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Shared Decision Making Tools for People Facing Stroke Prevention Strategies in Atrial Fibrillation: A Systematic Review and Environmental Scan

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Objective. Shared decision making (SDM) tools can help implement guideline recommendations for patients with atrial fibrillation (AF) considering stroke prevention strategies. We sought to characterize all available SDM tools for this purpose and examine their quality and clinical impact. **Methods**. We searched through multiple bibliographic databases, social media, and an SDM tool repository from inception to May 2020 and contacted authors of identified SDM tools. Eligible tools had to offer information about warfarin and $\geq$1 direct oral anticoagulant. We extracted tool characteristics, assessed their adherence to the International Patient Decision Aids Standards, and obtained information about their efficacy in promoting SDM. **Results**. We found 14 SDM tools. Most tools provided up-to-date information about the options, but very few included practical considerations (e.g., out-of-pocket cost). Five of these SDM tools, all used by patients prior to the encounter, were tested in trials at high risk of bias and were found to produce small improvements in patient knowledge and reductions in decisional conflict. **Conclusion**. Several SDM tools for stroke prevention in AF are available, but whether they promote high-quality SDM is yet to be known. The implementation of guidelines for SDM in this context requires user-centered development and evaluation of SDM tools that can effectively promote high-quality SDM and improve stroke prevention in patients with AF.

Keywords
anticoagulation, atrial fibrillation, cardiovascular prevention, decision aids, shared decision making

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Atrial fibrillation (AF) is a heart arrhythmia associated with a 5-fold increase in the risk of stroke. It is estimated that 30% of people with AF develop at least 1 cerebrovascular event in their life time[1–3]; this event is more likely to be fatal in patients with AF (19%–35%) compared to patients without AF (5%–14%).[4] Stroke survivors live with physical and cognitive disabilities, and their families and caregivers often experience social, physical, emotional, and financial difficulties.[5–7]

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Large randomized trials have demonstrated the benefits of anticoagulation in reducing the risk of AF-related strokes,[8] yet many at-risk patients do not receive these benefits[9–11] as less than 50% of high-risk patients are treated with anticoagulation therapy[12] and more than 40% discontinue therapy within 12 months.[13–18] There are multiple patient- and clinician-associated factors that may lead to underuse of anticoagulants within this population such as inadequate patient/caregiver resources, lack of understanding about risks and benefits, and difficulties with effective communication.[19,20]

In response to these challenges, and to realize the full benefits of anticoagulation, the 2014 and 2019 guidelines from the American Heart Association, American College of Cardiology, and The Heart Rhythm Society for the management of patients with AF recommended that shared decision making (SDM) be used to individualize antithrombotic care.[9,21] This call for SDM emphasizes its role as a patient-centered strategy in forming plans of care that respond well to the threat of stroke in each patient's clinical and personal contexts.[22,23]

SDM tools could support the implementation of these guideline recommendations. Effective tools should be feasible to implement in busy clinical practices and could help 1) share tailored information about the available options, 2) clarify the different attributes of the options in patients' lives and develop preferences about these, 3) support patient-clinician conversations in which these options are considered in the lives of patients, and 4) arrive at an implementable decision. A systematic search conducted in 2016 identified 6 SDM pertinent tools.[24] Since then, direct oral anticoagulants (DOACs), included in only 1 of the 6 tools, have increased in use, and the Centers for Medicare & Medicaid Services (CMS) tied reimbursement to performance and documentation of SDM for patients with AF considering a left atrial appendage closure (LAAC) device.[25]

These events have significantly affected SDM surrounding stroke prevention among AF patients. We, therefore, determined that an updated scan of the published record and online resources would be beneficial. The goal of this review was to identify available SDM tools designed to support SDM about stroke prevention for patients with AF and assess their quality and impact on SDM outcomes.

Methods

We conducted a systematic review of academic databases and environmental scanning to collect SDM tools and associated literature about their development and efficacy. The current report follows the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA).[26] The protocol of this study can be accessed by request.

Eligibility Criteria

Eligible SDM tools were developed to support SDM about pharmacological and nonpharmacological strategies (e.g., LAAC device) for stroke prevention in patients with AF. These tools were either patient decision aids (supporting the preparation of patients for SDM) or encounter tools (supporting both patients and clinicians participating in SDM). They were required to include warfarin and $\geq$1 DOAC as stroke prevention options. We also included any study assessing the impact of any eligible SDM tool v. usual care or other active control on SDM.

