mean difference −0.19; 95% CI −0.30 to −0.08; p=0.001; I^2=26.5%; moderate certainty evidence) corresponding to a decrease in 12.4 units on a scale of 0 to 100 (95% CI −19.5 to −5.2) and improvement in patient knowledge (2 RCTs (n=1057); risk difference 0.72, 95% CI 0.68, 0.76, p<0.001; I^2=0%; low certainty evidence) favouring digital patient decision-support tools compared with usual care. Four of the 11 tools were publicly available and 3 had been implemented in healthcare delivery.

Conclusions In the context of stroke prevention in AF, digital patient decision-support tools likely reduce decisional conflict and may result in little to no change in patient knowledge, compared with usual care. Future studies should leverage digital capabilities for increased personalisation and interactivity of the tools, with better consideration of health literacy and equity aspects. Additional robust trials and implementation studies are warranted.

PROSPERO registration number CRD42020218025

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Treatment decisions in atrial fibrillation (AF) are complex. Patient decision-support tools, including educational tools and patient decision aids, can support shared decision-making.

WHAT THIS STUDY ADDS

⇒ Digital patient decision-support tools for treatment decisions in AF, likely reduce decisional conflict but make little to no difference in patient knowledge, compared with usual care. Implementation in healthcare delivery was low.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Digital patient decision-support tools may be warranted in shared decision-making for AF treatment choices. Studies are needed to understand barriers and enablers to implementation.

Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia and a key risk factor for embolic stroke and heart failure, with an increasing global burden as the population continues to age.[1,2] AF treatment involves stroke prevention, symptom management, and cardiovascular and comorbidity optimisation.[2,3] Treatment decisions in AF are complex because there are multiple treatment options and evidence gaps, often with more than one medically appropriate option. Recent AF guidelines acknowledge this uncertainty and emphasise the importance of shared decision-making in AF treatment decisions, considering patients' values, goals and preferences.[2,4]

A key component of shared decision-making is providing evidence-based information on the benefits and harms of existing treatment options, which can be supported by patient education tools.[5] Patient education tools aim to increase the patient's (ie, decision-maker) knowledge to enable discussion and informed uptake of a treatment choice.[2,4,6] Whereas, when there are two or more reasonable treatment alternatives, a patient decision aid may be more appropriate (eg, patients at 'moderate stroke risk').[2] Patient decision aids support preference-sensitive decisions by describing the health problem and making explicit the decision, providing information on options' benefits and harms, and helping patients clarify which benefits and harms matter most to them.[7] Patient education tools and patient decision aids (ie, patient decision-support tools) can facilitate shared decision-making and improve treatment adherence, leading to better outcomes.[6,8,9]

To date, four systematic reviews[10–13] (only one with meta-analysis)[11] have evaluated patient decision-support tools for anticoagulation and stroke prevention in AF, suggesting improvements in decisional conflict. However, these reviews included mostly non-digital tools (eg, paper-based), which are limited in their ability to personalise and present information. Digital health—the development and use of digital technologies to improve health[14]—offers new opportunities to deliver personalised and engaging information to support patients in shared decision-making. At present, it is uncertain whether digital delivery of patient decision-support tools for AF treatment decisions can improve decisional conflict and patient knowledge. The aim of this systematic review was to assess the effects of digital patient decision-support tools for AF treatment decisions in adults with AF.

Methods

We followed the Cochrane handbook[15] for conducting this systematic review and reported according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses[16] (online supplemental file 1). We registered the systematic review protocol with PROSPERO (CRD42020218025) and was modified on 7 February 2023 (online supplemental file 2).

Eligibility criteria

Eligible studies were experimental trials (randomised controlled trials (RCTs) or quasi-experimental), where adults diagnosed with AF were provided with digital patient decision-support tools to facilitate decision-making regarding treatment options for the management of AF. We classified patient decision-support tools as a patient decision aid if reported as such in the article; otherwise, the tool was classified as an educational tool. All these tools had to be delivered in a digital format (ie, app, web-based or desktop) to meet study inclusion. We excluded clinician decision-support tools, which are focused on supporting clinicians in choosing the most ideal therapy based on patient characteristics. Any comparisons were accepted, including usual care. Outcomes of interest included decision-related measures (eg, decisional conflict), patient knowledge, change in treatment and medication adherence. The Decisional Conflict Scale is the most commonly used measure related to decision-making[17] and consists of a 16-item scale that evaluates an individual's degree of uncertainty about the choice (4 subscales: informed; values clarity; support; uncertainty; effective decision), with a score ranging from 0 to 100, and higher scores indicating greater decisional conflict.[18]

Information sources

We searched MEDLINE (PubMed interface), EMBASE (Ovid platform) and Scopus (Elsevier platform) in October 2020 and updated the search in February 2023, for eligible studies published in English since 2005 (online supplemental file 3). We restricted the search to English studies published from 2005 onwards because the consensus on criteria for judging the quality of patient decision aids was established in 2005 by the International Patient Decision Aids Standards (IPDAS) collaboration.

