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ESC European Society of Cardiology

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REVIEW ARTICLE

Patient decision aids for aortic stenosis and chronic coronary artery disease: a systematic review and meta-analysis

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Aims Shared decision-making is recommended for patients considering treatment options for severe aortic stenosis (AS) and chronic coronary artery disease (CAD). This review aims to systematically identify and assess patient decision aids (PtDAs) for chronic CAD and AS and evaluate the international evidence on their effectiveness for improving the quality of decision-making.

Methods and results Five databases (Cochrane, CINAHL, Embase, MEDLINE, and PsycInfo), clinical trial registers, and 30 PtDA repositories/websites were searched from 2006 to March 2023. Screening, data extraction, and quality assessments were completed independently by multiple reviewers. Meta-analyses were conducted using Stata statistical software. Eleven AS and 10 CAD PtDAs were identified; seven were less than 5 years old. Over half of the PtDAs were web based and the remainder paper based. One AS and two CAD PtDAs fully/partially achieved international PtDA quality criteria. Ten studies were included in the review; four reported on the development/evaluation of AS PtDAs and six on CAD PtDAs. Most studies were conducted in the USA with White, well-educated, English-speaking participants. No studies fulfilled all quality criteria for reporting PtDA development and evaluation. Meta-analyses found that PtDAs significantly increased patient knowledge compared with 'usual care' (mean difference: 0.620; 95% confidence interval 0.396–0.845, $P < 0.001$) but did not change decisional conflict.

Conclusion Patients who use PtDAs when considering treatments for AS or chronic CAD are likely to be better informed than those who do not. Existing PtDAs may not meet the needs of people with low health literacy levels as they are rarely involved in their development.

Registration PROSPERO: CRD42021264700.

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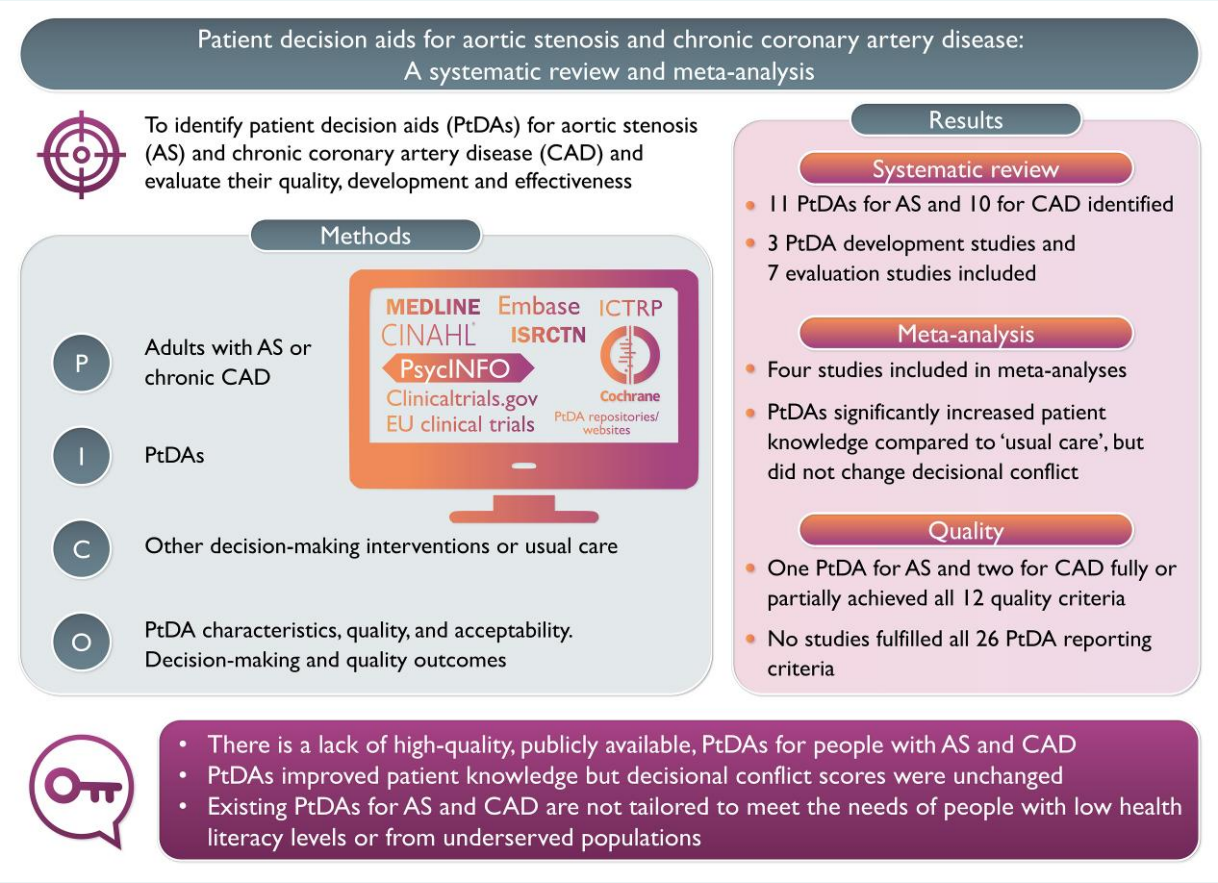
Graphical Abstract



Keywords Aortic stenosis • Coronary artery disease • Patient decision aids • Patient education • Shared decision-making

Novelty

- This is the first review to systematically identify and evaluate the availability, characteristics, and quality of patient decision aids for use in severe aortic stenosis and chronic coronary artery disease patient pathways.
- A barrier to implementing shared decision-making for people with heart disease or aortic stenosis is the lack of high-quality, up-to-date, publicly available patient decision aids.
- Existing patient decision aids are not tailored to meet the needs of people with low health literacy levels or from underserved populations.
- Patient decision aids in this review improved patient knowledge, but decisional conflict scores were unchanged, possibly due to a ceiling effect.