Data Sources and Search Strategy

Literature search. An experienced librarian (L.P.) designed a search strategy that was carried out in Ovid MEDLINE and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, and Daily, Ovid EMBASE, Ovid PsycINFO, Ovid Cochrane Central Register of Controlled Trials, Ovid Cochrane Database of Systematic Reviews,

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Web of Science, and Scopus. The search was conducted from each database's inception to May 19, 2020 (Supplemental Material 1). There were no restrictions on study design, language, or date of publication.

Environmental scan. A systematic search of social media platforms Facebook and Twitter was conducted and updated as of July 10, 2020, by introducing different combinations of the words *atrial fibrillation* and *shared decision making* in their search bars (Supplementary Material 2). In addition, during the data extraction for the systematic review, we extracted all author names and emails. Each author was emailed up to 2 times and asked to verify the information collected about their SDM tool, to identify missed SDM tools, and to provide access to the content of their tools when not otherwise freely available (Supplementary Material 3). Finally, we conducted a search of the Ottawa Health Research Institute SDM tool inventory,[27] using the terms *atrial fibrillation*, *anticoagulation*, and *stroke*.

Study and SDM Tool Selection

Nine reviewers (V.T.R., O.J.P., N.E.S., T.B., F.B., A.D.T., P.W.O., F.B., and S.J.) working independently and in duplicate assessed each report for eligible SDM tools. To ensure quality and consistency, we performed multiple pilots and teaching rounds until we reached at least 90% of agreement before each phase. Disagreements resulting from full-text screening were resolved by a third author (J.P.B.). Three reviewers (V.T.R., O.J.P., and J.P.B.), working independently and in duplicate, assessed the eligibility of the SDM tools identified through the environmental scan.

Data Extraction

Five reviewers (V.T.R., M.U.-S., N.E.S., C.L.-S., and O.J.P.) extracted features of each SDM tool and each efficacy study. For risk-of-bias assessment, we used the Cochrane Collaboration's tool[28] on randomized clinical trials and the Newcastle-Ottawa tool[29] on nonrandomized studies.

SDM Tool Features

Two reviewers (J.P.B. and V.T.R.) checked each SDM tool against the International Patient Decision Aids Standards instrument (IPDAS) version 4.0.[30] All conflicts were resolved by discussion. This 35-item tool (Supplementary Material 4) groups standards into 9 domains: information (8 items), outcome probabilities (6 items), values (2 items), decision guidance (2 items), development (6 items), evidence (6 items), disclosure (2 items), plain language (1 item), and evaluation (2 items).

The funding source had no role in the study conception, design, analysis, or interpretation.

Results

Figure 1 describes the results of our search. Table 1 and Supplementary Material 5 describe the 14 included SDM tools.[31–55] All but 2 were in English; the mAF app[42] was in Chinese and MATCh AFib[43,44] in Portuguese. When examining their intended use, 3 were patient decision aids, 5 were encounter tools, 4 had features of both, and 2 were not classifiable because of either lack of information or access to the tool itself. Most tools offered information about the available treatment options, mostly warfarin and DOACs, and the probabilities of specific outcomes. All the tools included tailorable risks of stroke and bleeding (mostly using CHA2DS2-VASc and HASBLED calculators) and compared different options of anticoagulation based on dosing, frequency of laboratory testing, drug side effects/interactions, and costs.

SDM Tool Quality Assessment

Twelve decision aids met more than 50% of the IPDAS items (Figure 2). The top-rated tools were PtDA,[51–53] Anticoagulation Choice,[45–48] Don't Wait to Anticoagulate,[38] and PDA,[55] which met >70% of all IPDAS items. PtDA was the only tool that assessed for readability. Only 2 tools, Anticoagulation Choice and Don't Wait to Anticoagulate, reported field testing with patients and clinicians.

SDM Tools' Effectiveness and Risk-of-Bias Assessment

Six studies, including 2 randomized trials[42,48] and 4 nonrandomized studies,[34,43,53,55] at high risk of bias reported the effect of SDM tools on SDM outcomes (Table 2 and Supplementary Material 6).