Selection of studies and data extraction

Two reviewers independently performed title and abstract screening and subsequent full-text screening. Disagreements were resolved with a third reviewer. We used Cohen's κ to measure the intercoder agreement in each screening phase. Two researchers conducted data extraction, and a third researcher reviewed the extracted data. We contacted authors if any data were missing and reported unavailable data.

Two reviewers independently assessed the reporting of patient decision aid evaluation studies using the Standards for UNiversal reporting of patient Decision Aid Evaluations (SUNDAE checklist), a 26-item checklist that aims to ensure that reports of these studies are understandable, transparent and of high quality.[19]

Risk of bias assessment

Two reviewers independently assessed the quality of included studies using the Cochrane Risk of Bias Tool 2 for RCTs and cluster RCT and the ROBINS-I tool for quasi-experimental.[20,21] Conflicts in all assessments were resolved by discussion with a third reviewer.

Data synthesis

We conducted a narrative synthesis for all studies and meta-analyses for the two most common outcomes across RCTs: decisional conflict and patient knowledge. We calculated effect sizes of continuous outcomes as standardised mean difference (SMD). We expressed patient knowledge as a proportion of correct answers and converted it to a percentage and raw value on a scale 0–100. We pooled estimates using random effects meta-analysis with a restricted maximum likelihood estimator; the between-studies variance (T^2) was estimated using the methods of moments. I^2 was used to describe the proportion of variance in observed effects due to variance in true effects.[22] For ease of interpretation, we converted estimates of decisional conflict effect sizes from SMD to mean difference in a scale of 0 (no decisional conflict) to 100 (extremely high decisional conflict) (online supplemental file 4). We evaluated the presence of publication bias by using a funnel plot and the Duval and Tweedie trim-and-fill method.[15] Analyses were undertaken with metafor package in R V.4.2.2 (R Project for Statistical Computing in Vienna, Austria).[23]

Grading the certainty of evidence

Two reviewers independently used the Grading of Recommendations Assessment, Development and Evaluation approach to

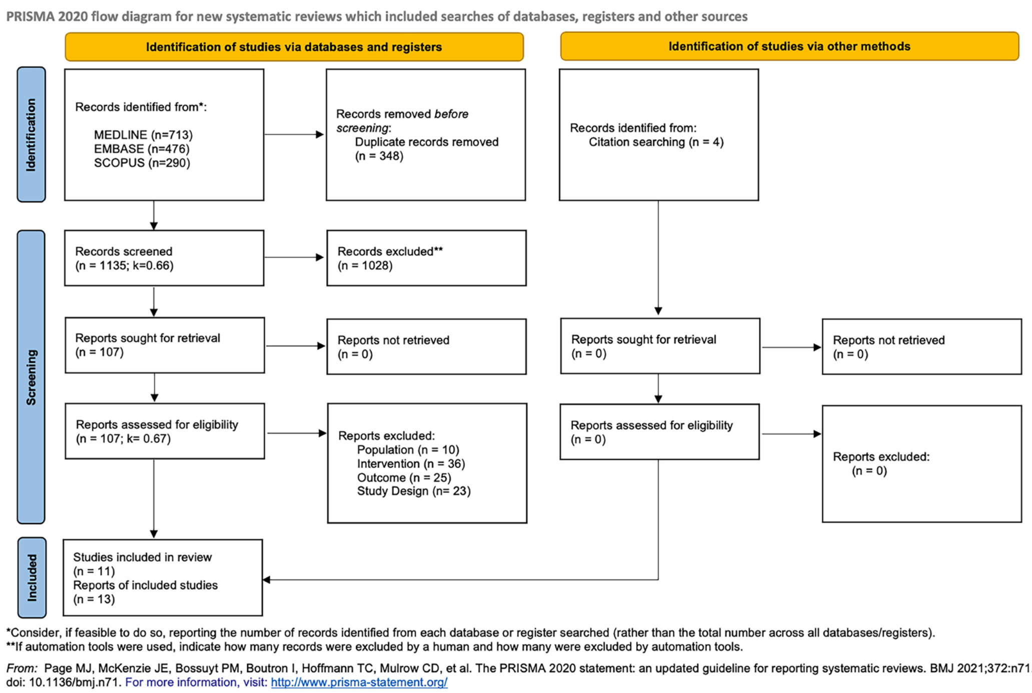

Figure 1 PRISMA flow diagram of included studies. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

rate the certainty of evidence for primary outcomes (ie, decisional conflict and patient knowledge) on each of the following domains: risk of bias, inconsistency, imprecision, indirectness and publication bias.[24] We downgraded the certainty of evidence if a serious flaw was present in the domains of risk of bias, inconsistency, imprecision and publication bias. We initially classified certainty of evidence as high then as moderate, low or very low.[24]

Patient and public involvement

The perspectives of patients with AF informed this study. The results from the present study will be disseminated in lay language.