Introduction

Over the last 60 years, technological innovations have revolutionized the field of interventional cardiology. Two of the most common interventions are percutaneous coronary intervention (PCI) and transcatheter aortic valve implantation/replacement (TAVI). Over 965 000 PCIs are performed annually in the USA alone.[1] Global projections of the annual number of TAVI procedures are estimated to rise to 300 000 implants by 2025.[2] Both interventions have the potential to relieve symptoms that negatively impact quality of life[3,4]

Patients with chronic coronary artery disease (CAD) may experience symptoms of angina. First-line treatment is medication, but if this is not effective, PCI is a treatment option to consider.[5] Patients with severe aortic stenosis (AS) also live with unpleasant symptoms associated with heart failure. Clinical guidelines indicate that a multi-disciplinary heart team should evaluate the degree of AS along with clinical and anatomical characteristics to inform their recommendations to patients about treatment options, such as TAVI or surgical aortic valve replacement (SAVR).[6]

Whilst PCI and TAVI are different interventions, the decision-making processes share common features; the decision to go ahead with the treatment is considered to be 'preference sensitive'; i.e. two or more treatment options exist but the 'best' treatment depends on how acceptable the patient views the potential risks and benefits of each.[7] In these situations, a process of shared decision-making (SDM) helps patients make an informed choice.[8] Accordingly, The American College of Cardiology and European Society for Cardiology recommend that

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SDM should take place before a patient agrees to an interventional procedure for chronic CAD or AS.[5,6,9,10]

Shared decision-making involves a two-way discussion in which patients are informed by their doctors and nurses about what a treatment involves, the benefits and risks, and alternative options and what the outcome might be if they decided against having treatment. Importantly, SDM means that patients are encouraged to consider their unique preferences, goals, and values (i.e. what matters most to an individual about attributes of a health decision).[11,12] In today's clinical practice, SDM may be difficult to achieve. Patients' preferences and goals for treatment are not routinely discussed.[13] Moreover, patients treated with PCI often misunderstand the treatment benefits and risks and perceive their treatment as a 'fix'.[14,15] Patients considering TAVI experience uncertainty about their treatment decision[16] and want to understand the risks and benefits of all potential treatment options and outcomes (e.g. TAVI, SAVR, or no intervention).[17]

Patient decision aids (PtDAs) are effective interventions known to improve the quality of both the decision-making process and the choice made.[18] Evidence shows that PtDAs increase patients' knowledge about treatments and support more accurate perceptions of associated benefits and risks.[18] However, PtDAs are not routinely used in clinical practice despite the potential benefits.[19] Some cardiologists' do not perceive PtDAs to be of benefit to their patients.[20] Unfamiliarity and a lack of awareness of PtDAs and disagreement with the content are also factors that compromise implementation.[21]

A recent meta-analysis reported that cardiology PtDAs improved two key decision outcomes: decisional conflict and patient knowledge.[22] These findings support the use of PtDAs. However, the review did not report the availability, content, and quality of the PtDAs, include PtDAs for AS, or summarize evidence on other decision-making constructs, leaving gaps in the evidence base. Accordingly, the aims of this review were to (i) identify PtDAs for chronic CAD and AS that include PCI and TAVI as treatment options and evaluate their availability, characteristics, and quality; (ii) identify and describe the quality of studies reporting on the development and evaluation of identified PtDAs; and (iii) evaluate their effectiveness on improving the quality of the decision-making process and the choice made. Findings will provide cardiology teams with an international overview of available PtDAs designed to improve the quality of SDM for chronic CAD and AS.

Methods

Review approach

Our review methods were informed by previous reviews[23,24] and Cochrane guidance.[25] To support the robustness of this review, the protocol was developed and registered on PROSPERO (CRD42021264700) *a priori* and Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines[26] implemented (see Supplementary material online, *Table S1*).

Search strategy

A search of multiple databases, trial registries, PtDA repositories, and websites was conducted, to identify eligible PtDAs and published articles that described their development or evaluation. A search strategy was developed by an information technologist (H.C.), piloted on MEDLINE (Ovid), refined, and applied to five databases in all languages: CENTRAL via the Cochrane Library, CINAHL (EBSCO), Embase, Ovid MEDLINE, and APA PsycInfo (ProQuest). Four trial registers were searched: EU clinical trials register, ClinicalTrials.gov, ISRCTN Registry, and ICTRP (WHO). Searches were limited to articles published since 1 January 2006, because the consensus on criteria for judging the quality of PtDAs was published in 2006 by the International Patient Decision Aid Standards (IPDAS) Collaboration.[27] Thirty PtDA repositories/websites were also hand searched. Searches were conducted in July 2021 and updated in March 2023. See Supplementary material online, *Tables S2–S7* for search terms and the list of PtDA repositories/websites.

Patient decision aid eligibility and selection

Patient decision aids were defined as tools designed to help facilitate SDM between patients and health professionals.[18] Patient decision aids were eligible for inclusion if they fulfilled the following criteria:

- Identified as a PtDA, decision tool or an aid to support SDM in their name/title, or by the developers/authors, or listed within a PtDA repository.
- Designed for patients (18+ years) with chronic CAD or AS.
- Included at least two treatment options, one of which must either be PCI or TAVI.

All identified PtDAs were independently screened for inclusion by two reviewers (E.H. and A.B.). The authors, or organizations listing PtDAs not publicly available, were contacted to request a copy. Eligible PtDAs that met the criteria, but were not available in full, were included in the overview (*Table 2*) but not in the evaluation of PtDA characteristics (*Table 2*).

Article eligibility and selection

Search results were independently screened for inclusion by at least two reviewers (E.H. and A.B./F.A.) in three phases: title, abstract, and full-text screening. Where disagreement occurred, consensus was achieved through discussion. Articles and study reports of any design were included providing they reported on the development, user-testing, acceptability, or evaluation of eligible PtDAs. Articles reporting on ineligible PtDAs, literature reviews, and editorials were excluded.

Data extraction

Data from each included study were independently extracted by two reviewers (E.H., D.C., A.Y.C., J.S., and A.B.) into a datasheet. Characteristics from included PtDAs were extracted by one reviewer and independently checked for accuracy by a second author. Any discrepancies in data extraction were resolved by consensus. Data were synthesized into tables and presented in a narrative.

Statistical analysis

Studies evaluating the effectiveness of PtDAs were assessed for suitability and those with the same primary endpoint pooled for a meta-analysis. Due to the heterogeneity of outcome measures, only two meta-analyses were conducted on the primary interval-level outcomes of patients' Knowledge score and Decisional Conflict score. The meta-analyses were formulated as random effects using the DerSimonian and Laird model[28] to reflect clinical and methodological heterogeneity. For both outcomes, standardized mean differences, based on post-test statistics in intervention and control groups (intervention minus control), and associated 95% confidence intervals (CIs) were measured. For the Knowledge score outcome, clinical improvement was represented by increases in reported scores. For the Decisional Conflict score outcome, clinical improvement was represented by decreases in reported scores. Forest plots were conducted for meta-analyses of both primary outcomes, reporting synthesized estimates, and associated 95% CIs, and a *Z*-test for the standardized mean difference. Heterogeneity statistics were also reported, including Cochran's *Q* test for heterogeneity, and the I^2 statistic.