The outcomes evaluated included knowledge, decisional conflict, quality of life, and medication adherence. These results are further described in Table 3. In summary, knowledge was evaluated and found significantly improved with the use of SDM tools in 5 studies. One of the trials[48] reported minimal change in knowledge probably due to

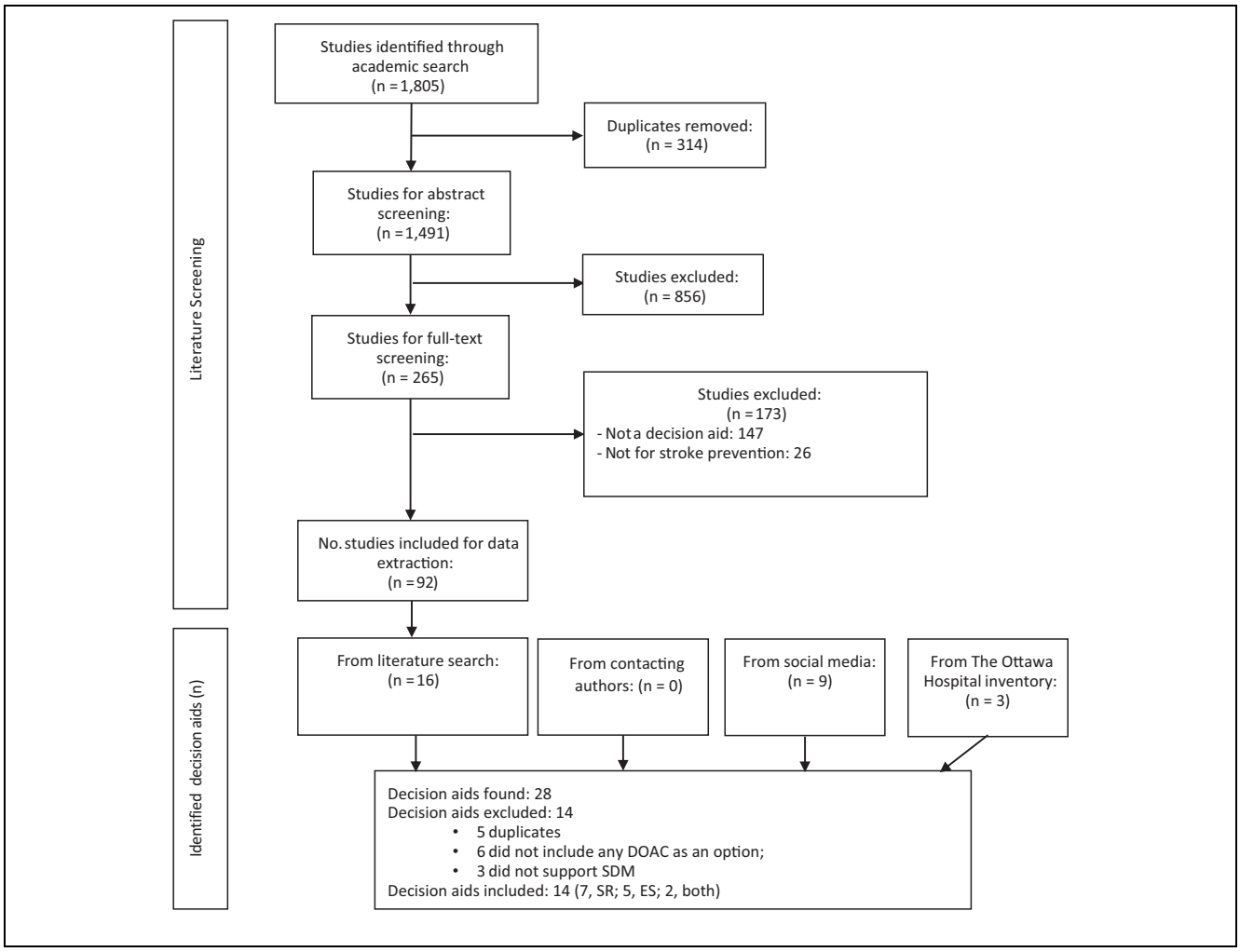

Figure 1 Eligibility of decision aids.