Results

Search and screening results

The database search(s) retrieved 1482 citations (figure 1). Excluded studies after full-text screen are listed in online supplemental file 5. The kappa statistic measuring intercoder agreement was 0.66 for title and abstract screening, and 0.67 for full-text screening (moderate agreement). 13 articles were included in the systematic review, reporting on 11 studies (table 1).[25–37]

Description of included studies

13 articles reported on 11 studies: 4 RCTs,[25–31] 1 cluster RCT[29] and 6 single-group quasi-experimental studies (table 1).[32–37] Three articles reported on different outcomes from the same RCT.[25–27] Studies were published between 2007 and 2022, with most studies conducted in the USA.[25–28 30 34 36] Follow-up ranged from immediately postintervention to 10 months.[26 28] Regarding risk of bias for decisional conflict and patient knowledge, one of the four RCTs had low risk,[25] two were assessed as high risk[30 31] and for the remaining trial there were some concerns with bias (figure 2; online supplemental 6).[28] One cluster RCT[29] had high risk of bias for patient knowledge (online supplemental file 6). Of the six quasi-experimental trials,five had high or unclear risk of bias in six of the seven domains (online supplemental file 7).

Characteristics of study participants

There were 2714 participants across all studies (n=2372 in RCTs), with a mean age of 71 years and 26% were women (table 1; online supplemental 8). Seven studies (n=2508) focused on non-valvular AF[25 26 28–32 36] (four studies did not report type of AF) and the weighted mean CHAD2DS2-VASc[25 28–31 34–37] across studies was 3.2 and HAS-BLED[25 29–31 35–37] was 1.9. Of the 5 studies that reported on educational level, 790 of 1275 participants had college or postgraduate studies[28 30 32 35 36]; 1 study reported on schooling years, with over 26% of the sample having 8 or more years of schooling.[37] Five studies did not report on educational level or schooling years,[25 29 31 33 34] with one of them reporting instead that 8% of the sample had inadequate health literacy.[25] Five studies reported on ethnicity (>80% participants were white) and only one study[32] reported on household income (online supplemental file 8).

Characteristics of the digital patient decision-support tools

Out of the 11 tools, 7 were educational decision-support tools[25 28 29 33 34 36 37] and 4 were patient decision aids (table 1).[30–32 35] The digital patient decision-support tools were used either previsit (at home[29 34 35] or in the waiting room[28 30 33 34 36]) or during the consultation,[25 31 32 36 37] in primary care,[30 31] secondary care (eg, cardiology outpatient setting),[32–34 36 37] or in both primary and secondary care.[25 28] The tools were delivered using a mobile application,[29 32 34 37] web-based application,[25 28 33 35 36] or a desktop (table 2; online supplemental file 9).[30 38] Only two RCTs reported on the difference in encounter times between intervention and control arm: one RCT reported a longer visit duration with the patient decision-support tool (average increase of 10 min compared with control, no test of significance reported)[31] and another RCT reported no significant difference in clinical encounter times between the two arms.[25]

All tools focused on supporting decisions related to anticoagulation treatment for thromboembolic stroke prevention in the