Leave-one-out sensitivity analyses were conducted on the meta-analyses of both primary outcomes to assess the robustness of the derived estimates. Each of the *k*-included studies was omitted in turn, and a meta-analysis was conducted based on the remaining ($k - 1$) studies. Any study that was suspected of excessive influence was flagged as an influential study. Funnel plots were proposed for analyses of small-study effects for meta-analyses in which the number of identified studies reached the recommended minimum[25] but were not conducted. No sub-group analyses were identified. All analysis was conducted using Stata statistical software (Version 17 I/C).[29]

Quality assessment

To support the rigour of this review, three approaches were implemented to evaluate the quality of included studies and associated PtDAs. First, the quality of PtDAs was evaluated using the six qualifying and six certification criteria of the IPDAS version four checklist,[30] which are the minimum

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standards for tools to be defined as a PtDA and deemed as adequate for patient use. As these criteria are designed for the evaluation of 'full' PtDAs, we excluded brief one- to two-page consultation/conversation aids from this assessment. Second, studies reporting an evaluation of PtDAs were assessed using the 'Standards for UNiversal reporting of patient Decision Aid Evaluations' (SUNDAE) checklist.[31] A modified version of this checklist was used for PtDA development studies. The IPDAS and SUNDAE checklists were independently completed by two reviewers and disagreements were resolved through discussions with a third reviewer (E.H. and A.B./F.A.). To increase the consistency of the assessments, three response options were developed: yes, partially, and no (see Supplementary material online, *Tables S8 and S9*). Third, the studies included in the meta-analyses were independently assessed by two reviewers (E.H. and F.A./J.S.) for risk of bias using either the Cochrane Risk of Bias 2 tool (RoB2[32]) or the NHLBI Quality Assessment of Controlled Intervention Studies.[33]

Results

Figure 1 shows the search results for AS and PCI PtDAs combined. In summary, 10 studies were eligible and included in the review, which, in total, reported on the development or evaluation of 11 PtDAs. A further 10 PtDAs were identified from a trial registry record and from online PtDA repositories and relevant websites. Therefore, a total of 21 PtDAs (11 AS and 10 CAD PtDAs) were included in this review. Results for the two groups of PtDAs are presented separately by condition (A.S. and C.A.D.).

Patient decision aids for aortic stenosis

Availability of patient decision aids for aortic stenosis

The search identified 11 PtDAs designed for patients with AS considering TAVI (see *Table 1* for an overview). Comparative treatment options included SAVR ($n = 9$) or symptom management ($n = 2$). Five PtDAs included the same content but were adapted for use by different age groups (MAGIC TAVI vs. SAVR PtDAs[44–48]). Patient decision aids were developed either in the USA ($n = 5$),[34,38,39,41,43] Canada ($n = 1$),[36,37] or by an international panel of experts ($n = 5$).[44–48] All were written in English and seven were available in other languages (two in Spanish and French[39,41] and five in Norwegian with translation of some sections available in 12 other languages[44–48]). Over half ($n = 8$) were web-based PtDAs[34,36,38,44–48] and the other three were paper based.[39,41,43] Five web-based PtDAs could be converted into a printable format.[44–48] Three PtDAs were less than five years old[36,38,41] but only one was publicly available,[41] which also fully or partially achieved all 12 IPDAS quality criteria (see Quality of patient decision aids for aortic stenosis).

Characteristics of patient decision aids for aortic stenosis

The characteristics of eight PtDAs for AS were evaluated (*Table 2*).[39,41,43–48] The remaining three were unavailable for evaluation due to website deactivation[34] or ongoing development.[36,38]

Two types of PtDAs were identified: a PtDA booklet (eight pages) to be reviewed by the patient at home[39,41] and an 'encounter PtDA' (paper or web-based) to be used during the consultation with a health professional.[43–48] The type and presentation of information varied between PtDAs. One 'encounter PtDA' presented information about the risks and benefits of treatment options on a single page,[43] whereas the other 'encounter PtDAs' were web based and required health professionals to navigate between different sections to present the information.[44–48] All PtDAs included icon arrays to present the risks and benefits of treatment options. Patient stories were only included in the two booklet PtDAs.[39,41] Three PtDAs incorporated an explicit values clarification method[39,41,43] (i.e. determining what matters to