nearly optimal levels at baseline. Five studies reported low decisional conflict immediately postintervention (9–19 out of 100 points).[34,43,48,53,55] The only study that reported pre-intervention scores demonstrated a large effect associated with the intervention.[34] Quality of life was evaluated in only 1 randomized trial, which had substantial between-arm imbalance at baseline.[42] Two studies measured and reported statistically significant improvements in adherence to anticoagulants with the use of the SDM tool when compared to adherence at baseline and in the control group.[34,42]

Discussion

We found 14 SDM tools for patients with AF considering stroke prevention strategies. Most were patient decision aids that offered information about the available treatment options, described probabilities of specific outcomes, included some type of value clarification activity, and included information about cost, required lab tests, dosing, potential changes in diet, and potential side effects; very few included information about other lifestyle changes and the burden of treatment (e.g., what it means to take a pill daily or what it takes to attend periodic clinic appointments). Patient decision aids improve patient knowledge and decisional conflict. Encounter SDM tools have not been evaluated. None of the 14 tools met all IPDAS certification criteria,[30] although most met 50% to 75% of them. Finally, in light of the CMS statement about the mandatory use of SDM when considering percutaneous LAAC,[25] we

Table 1 List and Overall Characteristics of Decision Aids

Decision Aid	Institution	Period of Development	Platform	Patient or Encounter Decision Aid	Availability
AF Manager[31,32]	European Society of Cardiology (ESC)	2013	Mobile application	Patient and encounter decision aid	Through "ESC pocket guidelines" app for apple and android devices
Afib: Which anticoagulant should I take to prevent stroke?[41]	Healthwise, Inc., Canada	2017	Web application	Patient decision aid	https://www.uwhealth.org/health/topic/decisionpoint/atrial-fibrillation-which-anticoagulant-should-i-take-to-prevent-stroke/abl2009.html
Anticoagulation Choice[45–48]	Mayo Clinic, USA	2016	Web application	Encounter decision aid	https://anticoagulationdecisionaid.mayoclinic.org/
Atrial Fibrillation Shared Decision Making (AFSDM) Tool[33–35]	University of Cincinnati, USA	NA	Web application	Encounter decision aid	Not available
Blood Thinners for Atrial Fibrillation[36]	Healthwise, Inc., Canada	2015	Web application	Not sure	https://decision.healthwise.net/Decision-Aids/AFIB-Patient-View/
CardioSmart[37]	American College of Cardiology, USA	2017	Web application and paper-based aid	Not sure	https://www.cardiosmart.org/SDM/Decision-Aids/Find-Decision-Aids/Atrial-Fibrillation
Don't Wait to Anticoagulate (DWAC)[38]	West of England Academic Health Science Network, UK	2016	Web application and paper based aid	Patient and encounter decision aid	http://www.dontwaittoanticoagulate.com/
Healthdecision[39,40]	UW Health, USA and Dartmouth–Hitchcock Medical Center, USA	2017	Web application	Encounter decision aid	https://www.healthdecision.org/tool.html
mAF app[42,a]	Chinese PLA General Hospital, China	NA	Mobile application	Patient decision aid and encounter decision aid	Not available
Mhealth Application for Anticoagulation Care in Atrial Fibrillation (MATCh AFib)[43,44,a]	Instituto de Cardiologia—Fundação Universitária de Cardiologia (IC/FUC), Brazil	2017	Mobile application	Encounter decision aid	Not available
PtDA (Patient Decision Aids)[51–53]	McMaster University	NA	Paper-based aid	Patient decision aid	https://rsjh.ca/holbrook/NOACs_warfarin_decision_aid_booklet_chart_May26_16.pdf
NICE Decision Aid[49,50]	The National Institute for Health and Care Excellence, UK	2014	Paper-based aid	Patient decision aid and encounter decision aid	https://www.nice.org.uk/guidance/cg180/resources/patient-decision-aid-pdf-243734797
WISDM for A FIB[54]	EBSCO health, USA	2017	Web application	Encounter decision aid	http://wisdmforafib.com/
PDA[55]	The University of British Columbia	2016–2017	Web application	Patient decision aid	Contact the authors to request access

NA, not available.
[a]All but these 2 decision aids are available in English: the content of mAF app and MATCh AFib are in Chinese and Portuguese, respectively.