Table 1 Characteristics of included articles

Study (authors, year, country)	Study design and sample size	Population characteristics: mean age; % women	Setting	Type of tool* (treatment decision-support options)	Comparator	Primary outcome
1. Kunneman *et al*, 2020, USA[25] 2. Noseworthy *et al*, 2022, USA[26] 3. Kamath *et al*, 2021, USA[27]	1. RCT (2 arms) Intervention:463 Control:459 2. 10-month follow-up of Kunneman 2020 RCT (88% of original sample) 3. Secondary analysis[25]	71 years; 20% women	Primary and secondary care (in emergency and inpatient hospital departments and outpatient safety-net, primary care and cardiology clinics)	Educational Web application† (Warfarin vs DOAC vs no anticoagulant medication)	Usual care	1.Quality of shared decision-making (composite outcome, measured immediately postvisit): communication quality, knowledge transfer to patient, concordance between clinician and patient's agreed treatment plan, Decisional Conflict Scale. 2.Anticoagulation start and continuation rates 3.Conversations about cost
Wang *et al*, 2022, USA[28]	RCT (2 arm) Intervention: 495 Control: 506	69 years; 40% women	Primary and secondary care Clinicians received training.	Educational Web application‡ (No antithrombotic treatment Warfarin vs DOAC vs aspirin or other antiplatelet)	Usual care	Decisional Conflict Scale (1-month post-visit)
Guo *et al*, 2017, China[29]	Cluster RCT (2 arms) Intervention: 113 Control: 96	69 years; 44% women	Self-utilised by patient at home	Educational Mobile application (No antithrombotic treatment vs warfarin vs DOAC)	Usual care	Not specified: Patients' knowledge, quality of life, drug adherence and anticoagulation satisfaction
Fraenkel *et al*, 2012, USA[30]	RCT (2 arms) Intervention: 69 Control: 66	NR (majority over 75 years); 1.5% women;	Primary care	PtDA§ Computer-based tool (no antithrombotic treatment vs aspirin vs warfarin)	Usual care	Decisional Conflict Scale (subscales: 'Feeling informed' and 'Having clear values'; immediately post-visit)
Thomson *et al*, 2007, England[31]	RCT (2 arms) Intervention: 53 Control: 56	73.4 years; 44% women	Primary care	PtDA computer-based tool (warfarin vs no warfarin)	Usual care	Decisional Conflict Scale (measured immediately post-visit)
de Castro *et al*, 2021, Philippines [32]	Quasi-experimental (1 arm) Intervention: 67	61 years; 10% women	Secondary care (hospital clinics)	PtDA§ Mobile application (Aspirin, warfarin, apixaban, rivaroxaban, dabigatran)	Pre–post	Not specified: Decisional Conflict Scale, knowledge
Kovoor *et al*, 2021, Australia[33]	Quasi- experimental (1 arm) Intervention: 116	NR	Secondary care (cardiology outpatient–waiting room)	Educational Web application (unspecified medication options, lifestyle modifications)	None (post-intervention measures only)	Patient-perceived utility in improving patient decision-making
Kapoor *et al*, 2021, USA[34]	Quasi-experimental (1 arm) Intervention: 37	(NR) 46% over 75 years; 38% 65–74 years; 30% women	Self-utilised at home by patient or at waiting room (cardiology outpatient)	Educational Mobile application¶ (Unspecified anticoagulation options)	Pre–post	Not specified: app usability; perceived usefulness

Continued

Table 1 Continued

Study (authors, year, country)	Study design and sample size	Population characteristics: mean age; % women	Setting	Type of tool* (treatment decision-support options)	Comparator	Primary outcome
Loewen *et al*, 2019, Canada[35]	Quasi-experimental (1 arm) Intervention: 37	71 years; 57% women	Self-utilised at home by patient	PtDA§ Web application (No antithrombotic treatment vs aspirin vs Warfarin vs DOAC (ie, (apixaban, dabigatran, edoxaban, rivaroxaban))	Pre–post	Decisional Conflict Scale
Eckman *et al*, 2018, USA[36]	Quasi-experimental (1 arm) Intervention: 65	65.7 years; 35% women	Primary care	Educational Web application** (No antithrombotic therapy vs aspirin vs warfarin vs DOAC: dabigatran, apixaban, rivaroxaban, edoxaban)	Pre–post	Decisional Conflict Scale
Stephan *et al*, 2018, Brazil[37]	Quasi-experimental (1 arm) Intervention: 20	67.7 years; 60% women	Secondary care (cardiology outpatient—waiting room	Educational Mobile application (No antithrombotic therapy vs aspirin+clopidogrel vs warfarin vs DOAC)	Pre–post	AF knowledge††

*We classified tools as a PtDA if so reported in the article; otherwise, the tool was classified as 'educational tool'.
†Online free app 'anticoagulation choice decision aid' (https://anticoagulationdecisionaid.mayoclinic.org/).
‡'Stanford Guide to Afib Stroke Prevention' (https://afibguide.com/).
§Study states their decision aids adhere to International Patient Decision Aids Standards.[7]
¶Afib 2gether mobile app, developed by Pfizer (https://play.google.com/store/apps/details?id=com.pfizer.us.AfibTogether&hl=en_US&gl=US).
**Atrial Fibrillation Shared Decision Making web app (http://chi.uc.edu/afib/1131).
††Assessed by AF Knowledge Questionnaire (scale from 0 to 8; 8 as all correct answers). Researcher-developed questionnaire with validation status unclear.
AF, atrial fibrillation; app, application; DOAC, direct oral anticoagulant; PtDA, Patient Decision Aid ; RCT, randomised controlled trial.