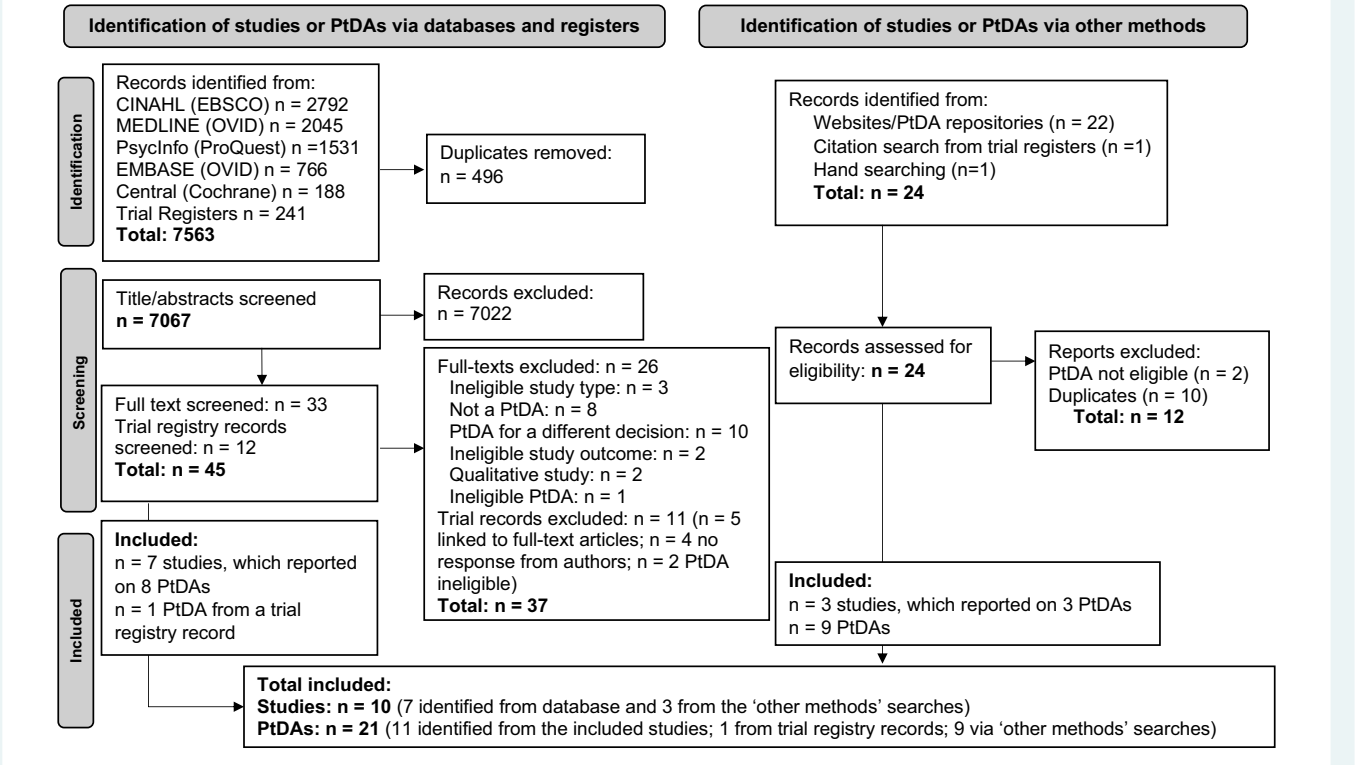

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 flow-diagram.[26]

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Table 1 Overview of patient decision aids

PtDA	Treatment options	Author(s) and/or developing organization	Date developed or updated	Country and language	Format	Availability	Source of identification
PtDAs for aortic stenosis treatment options							
ADVICE: Navigating Aortic Valve Treatment Choices[34]	• TAVI • SAVR	Brennan *et al.*, Duke University	2017	USA, English	Web based	Not available: Website deactivated.	Literature[35] identified via online sources[a]
Aortic Stenosis Choice (CHOICE-AS)[36,37]	• TAVI • SAVR	Lauck *et al.*[37]	Ongoing	Canada, English	Web based	Not currently available. PtDA development and testing study ongoing. Contact authors for access.	Online sources[b]
Aortic valve improved treatment approaches (AVITA) tool[38]	• No valve replacement (medications/comfort care) • TAVI • SAVR	Shared Decision-Making Resources collaborating with Edward Lifesciences	Ongoing	USA, English	Web based	Not currently available. PtDA development and pilot study ongoing. Contact authors for access.	Trial registry NCT04755426
A decision aid for treatment options for severe aortic stenosis (TAVI vs. symptom management)[39]	• Symptom management (taking medications only) • TAVI	American College of Cardiology	August 2017	USA, English, Spanish, French	Eight-page booklet (pdf)	https://www.cardiosmart.org/assets/decision-aid/choosing-between-tavr-and-symptom-management	Literature[40]
A decision aid for treatment options for severe aortic stenosis for patients deciding between TAVI and surgery[41]	• TAVI • SAVR	American College of Cardiology	July 2020	USA, English, Spanish, French	Eight-page booklet (pdf)	https://www.cardiosmart.org/assets/decision-aid/choosing-between-tavr-and-surgery	Literature[40,42]
Severe Aortic Stenosis Decision Aid[43]	• Symptom Management (Palliative care) • TAVI	American College of Cardiology	2014	USA, English	One-page pdf	https://sharedcardiology.org/tools/and available in *Figure 1* in published study[20]	Literature[20]
TAVI vs. SAVR for patients with severe symptomatic aortic stenosis at low to intermediate perioperative risk: for patients above 85 years with severe symptomatic aortic stenosis, at low or intermediate perioperative risk[44]	• TAVI • SAVR	MAGIC Evidence Ecosystem Foundation (BMJ RapidRecs)	May 2017	Multiple countries, English, Norwegian; partial translation into 12 other languages on website	Web based with option to create a 13-page pdf	https://app.magicapp.org/#/guideline/1308	Online sources[a]
TAVI vs. SAVR for patients with severe symptomatic aortic stenosis at low to intermediate perioperative risk: for patients 75–85 years with severe	• TAVI • SAVR	MAGIC Evidence Ecosystem Foundation (BMJ RapidRecs)	May 2017	Multiple countries, English, Norwegian; partial translation	Web based with option to create a 13-page pdf	https://app.magicapp.org/#/guideline/1308	Online sources[a]

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Table 1 *Continued*

PtDA	Treatment options	Author(s) and/or developing organization	Date developed or updated	Country and language	Format	Availability	Source of identification
symptomatic aortic stenosis who are at low or intermediate perioperative risk[45]				into 12 other languages on website			
TAVI vs. SAVR for patients with severe symptomatic aortic stenosis at low to intermediate perioperative risk: for patients aged 65 to <75 years and eligible for transfemoral TAVI or SAVR[46]	• TAVI • SAVR	MAGIC Evidence Ecosystem Foundation (BMJ RapidRecs)	May 2017	Multiple countries, English, Norwegian; partial translation into 12 other languages on website	Web based with option to create a 13-page pdf	https://app.magicapp.org/#/guideline/1308	Online sources[a]
TAVI vs. SAVR for patients with severe symptomatic aortic stenosis at low to intermediate perioperative risk: for patients aged <65 years and eligible for transfemoral TAVI or SAVR[47]	• TAVI • SAVR	MAGIC Evidence Ecosystem Foundation (BMJ RapidRecs)	May 2017	Multiple countries, English, Norwegian; partial translation into 12 other languages on website	Web based with option to create a 13-page pdf	https://app.magicapp.org/#/guideline/1308	Online sources[a]
TAVI vs. SAVR for patients with severe symptomatic aortic stenosis at low to intermediate perioperative risk who cannot undergo transfemoral TAVR but can undergo transapical approach[48]	• TAVI • SAVR	MAGIC Evidence Ecosystem Foundation (BMJ RapidRecs)	May 2017	Multiple countries, English, Norwegian; partial translation into 12 other languages on website	Web-based with option to create a 13-page pdf	https://app.magicapp.org/#/guideline/1308	Online sources[a]
PtDAs for chronic coronary artery disease treatment options							
Angina treatment: stents, drugs, lifestyle changes—What's best?[49]	• Medications • Angioplasty and stent placement • Enhanced external counter-pulsation (EECP) therapy • Lifestyle changes	Mayo Clinic	May 2021	USA, English	Web based	https://www.mayoclinic.org/diseases-conditions/coronary-artery-disease/in-depth/angina-treatment/art-20046240	Online sources[c]
Angina: treatment options, Option Grid™[50]	• Medical management • Stenting (angioplasty)	Option Grid Collaborative	2015/16	USA, English	Web based	Out of date: no longer available.	Literature[51]
Chest pain (stable angina) treatment options, Option Grid™[52]	• Non-invasive treatment	DynaMed Decisions, EBSCO Health	December 2021. Updated when	USA, English	Web based with option to	Not publicly available. Contact	Online sources[d]