			Decision aids														
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	%
Information	QF	Describes condition	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
	QF	States the decision		✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	79
	QF	Describes options		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	86
	QF	Positive features		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	86
	QF	Negative features		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	86
	CT	Equal details		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	86
	QL	Natural course		✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓	79
	QL	Fair comparison		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	86
Probabilities	QL	Outcome probabilities		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	86
	QL	Reference class		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	93
	QL	Event rates			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		71
	QL	Same time period			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	79
	QL	Same denominator			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	79
	QL	Viewing probabilities			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		71
Val	QF	Describes what it is like		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	79
	QL	What matter most		✓	✓		✓	✓		✓			✓	✓		✓	57
DG	QL	Step-by-step decision		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	86
	QL	Worksheets		✓			✓	✓									21
Development	QL	Patients' needs			✓				✓			✓	✓			✓	36
	QL	Professionals' needs			✓	✓			✓				✓			✓	36
	QL	Review by patients			✓				✓				✓			✓	29
	QL	Review by professionals			✓											✓	14
	QL	Tested with patients			✓				✓								14
	QL	Tested with doctors			✓				✓							✓	21
Evidence	CT	Provides citations	✓	✓	✓	✓	✓		✓				✓	✓	✓	✓	71
	CT	Publication date	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	93
	CT	Update policy								✓							7
	CT	Levels of uncertainty		✓				✓					✓	✓			29
	QL	Evidence synthesis			✓	✓						✓	✓				29
	QL	Quality of evidence			✓								✓		✓		21
Disc	CT	Funding source	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓	✓	86
	QL	Credentials	✓	✓	✓		✓	✓	✓	✓			✓	✓		✓	71
PL	QL	Readibility evaluated											✓				7
Ev	QL	Better choices				✓					✓	✓	✓			✓	36
	QL	Improves knowledge				✓					✓	✓	✓			✓	36
		IPDAS score (%)	**14**	**52**	**83**	**63**	**54**	**60**	**71**	**54**	**14**	**63**	**86**	**63**	**54**	**74**	
		Qualifying criteria, n out of 6	1	6	6	5	6	6	6	6	1	6	6	6	5	6	
		Certification criteria, n out of 6	3	5	4	4	2	4	4	4	1	3	5	5	4	4	
		Quality criteria, n out of 23	1	7	19	13	11	11	15	9	3	13	19	11	10	16	

Figure 2 Quality of decision aids: IPDAS checklist.

Table 2 Characteristics of Studies Evaluating Effectiveness

Study, Year	No. of Participants	Participants	Design	Decision Aid	Setting	Mean Age, y	Female (%)	CHA2DS2-VASC Mean	HAS-BLED Mean	Prior Stroke (%)	Overall Risk of Bias
Kunneman et al., 2020[48]		Adults with atrial fibrillation	Randomized controlled trial	Anticoagulation Choice	Outpatients and inpatients, USA	71	39.2	3.46	2.08	NA	High
Loewen et al., 2019[55]	37	Adults with chronic atrial fibrillation	Nonrandomized study, single arm	PDA	Outpatient, Canada	71	57	2.38	2.18	8	High
Eckman et al., 2018[34]	76	Adults with atrial fibrillation or atrial flutter	Nonrandomized study, single arm	AFSDM	Outpatient, USA	65.7	35	3	1.9	11	High
Stephan et al., 2018[43]	20	Adults with atrial fibrillation	Nonrandomized study, single arm	MATCH-Afib	Outpatient, Brazil	67.7	40	3	2	17	High
Guo et al., 2017[42]	209	Adults with atrial fibrillation	Randomized controlled trial	mAF app	General hospital, China	69	44	2.6	1.5	9	High
Hong et al., 2013[53]	35	Adults aged >60 y	Nonrandomized study, single arm	PtDA	Inpatient and outpatient, Canada	62.7	37	NA	NA	20	High

AFSDM, Atrial Fibrillation Shared Decision Making; NA, not available; PDA, patient decision aid.

found only 1 SDM tool (CardioSmart) that included LAAC as an option.