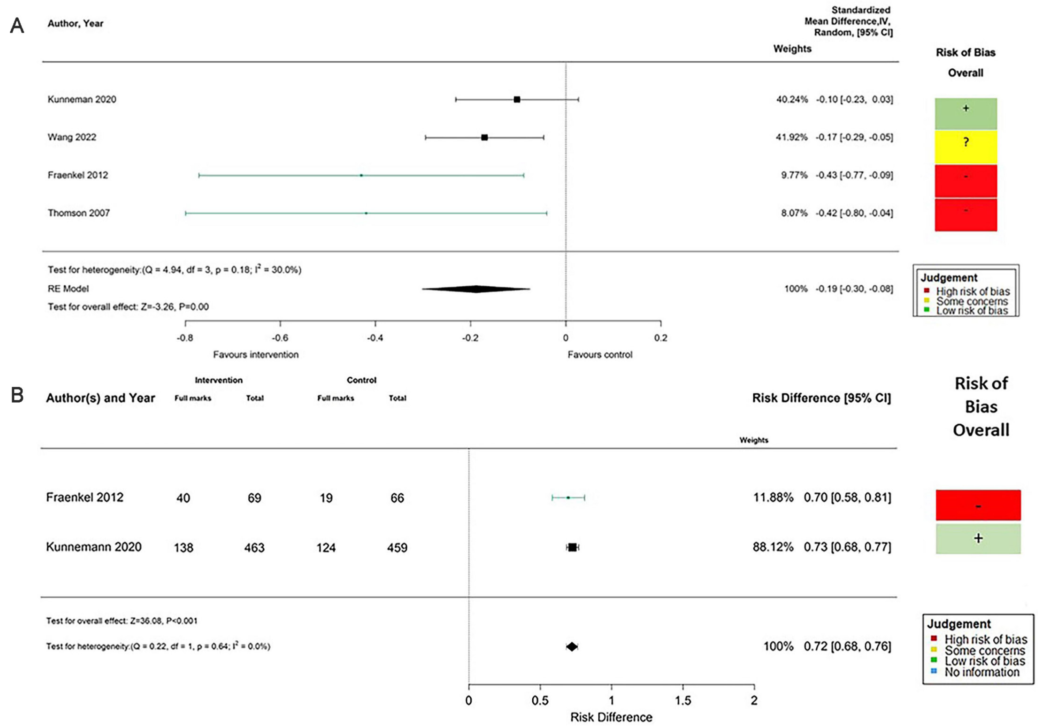

Figure 2 (A) Forest plot of effect sizes and 95% CIs representing the effects of digital patient decision-support tools on Decisional Conflict Scale. Fraenkel *et al*'[30] show results for the informed subscale; Kunneman *et al*, Wang *et al* and Thomson *et al* show results for overall scale score.[25 28 31] Green lines denote studies that have classified tools specifically as a patient decision aid. (B) Forest plot of effect sizes and 95% CI representing the risk difference between the electronic patient decision-support tools and usual care on patient knowledge scored at full marks in respective questionnaires. Green denotes studies that have classified tools as a patient decision aid if reported as such in the article.[30]

long-term management of AF. None of the included articles focused on symptomatic pharmacotherapy or non-pharmacological interventions, such as ablation. Of the 11 tools, 10[25 28–32 34–37] could calculate individualised stroke risk at 1 or 5 years (two tools did it automatically using information from the electronic health record),[29 36] 8 (25, 28, 30–32, 35–37) calculated stroke risk and 8 (25, 29–32, 35–37) also recalculated stroke and bleeding risk for each of the treatment options. One of the three tools not calculating risk of bleeding was sponsored by a drug company.[34] Risk was communicated to patients most commonly as a percentage (8 studies)[25 28 30–32 35–37] or in the form of 100-person pictographs (7 studies).[25 30–32 36 37]

Out of the four patient decision aid studies, two [32 35] adhered to most of the items of the SUNDAE checklist (online supplemental file 10).[39] Less reported items of the SUNDAE checklist included: information about the development of the decision aid and on how to identify and access it; fidelity of implementation; and lack of a process evaluation to better understand how or why the tool worked. All four patient decision aids[30–32 35] adhered to the qualifying criteria for patient decision aids[7]: describing the health condition or problem; explicitly stating the decision in consideration; describing the options available for the index decision; describing both the positive features and negative features of each option and stating consequences of treatment options (eg, out-of-pocket costs, impact on diet) (online supplemental file 11). Other criteria from the IPDAS were mostly met, except for providing more than one way of viewing the probabilities; asking patients to think about which positive and negative features of the options matter most to them; including clinicians in the development process; having an update policy; providing information about the levels of uncertainty around event or outcome probabilities and reporting on readability levels (online supplemental file 11).