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Table 1 *Continued*

PtDA	Treatment options	Author(s) and/or developing organization	Date developed or updated	Country and language	Format	Availability	Source of identification
	(medicines, lifestyle changes) • Invasive treatment (stent or bypass surgery)		new relevant scientific evidence becomes available		create a 4-page pdf	EBSCO Health for cost (www.ebsco.com).	
CONNECT: COroNary aNgioplasty dECision Tool[53]	• Medicines only • Coronary angiogram test and treatment with coronary angioplasty, if beneficial, AND medicines	Harris *et al.*[54]	February 2021	UK, English	Web based	Not currently publicly available. Randomized feasibility study ongoing. Contact authors for access.	Literature[54]
Coronary artery disease: What treatment would you prefer?[55]	• Medicines only • Angioplasty (stent) • Bypass surgery	Duke University Medical Center clinicians and Healthwise	2015	USA, English	Web based; eight-page paper version available within publication	Web version: access unknown. Paper version shown in the supplementary material in published study[56]	Literature[56]
Deciding what to do about stable angina[57]	• Lifestyle changes • Medical treatment • Revascularization (angioplasty or coronary artery bypass graft)	NHS England Vale of York Clinical Commissioning Group	January 2017	UK, English	Nine-page pdf	https://www.valeofyorkccg.nhs.uk/rss/home/patient-decision-making/shared-decision-making/	Online sources[e]
PCI Choice: Class I/II Stable Angina[58]	• Medicines alone • Medicines + stents	Mayo Foundation for Medical Education and Research	2012	USA, English	Two-page pdf	https://carethatfits.org/pci-choice/	Literature[59,60]
PCI Choice: Class III Stable Angina[61]	• Medicines alone • Medicines + stents	Mayo Foundation for Medical Education and Research	2012	USA, English	Two-page pdf	https://carethatfits.org/pci-choice/	Literature[59,60]
Should I have angioplasty for stable chest angina?[62]	• Take medicines and have a healthy lifestyle • Angioplasty, along with taking medicines and having a healthy lifestyle	Healthwise	Updated 2022	USA, English	Web-based with option to create a 19-page 'printer friendly' version	https://decisionaid.ohri.ca/Azsumm.php?ID=1202 Licence required for distribution to patients or consumers.	Literature[63]

Continued

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Table 1 *Continued*

PtDA	Treatment options	Author(s) and/or developing organization	Date developed or updated	Country and language	Format	Availability	Source of identification
Treatment choices for stable chest discomfort[64]	• Medical therapy • Percutaneous coronary intervention (PCI)	Health Dialog and Foundation for Informed Medical Decision Making	2014 version	USA, English	Booklet (36-page paper) and DVD (20 min)	Not publicly available. Contact Health Dialog for cost.	Literature[63]

[a]https://sharedcardiology.org.
[b]European Society of Cardiology Website https://www.escardio.org/.
[c]The Ottawa Hospital Research Institute Decision Aid Library Inventory https://decisionaid.ohri.ca/index.html.
[d]EBSCO Health care https://www.ebsco.com/health-care/products/my-health-decisions.
[e]Vale of York NHS https://www.valeofyorkccg.nhs.uk/rss/home/patient-decision-making/shared-decision-making/.

patients about a given health decision by using an approach that requires interaction[12]). The method in the two booklet PtDAs invited patients to write their hopes and concerns for the treatment options and any questions for their doctor and family.[39,41] The one-page 'encounter PtDA' invited patients to verbally respond to the question during a consultation, about what was important to them about their treatment.[43] This was the only PtDA to invite patients to indicate their preferred treatment. The readability score was not reported for any PtDA. Two PtDAs did not report their development method.[39,41]

Quality of patient decision aids for aortic stenosis

Seven PtDAs[39,41,44–48] were included for quality appraisal using the recommended IPDAS checklist ('encounter PtDAs' were excluded[43]). Results are summarized in *Table 2* (full evaluation in Supplementary material online, *Table S10*). To 'qualify' as a PtDA, six IPDAS criteria need to be achieved; only the two booklet PtDAs fulfilled these.[39,41] In total, the PtDAs fulfilled between 67% and 92% (median 67%) of all 12 IPDAS criteria. Two IPDAS criteria were not achieved by all PtDAs: 'describes the condition related to the decision' and 'the level of uncertainty around outcome probabilities' (i.e. the likelihood of an adverse or positive outcome occurring following treatment).

Patient decision aids for chronic coronary artery disease

Availability of patient decision aids for coronary artery disease

Ten PtDAs designed for patients with chronic CAD considering PCI were identified (*Table 1*). The comparative treatment options presented were medical therapy ($n = 10$), lifestyle changes ($n = 4$), and coronary artery bypass graft (CABG) surgery ($n = 4$). The two 'PCI Choice' PtDAs[58,61] included the same content but adapted the risks/benefits probabilities for either Class I/II or Class III stable angina. Eight PtDAs were developed in the USA[49,50,52,55,58,61,62,64] and two in the UK,[53,57] and all were only available in English. Six were web-based PtDAs[49,50,52,53,55,62] and four were paper based[57,58,61,64] (one also included a 20-min DVD[64]). One web-based PtDA had a paper-based version[55] and two others could be converted into a printable format.[52,62] Four PtDAs were less than five years old[49,52,53,62] but only one was publicly available.[49] This PtDA[49] fulfilled only five of the 12 IPDAS criteria.