One possible limitation of this study might have been not including government or nongovernmental organizations' websites in our search strategy. We believe, however, that our search strategy ensured the inclusion of the SDM tools more available to clinicians and patients. In addition, the data on the development of the SDM tools were scarce. Most authors did not publish a article explaining the development process or included this information on their websites. Lack of reporting was considered as unmet IPDAS criteria by our group because we considered that the information of the development process should have been available to users in their published manuscripts, websites, or tools themselves. This decision could have led to lower IPDAS scores across all tools included in this analysis. The current study updates the database of existing SDM tools about anticoagulation for patients with AF. Compared to the review by O'Neill et al.,[24] we found 5 additional tools, including the PtDA,[51–53] which met the largest number of IPDAS standards. Our review also draws attention to the lack of participation of patients and clinicians in the content, design, and implementation of the tools and the lack of development of the tools within the context of their use.[56] If we expect tools to be applied within the clinical setting, they must be developed in a way that places the patient at the center of the development process. This can best be done through early and frequent testing of prototypes within actual clinical encounters of clinicians and AF patients facing the decision about whether and how to anticoagulate. Furthermore, for SDM tools to be ready for use and implementation, they should undergo rigorous efficacy testing. Yet, our review found that only a small subset of the tools underwent any type of testing. These studies, at high risk of bias, showed that the tools improve outcomes such as knowledge and decisional conflict, which may be useful to achieve SDM but at the same time might not be enough by themselves. None of studies directly tested whether the tools facilitated SDM. Some studies measured long-term, yet still indirect, consequences of SDM such as adherence and quality of life, but the results were inconclusive.

Conclusions

Several SDM tools are available, but their efficacy in promoting high-quality SDM is unknown. SDM tools should be rigorously evaluated in terms of their ability to support SDM and affect patient care.

Table 3 Summary of Findings

Study, Year	DCS	Knowledge	Quality of Life	Adherence
Kunneman et al., 2020[48]	DCS (0–100). Low mean decisional conflict in both arms (SD): intervention, 16.6 (14.4), and control 17.9 (14.9); the effect size was nonsignificant: −1.2 (95% CI, −3.2 to 0.6)	Knowledge test (0.6). The number of patients achieving a perfect score was similar to intervention (31.0%) and control (28.6%) (effect size: 1.01; 95% CI, 1.0 to 1.02).	NA	NA
Loewen et al., 2019[55]	DCS (0–100). Significantly lower decisional conflict postintervention (mean, 13.7) compared to baseline (mean, 34.9).	AFKA (0–10) Significantly increased participants' AF knowledge from baseline (mean, 7.93) compared to postintervention (mean, 8.61; $P = 0.02$).	NA	NA
Eckman et al., 2018[34]	DCS (0–100). Significant decrease postintervention (mean, 9.1) compared to baseline (mean, 31.4).	Knowledge test (0–10). Statistically significant increase after intervention (mean, 9.1; SD, 1.25) compared to baseline (mean, 8.4; SD, 1.5).	NA	The Morisky Medication Adherence Scale (0–7). Increase after intervention (mean, 6.4; SD, 0.87) compared to baseline (mean, 5.9; SD, 1.3).
Stephan et al., 2018[43]	DCS (0–100). Low decisional conflict after intervention (mean, 11; SD, 16). No baseline data.	Knowledge test (0–8). Statistically significant increase after decision aid (mean, 7.2) compared to baseline (mean, 4.7).	NA	NA
Guo et al., 2017[42]	NA	Knowledge test (0–11). Statistically significant increase after 3 months in the intervention arm compared to controls. However, magnitude was not reported.	EuroQol (0–100). Statistically significant difference between intervention (mean, 87.2) and control arms (mean, 69.9). Baseline QoL was very different among groups (86.5 v. 71.3, respectively).	Pharmacy Quality Alliance adherence measure (0–36). At 3 months, lower propensity to leave the medication was observed in the intervention (mean, 2) than controls (mean, 4).
Hong et al., 2013[53]	DCS (0–100). Low decisional conflict after intervention (mean, 18.9; SD, 10.8). However, no baseline data.	Knowledge test (0–7). Statistically significant increase after intervention (mean, 6.43; SD, 0.8) compared to baseline (mean, 4.6; SD, 1.5).	NA	NA

AF, atrial fibrillation; AFKA, AF knowledge assessment; CI, confidence interval; DCS, decisional conflict score; NA, not avaialble; QoL, quality of life.

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Supplemental Material

Supplementary material for this article is available on the *Medical Decision Making* website at http://journals.sagepub.com/home/mdm.

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