Nine of the 11 tools (3 patient decision aids) provided a patient report with additional information and education[25 28–30 32 34–37] and 4 tools incorporated videos to support patient education.[28 33 34 37] Five tools (three patient decision aids) included a specific feature to elicit values and/or preferences regarding the treatment decision.[25 30 35–37] Seven out of 11 tools (3 out of 4 patient decision aids) were co-designed with clinicians[25 31–35 37] and 9 (4 out of 4 patient decision aids) with patients.[25 28–32 35–37] Only one article indicated the readability of the materials (below eighth grade).[33] Four tools were publicly available,[25 28 34 36] and three seemed to have been implemented in clinical practice.[25 28 33] Most articles reported favourable user feedback regarding the use of the digital patient decision-support tools, such as high perceived usefulness, user-friendliness and overall satisfaction (online supplemental file 12).[25 28–30 32–36]

Characteristics of control groups

All RCTs described the control groups as some form of usual care, with definitions varying slightly between studies (eg, usual clinical care,[25 28 29] evidenced-based paper guidelines,[31] regular scheduled visits[30], online supplemental file 13).

Outcomes

Decisional conflict

A meta-analysis of the 4 RCTs using the Decisional Conflict Scale showed digital patient decision-support tools likely reduce decisional conflict in comparison with usual care (4 RCTs (n=2167); SMD −0.19, 95% CI −0.30 to −0.08, p=0.001; I^2=26.5%, moderate certainty evidence) corresponding to a reduction in 12.4 units on a scale of 0 to 100 (95% CI −19.5 to −5.2) (figure 2; table 3). Of the 4 RCTs, 3 reported overall scores[25 28 31] (2 RCTs reported on a 0–100 scale and 1 RCT on a 0–5 scale[31]) and 1 RCT[30] only reported scores

Table 2 Characteristics of digital patient decision-support tools (shaded rows are patient decision aids; non-shaded are educational tools)*

Study	Digital delivery mode			Completion in pathway of care			Frequency of use by patients		Calculation of individualised stroke risk and /or bleeding risk			Risk communication			Additional resources			Co-design	
	Mobile app	Web app	Computer-based	Waiting room	During consult	Self-utilised at home, pre-visit	Single	Multiple	Stroke risk	Bleeding risk	Recalculates risk with treatment	100-persons pictographs	Score (eg, CHAD2DS2-VASc	Numeric (%, 1 in X chance)	Patient report	Elicits patient values / preferences	Videos	With patients	With clinicians
Kunneman 2020[25–27]		√			√		√		Manual	Manual	√	√		√	√			√	√
Wang 2022[28]		√		√			√		Manual	No	√	√	√	√	√		√	√	
Guo 2017[29]	√					√		√	Automatic†	Automatic†			√		√			√	
Fraenkel 2012[30]			√	√			√		Manual	Manual	√	√		√	√	√		√	
Thomson 2007[31]			√		√		√		Manual	Manual	√	√		√	√	√		√	√
De Castro 2021[32]	√				√		√		Manual	Manual	√	√	√	√				√	√
Kovoor 2021[33]		√		√			√		No	No							√		√
Kapoor 2021[34]	√			√		√	√		Manual	No			√		√		√		√
Loewen 2019[35]		√				√	√		Manual	Manual	√			√	√	√		√	√
Eckman 2018[36]		√		√	√		√		Automatic†	Automatic†	√	√	√	√	√	√		√	
Stephan 2018[37]	√				√		√		Manual	Manual	√	√	√	√	√	√	√	√	√

*Additional information is available in online supplemental file 8.

†Automated risk calculation using data from the electronic medical record.

√, characteristic present.

Table 3 Summary of findings table

Summary of findings:

Patient or population: Patients with atrial fibrillation
Setting:
Intervention: digital decision-support tools
Comparison: usual care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with usual care	Risk with digital decision-support tools				
Decisional Conflict (DCS) assessed with: Decisional Conflict Scale	–	SMD 0.19 SD lower (0.3 lower to 0.08 lower)	–	2167 (4 RCTs)	⊕⊕⊕◯ Moderate†	The evidence suggests Digital Decision Support Tools reduce Decisional Conflict slightly.
Patient Knowledge (Pt know) assessed with: Patient Knowledge Questionnaire	27 per 100	20 per 100 (19 to 21)	Risk difference 0.72 (0.68 to 0.76)	1057 (2 RCTs)	⊕⊕◯◯ Low†‡	Digital Decision Support Tools may result in little to no difference in patient knowledge.

GRADE Working Group grades of evidence high certainty: we are very confident that the true effect lies close to that of the estimate of the effect. Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

†We downgraded one level due to issues regarding risk of bias. The majority of studies had some concerns or high risk of bias.

‡We downgraded one level due to issues regarding indirectness. We are uncertain of whether the questionnaires in the included studies sufficiently covered patient knowledge of different treatment options.

GRADE, Grading of Recommendations Assessment, Development and Evaluation; RCTs, randomised controlled trials; SMD, standardised mean difference.

for two subscales ('informed' and 'values clarity' subscales, in a 0–100 scale). A sensitivity analysis including a combined effect size for the two subscales (feeling informed and feeling unclear about values) was also statistically significant with a minimal difference to the overall effect (p=0.01) (online supplemental file 14). The funnel plot and Egger's test suggest signs of publication bias for decisional conflict (online supplemental file 15).