Characteristics of patient decision aids for coronary artery disease

The characteristics of seven PtDAs for chronic CAD were evaluated (*Table 2*).[49,53,55,57,58,61,62] The remaining three were unavailable for evaluation.[50,52,64]

The type of PtDA, approach, and time point of use in the patient journey varied. Two were short paper-based 'encounter PtDAs' (PCI Choice[58,61]) to be used by the doctor with the patient in a consultation prior to diagnostic cardiac catheterization. Three web-based PtDAs[53,62] (one had a paper version option[55]) could be reviewed by patients either at home or whilst in hospital before the procedure. One paper-based PtDA could be used either pre-consultation or during the consultation.[57] Details about the delivery of one web-based PtDA were absent.[49] The design of PtDAs varied from a basic table comparing treatments with the use of multi-media to explain health conditions, treatment options, and procedures. Treatment risks and benefits were presented using a wide range of approaches. All but two[49,57] included icon arrays to convey the likelihood of risks and benefits. One PtDA[49] omitted the major risks associated with PCI. Patient stories/scenarios were included in two PtDAs.[53,62] Two PtDAs included explicit value clarification methods: a rating scale[62] and

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Table 2 Characteristics of patient decision aids

PtDA	Format and delivery	Design and development	EVC method	Tx preference indication	Other interaction	Risk/benefits presentation	Patient stories	No. of IPDAS criteria achieved
PtDAs for aortic stenosis treatment options								
A decision aid for treatment options for severe aortic stenosis (TAVI vs. Symptom Management)[39]	Paper booklet reviewed by patient pre-consultation	Colour text, graphics, text boxes, photos of people, images to explain disease and procedure. 15-min video on website. Development not described.	Four questions with open-text responses about hopes, concerns, questions for HCPs and family	None	—	Side-by-side list and icon arrays (100 heart icons); natural frequencies (denominator: 100); positive and negative framing	Two scenarios. Patient's Tx choice shown	Fully: 11 Partially: 0 Not met: 1
A decision aid for treatment options for severe aortic stenosis for patients deciding between TAVI and surgery[41]	Paper booklet reviewed by patient pre-consultation	Colour text, graphics, text boxes, photos of people, images to explain disease and procedure. 18.5-min video on website. Development not described.	Four questions with open-text responses about hopes, concerns, questions for HCPs and family	None	—	Side-by-side list and icon arrays (10 people icons); natural frequencies (denominator: 10 and 100); mostly negative framing used; positive and negative used for survival	Two scenarios. Patient's Tx choice shown	Fully: 11 Partially: 1 Not met: 0
Severe Aortic Stenosis Decision Aid[43]	Brief one-page paper 'Encounter PtDA' reviewed during consultation with HCP	Colour text, text boxes, graphs Development briefly described[20]	Conversation guide with 1 question asking the patient 'What matters most to you?'	Open-text response to indicate patient and HCP's shared decision	—	Side-by-side list, icon arrays (100 circles) and line graphs; positive and negative framing	None	N/A
TAVI vs. SAVR for patients with severe symptomatic aortic stenosis at low to intermediate perioperative risk (5 versions for different age groups[44–48])	Web-based interactive 'Encounter PtDA' reviewed during consultation with HCP	Text, pop-up boxes, black/white icons Clinical content review described on website. Option to download as pdf.	None	None	Web version only: HCP navigates between sections to guide discussion and explore outcomes the patient wants to discuss	Icon arrays (1000 people icons); side-by-side natural frequencies (denominator: 1000); mix of positive or negative framing	None	Fully: 8 Partially: 3 Not met: 1

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Table 2 *Continued*

PtDA	Format and delivery	Design and development	EVC method	Tx preference indication	Other interaction	Risk/benefits presentation	Patient stories	No. of IPDAS criteria achieved
PtDAs for chronic CAD treatment options								
Angina treatment: stents, drugs, lifestyle changes—What's best?[49]	Website. Delivery not specified	Text, colour image to explain procedure. Development not described.	None	None	—	Only states one risk (blockage re-forming). Likelihood not provided.	None	Fully: 5 Partially: 2 Not met: 5
CONNECT: COroNary aNgioplasty dECision Tool[53,54]	Web-based reviewed by patient pre-consultation. Personalised summary to be shared with HCP during consultation	Text, drop-down boxes, pop-up boxes, tables, colour icons, colour diagrams to explain disease and procedure, multiple short animated videos, photos of people. Development fully described.[54]	Open-text box for patient to add the top 3 things that matter most to them when considering their Tx options	Multiple-choice question with 'not sure' as an option. A smiley face 5-point Likert scale to indicate level of certainty with choice	Patient input: navigation between sections; six-item multiple-choice Angina Symptom Evaluation Questionnaire; Open-text box to add worries or questions. Generates personal summary of answers.	Side-by-side comparison table; icon arrays (1000 people icons for PCI risks, 100 people for benefits of both options); natural frequencies (denominator: 1000 and 5000); positive and negative framing	Text and audio quotes from 5 fictional patients. Tx choice not shown.	Fully: 12 Partially: 0 Not met: 0
Coronary artery disease: What treatment would you prefer? (paper version only)[a55]	Web and paper reviewed by patient on the day of diagnostic angiogram	Paper version: Text, colour graphics, table, pictures and icons, colour diagrams to explain disease and procedures. Development described briefly.[56]	None	One question asking patient to record preferred Tx	—	Side-by-side lists; icon arrays (100 people icons); natural frequencies (denominator: 1000); negative framing	None	Fully: 9 Partially: 0 Not met: 3

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Table 2 *Continued*

PtDA	Format and delivery	Design and development	EVC method	Tx preference indication	Other interaction	Risk/benefits presentation	Patient stories	No. of IPDAS criteria achieved
Deciding what to do about stable angina[57]	Paper based reviewed by patient pre-consultation or with HCP during consultation	Text, diagram, tables. Development not described.	None	None	Six questions for the patient to consider (no space for patient answers)	Side-by-side comparison table; positively framed natural frequencies for symptom improvement for PCI/CABG option only (denominator: 100); negatively framed natural frequencies (denominator: 100) for medicines option; descriptive words for PCI and CABG (small, low, and higher)	None	Fully: 9 Partially: 1 Not met: 2
PCI choice (two versions for either Class I/II or Class III Stable Angina[58,61])	Brief two-page paper 'Encounter PtDA' reviewed during consultation with HCP	Colour text, text boxes, colour icons. Development fully described.[59]	None	Two questions asking for preferred Tx	None	Side-by-side icon arrays (100 circles icons); natural frequencies (denominator: 100) with positive and negative framing	None	N/A
Should I have angioplasty for stable chest angina?[62]	Web-based pre-consultation. Delivery determined by distributor. In publication,[63] the link to the PtDA website was e-mailed to patients' pre-consultation.	Web: Text, drop-down boxes, pop-up boxes, tables, colour diagrams to explain procedure with real angiogram X-ray image. Clinical content review described on website. Option to download as pdf.	Rating scales: Four 7-point 'importance' Likert scales for three pre-set attributes and 1 open-box for patient to add other important attributes/values.	Two 7-point Likert scales to indicate preferred Tx and level of certainty with choice	Patient input: navigation between sections; three-item yes/no knowledge test; 3 yes/no questions about support and understanding, open-text box to add worries or questions. Generates personal summary of answers.	Side-by-side list; icon arrays (100 people icons); side-by-side natural frequencies (denominator: 100) with positive and negative framing for benefits; negative framing for PCI risks	Quotes from four fictional patients. Tx choice shown.	Fully: 9 Partially: 3 Not met: 0

EVC, explicit values clarification; HCP, healthcare professional; Tx, treatment
[a]Only paper version evaluated, web version unavailable.

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Table 3 Overview of studies

Study details	Study design	Methods, sample, and setting	Results	No. of SUNDAE items met
Studies reporting on the development, acceptability, and evaluation of PtDAs for aortic stenosis treatment options				
Brennan *et al.*,[35] 2020, USA	Multi-methods development study of risk calculator and PtDA for patients with AS (**ADVICE**[34])	Setting: Duke University Medical Center 1) Development of risk calculator: Patient survey (SAVR $n = 10$; TAVR $n = 10$); registry data review and questionnaire by 3 caregivers and 5 patients to identify patient characteristics to include in risk models. 2) Feedback on risk calculator: 4 rounds of semi-structured interviews with 6 TAVR and SAVR patients and caregivers. 3) SDM education resource development: multiple teleconference calls with a multi-disciplinary team including 7 patients and 3 caregivers to determine content. 4) Feedback on PtDA: Review by patient and caregiver stakeholders and semi-structured interviews with 6 patients scheduled for TAVR.	• Web-based and mobile risk calculator developed. Risk models included 1-year outcomes for mortality, stroke, discharge location and QoL • Patient and caregivers wanted risks to be presented in multiple ways (numeric and pictographs) and for a personalised interpretation of their data. Website readability scores: FRE: 60.93; FKGL: 7.02 • Web-based resource developed with links to the risk calculator but no longer accessible (website deactivated). • Feedback incorporated into resource. Website visits in 11 months: 2589 users. Average time on website: 1.5 min. 'Engaged users' $n = 817$.	Fully: 13 Partially: 3 Not met: 2 N/a: 8
Coylewright *et al.*,[20] 2020, USA	Single-centre non-randomized pre-test post-test pilot study with 3 patient groups: UC (no PtDA); cardiologist's 1st use of PtDA (**Severe Aortic Stenosis Decision Aid**;[43]) cardiologist's 5th use of PtDA	Setting: 2 TAVR centres in Northern New England 35 patients (56% female) with severe AS, at high or prohibitive surgical risk, for whom HCPs agree potential equipoise for TAVR and SAVR. UC: Each cardiologist ($n = 4$) or pair ($n = 1$) audio recorded a consultation without PtDA with 5 patients each (25 total). Patients' mean (SD) age: 85 (7.5) years; 75% achieved high-school education or greater. 1st use of PtDA: Each cardiologist/pair used the PtDA with 1 patient (5 total). Patients' mean (SD) age: 82 (10.5) years; 100% achieved high-school education or greater (1 missing response). 5th use of PtDA: Each cardiologist/pair's 5th time of using the PtDA with a patient ($n = 5$). Patients' mean (SD) age*: 93 (2.7) years; 80% achieved high-school education or greater.	• SURE score for decisional conflict: ↔ • Post-consultation knowledge: ↑ with PtDA* • OPTION score for SDM: ↑ with PtDA* • Patient satisfaction: ↑ with PtDA*	Full: 19 Partial: 4 No: 3 N/a: 0

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Table 3 *Continued*

Study details	Study design	Methods, sample, and setting	Results	No. of SUNDAE items met
Einfeld,[40] 2020, USA	Single-centre uncontrolled pre-post intervention (peer support and use of PtDAs in patients considering TAVR) pilot study with 1 patient group 2 PtDAs: **Treatment options for severe aortic stenosis- TAVI vs. Symptom Management**[39] and **Treatment options for severe aortic stenosis for patients deciding between TAVI and surgery**[41]	Setting: Community hospital in Pacific Northwest Patients with AS ($n = 12$; 63–89 years; 42% Female) eligible for TAVR participated in peer-support (Mended Hearts programme). TAVR PtDAs integrated into UC consultations.	• Preparation for Decision Making Scale (post PtDA use): All patients felt that the PtDAs were 'somewhat' to 'a great deal' helpful in preparing for decision-making. • 11 patients completed peer-support • GAD-7 score: 4 patients ↓ anxiety, 5 ↔, 2 patients ↑ • Perceived cardiac self-efficacy with CSE scale before and after peer support: ↑ in 58% patients	Full: 19 Partial: 3 Not: 4 N/a: 0
Valentine *et al.*,[42] 2022, USA	Single-centre pilot 1:1 RCT (PtDA vs. UC) of a PtDA delivered to patients with AS considering TAVR or SAVR PtDA: **Treatment options for severe aortic stenosis for patients deciding between TAVI and surgery**[41] Comparator: UC in-clinic discussion of treatment options, risks, and benefits, and an animation of the TAVR procedure. No written materials.	Setting: Massachusetts General Hospital, USA Patients ($n = 60$, 100% White) with mild or moderate AS being assessed for either TAVR or surgical SAVR were randomized to PtDA or UC group. PtDA ($n = 31$): mean age 74 (SD 6) years; 39% female; 89% achieved college education or greater. UC ($n = 28$): mean age 71 (SD 8) years; 25% female; 75% achieved college education or greater.	• SURE scale for decisional conflict: ↔ • Knowledge: ↑ with PtDA* • CollaboRATE score: ↑ with PtDA* • SDM process scale: ↔ • Treatment preference: ↔ • Treatment received: ↔ • Preference concordance: ↑ with PtDA (NS) • Informed patient-centred decision: ↑ with PtDA (NS) 68% reported reviewing all the PtDA	Full: 19 Partial: 2 Not: 4 N/a: 1
Studies reporting on the development, acceptability, and evaluation of PtDAs for chronic coronary artery disease treatment options				
Coylewright *et al.*,[59] 2012, USA	Multi-phase development and single-centre acceptability study of PtDA (**PCI Choice**[58,61]) for patients with stable CAD facing treatment with either OMT or PCI + OMT	Setting: Mayo clinic 1) Evidence review and synthesis. 3) Prototype PtDA developed by 2 HCPs plus designer. 4) Tested by Diabetes Research Advisory Group (15–20 community members with DM), and Cardiovascular Patient and Family Advisory Council (over 25 patients and family members) to develop first prototype. 5) Observed use in clinical setting with 25 patients. Revised PtDA over 1–2 weeks after each clinical observation.	• Evidence from clinical guidelines and trials informed the risk and benefit information in the PtDA • Encounter PtDA developed, to be used 'upstream' from PCI procedure itself • Preference for reduction in text and increased use of pictographs to illustrate risks and benefits of OMT and PCI	Fully: 13 Partially:5 Not met: 0 N/a: 8