Three quasi-experimental studies also used the Decisional Conflict Scale showing reductions in decisional conflict postintervention (online supplemental file 16).[32 35 37]

Patient knowledge

All articles evaluated patient knowledge, with varied assessment measures, most showing improvements with the digital decision-support tool. Pooled estimates from 2 RCTs[25 30] showed digital decision-support tools may result in little to no difference in patient knowledge when compared with usual care (2 RCTs (n=1057); RD 0.72, 95% CI 0.68 to 0.76, p<0.001; I^2=0%, low certainty evidence; figure 2; table 3). Incomplete data limited the meta-analysis of two other RCTs; one of these RCTs reported an improvement in AF knowledge in the intervention group compared with control; the other RCT reported no difference.[28 31] One cluster RCT reported an improvement in the percentage of correct responses to 10 of the 11 questions in the questionnaire, compared with two in the control group.[29] Four single-arm quasi-experimental studies reported an increase in patient knowledge postintervention (online supplemental file 16).[32 35–37]

Other outcomes

Other outcomes, including medication-related outcomes, were reported infrequently (online supplemental files 17,18). Four studies (one RCT) measured medication changes,[26 30 34 36] with a reduction in medication changes in the intervention arm compared with usual care in the RCT.[26] Two RCTs reported medication adherence differently,[26 28] therefore, were not combined in a meta-analysis. One RCT showed an improvement in a number of patients with at least 80% of days covered by a direct oral anticoagulant (DOAC) in the intervention versus control group at the 10 months follow-up,[26] whereas the second RCT showed no difference in the number of patient-reported doses of anticoagulant missed in the past week or past month between the two groups.[28] One cluster RCT also showed improvements in medication adherence between groups at 1 and 3 months.[29] A secondary analysis of one RCT[25] showed cost conversations between the patient and the clinician (regarding the price of anticoagulants for treatment of AF) were more likely in the intervention group using the digital patient decision-support tool.[27]

Discussion

Main results

To our knowledge, this is the first systematic review and meta-analysis focusing on the digital delivery of patient decision-support tools for treatment decisions in AF. We found that digital patient decision-support tools likely reduce decisional conflict and may result in little to no difference in patient knowledge, compared with usual care. There were mixed results for medication adherence. Evidence could be strengthened by more standardised measurement. All the tools aimed to support decisions related to anticoagulation treatment for thromboembolic stroke prevention; none focused on symptomatic pharmacotherapy or procedures like ablation. Most tools allowed for personalised risk calculation (stroke and bleeding, with and without treatment), but only two tools did it automatically using data from the electronic health record (all others required manual input). Tools were heterogeneous in features and functions; four tools were patient decision aids. Only 4 of the 11 tools were publicly available and three seemed to have been implemented in healthcare delivery. The readability of content was reported in one study.

Comparison with existing literature

We found improvements in decisional conflict and knowledge with digital patient decision-support tools compared with usual care. Decisional conflict is defined as personal uncertainty about which choice to select among competing interests.[40 41] Reduced decisional conflict scores are associated with higher patient satisfaction with their decisions[17 42] and may indicate these tools benefit patients by informing their options and clarifying their personal values, further equipping them in shared decision-making.[43] Meta-analyses assessing patient decision aids in other contexts (eg, treatment and screening decisions in cancer) have also found reductions in decisional conflict, for both digital and non-digital tools.[44 45] Our findings report a reduction in decisional conflict of similar magnitude as a recent meta-analysis which pooled non-digital decision aids in AF treatment,[11] including two RCTs.[46 47] The improvements we found in patient knowledge are in line with previous systematic reviews of decision aids,[10–13] educational[48] and self-management[49] interventions in AF.

Current digital patient decision-support tools for AF treatment have some limitations. Despite most studies reporting codesign with patients, many lacked reporting on health literacy considerations in tool development, with only one study mentioning readability of the content. Socioeconomically disadvantaged groups were poorly represented in the included studies. A systematic review of non-AF patient decision aids showed knowledge improvements were greater in studies reporting strategies to reduce cognitive demand (eg, plain language, visual cues) in the tool development compared with studies that did not.[50] Co-production with target populations, including low health literacy patients and other disadvantaged groups, is key to ensure their needs and preferences are met.[39 50–55] In addition, developers of these tools should better leverage available resources to ensure tool quality, such as the IPDAS[56–58] and the Patient Education Materials Assessment Tool from the US Agency for Healthcare Research and Quality.[59]

Most studies in our review focused on single use of these tools (typically in the waiting room before a consultation or during the medical appointment) even though the shared decision-making process should ideally allow for enough time for patients to consider the information and deliberate outside of the clinical encounter.[60] The focus on use in a clinical context could also explain why only a few of these tools seem to have been implemented in the real-world, due to clinician inertia and fear of lengthier consultations.[54 61 62] We found encounter times in intervention and control arms were rarely compared, with no differences reported. Future studies could leverage the digital capabilities of these tools to enable remote delivery of patient education and decision-support (ideally integrated with the electronic health record for automated risk calculation), providing adequate time for patients to process the information and deliberate, before visiting their clinician.[54]

Strengths and limitations

The strengths of this review include the development and systematic adherence to a registered protocol, piloting of the screening procedures and the moderate agreement between reviewers in title and abstract and full-text screening. Included papers were limited to English language, limited in number and heterogeneous in design and outcomes evaluated. Including studies from 2005 onwards (based on the consensus from the IPDAS Collaboration) allowed for a broader assessment of different tools, with some predating the availability of novel treatment options used in current practice (ie, DOACs). We followed our protocol for assessment of publication bias, yet this analysis is constrained by the limited number of studies available. A subgroup analysis focusing on contemporary tools that reflect current practices in AF treatment was not possible due to the limited number of RCTs. Finally, there are known gaps in measuring AF knowledge, with current validated instruments either being too long, lacking validation in different populations or having low reliability.[9] Limitations in knowledge scales may explain the common use of non-validated study-specific questionnaires,[43] as we found in this review.

Implications

Digital patient decision-support tools can facilitate shared decision-making in AF stroke prevention, resulting in improvements in decision quality. Recent studies have shown that shared decision-making is not widely implemented in contemporary AF practice.[2 4 6] A recent study analysing the content of discussions between patients with AF and doctors regarding anticoagulation choice found imbalances in discussion of stroke versus bleeding risk, as well as persuasive communication from doctors to convince patients to accept anticoagulation with a DOAC instead of warfarin, with insufficient discussion of medication costs.[63] This suggests some specific treatment decision scenarios may particularly benefit from a patient decision-support tool: (1) DOACs versus no therapy in non-valvular AF patients with a low risk of stroke, (2) DOACs versus warfarin in special populations and in non-valvular AF patients if DOACs are cost-prohibitive and (3) anticoagulation versus none in patients with very high bleeding risk. Outside of these specific situations, patient decision-support tools may still be beneficial for all AF patients considering treatment decisions regarding stroke prevention, supporting objective understanding of the benefits, risks and other considerations relevant to patients, for an informed decision regarding long-term anticoagulation treatment.

There is a dearth of evidence regarding the use of digital patient decision-support tools for other treatment decisions in AF, such as rate and rhythm control decisions for symptom management.[2 64 65] Future research should also analyse the effect of these tools on other outcomes (eg, medication adherence), as well as their impact in disadvantaged groups.[66 67] In particular, it is important to consider the digital divide and health literacy levels of diverse groups and foster inclusive design strategies[68] in the development of these tools, to avoid worsening health disparities.

Despite their value, decision aids are not routinely used in clinical practice. The National Health Service (NHS) has attempted to increase the uptake of decision aids by launching a webpage in November 2023 with freely available decision-support tools for multiple health conditions developed according to the National Institute for Health and Care Excellence (NICE) shared decision-making support tools framework.[69 70] Although a useful starting point, this repository of documents provides limited options to personalise information. Another proposed solution is to create a ‘universal’ electronic decision-support tool where a template using a modular design can enable the incorporation of individualised user profiles (attributes, characteristics and values), and specific disease and treatment modules.[71]

The capacity of artificial intelligence (AI) to create more personalised content could improve the adoption and engagement with decision-support tools. Recent studies are starting to incorporate AI to provide tailored information based on patient-reported outcomes (eg, quality of life), for example, in a recent RCT assessing a patient decision aid for patients with knee osteoarthritis.[72] Another option to allow for individualised and engaging patient interactions with decision-support tools is the application of conversational AI (ie, the use of machine learning and natural language processing allowing computers to have human-like conversations).[73 74] Future research should evaluate the impact and acceptability of patient decision-support tools that are able to ‘chat’ with patients and support the decision-making process in a personalised manner.

Conclusions

Moderate certainty evidence suggests digital patient decision-support tools reduce decisional conflict, with low certainty evidence of knowledge improvement in the context of stroke prevention in patients with AF and mixed results for medication adherence. Digital capabilities could be further leveraged to optimise personalisation and interaction with the tools. Health literacy considerations and co-production with disadvantaged populations are key for the development of future tools. Additional robust trials and implementation studies are warranted to further evaluate digital features and to understand barriers and enablers to the use of these tools so they can be translated into the real world.

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