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Table 3 *Continued*

Study details	Study design	Methods, sample, and setting	Results	No. of SUNDAE items met
Coylewright *et al.*,[60] 2016, USA	Single-centre, randomized controlled (1:1) trial of PtDA (**PCI Choice**[58,61]) vs. UC (no PtDA)	Setting: Mayo clinic 124 Patients with stable CAD considering OMT +/– PCI treatment randomized to PtDA or UC group. PtDA ($n = 65$): mean age 69 (SD 10.9) years; 28% female; 100% White; 65% achieved college education or greater UC ($n = 59$): mean age 68 (SD 10.2) years; 25% female; 98% White; 71% achieved college education or greater.	• Overall DCS: ↔ • Informed subscale of DCS: ↓ with PtDA (NS) • Knowledge: ↑ with PtDA* • OPTION Scale for SDM: ↔ • PtDA fidelity score: 70.9%. contamination (i.e. discussion of SDM items) occurred in UC (50.6%) but significantly fewer SDM items were discussed compared to PtDA consultations*	Full: 18 Partial: 5 No: 3 N/a: 0
Doll *et al.*,[56] 2019, USA	Two-part study: A) Single-centre prospective non-randomized controlled pre-post-test study of PtDA (**Coronary Artery Disease: What treatment would you prefer?**[55]) vs. UC (no PtDA, no treatment preferences) B) Pilot cluster randomized study embedded within above study	Setting: Duke University Hospital. A) 203 patients with chest pain, angina (acute and chronic) or NSTEMI, referred for diagnostic coronary angiography and considering treatment with either medical therapy, PCI or CABG, non-randomized to PtDA or UC group. UC ($n = 100$): median age (IQR) 64 (56–70) years; 34% female; 76% White; 63% achieved college education or greater; Health literacy** mean (SD) 2 (2.6). PtDA ($n = 103$): median age (IQR) 63 (55–72) years; 43% female; 71% White; 71% achieved college education or greater; Health literacy** mean (SD) 1.5 (2.1). B) 103 patients in PtDA group randomized 50:53 to preference group (cardiologist received patients' treatment preferences) or control group (preferences not shared).	• Overall DCS: ↔ • Informed subscale of DCS: ↓ with PtDA* • Values clarity subscale of DCS: ↓ with PtDA* • Knowledge: ↑ with PtDA* • Control Preferences Scale: ↑ sense of SDM with PtDA* • Treatment preference: ↔ • Treatment received and concordance with patient preference: ↔	Full: 13 Partial: 8 Not: 5 N/a: 0

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Table 3 *Continued*

Study details	Study design	Methods, sample, and setting	Results	No. of SUNDAE items met
Harris *et al.*,[54] 2022, UK	Multi-phase, multi-centre development and acceptability testing of a PtDA for people with stable angina considering elective coronary angioplasty treatment (**CONNECT**[54])	Setting: 2 District General Hospitals in Northern England. 34 patients and 29 HCPs in total involved in various stages 1) Steering Group convened, evidence review, and 3 co-design workshops with 4 cardiologists, 9 nurses, and 9 members of heart support groups. 2) Alpha-testing of prototype 1 (cognitive interviews and acceptability questionnaire) with 9 HCPs and 6 patients, 1 patient/partner dyad in non-clinical settings. Patient sample: mean age 63 (SD 11) years; 29% female; 85% achieved college education; 71% had adequate HL. 3) PtDA refined and prototype 2 developed following consultations with 10 service users, 7 HCPs and the Steering Group. Feedback on prototype 2 collated from 9 new volunteers from community heart support groups, 1 Steering Group lay member, and 2 consultant cardiologists.	• Web-based PtDA designed to be delivered at point of referral for PCI. Clinical evidence informed risks and benefits of treatment options. • Participants felt the PtDA was acceptable, usable, comprehensible, and desirable; has potential to facilitate SDM; and may improve patient safety via evaluation and communication of symptoms. Some cardiologists disagreed with the risk information content. • CONNECT prototype 2 achieved all 12 applicable mandatory qualifying and certification criteria of the IPDAS checklist. Preferences for risk presentation varied.	Full: 16 Partial: 2 Not: 0 N/a: 8
Hinsberg *et al.*,[63] 2018, USA	Single-centre randomized comparator pilot trial to compare effects of two PtDAs for stable angina. DVD/booklet PtDA: **Treatment Choices for Stable Chest Discomfort**[64] Web-based PtDA: **Should I Have Angioplasty for Stable Chest Angina?**[62]	Setting: Massachusetts General Hospital Heart Centre Patients ($n = 28$) who had recently made decisions about treatment of stable CAD were randomized to DVD/paper booklet PtDA or web-based PtDA. DVD/booklet PtDA ($n = 15$): mean age 73 (SD 11.6) years; 60% female; 100% White; 80% achieved college education or greater. Web-based PtDA ($n = 13$): mean age 67 (SD 10.62) years; 23% female; 92% White; 54% achieved college education or greater.	• Total knowledge scores: ↑ with DVD/booklet PtDA* • Treatment preference for PCI: ↑ with web-based PtDA (NS) • Patient satisfaction: ↑ with DVD/booklet PtDA (NS) • Viewed all the PtDA: ↑ with DVD/booklet PtDA (NS) • >20 min viewing the PtDA: ↑ with DVD/booklet PtDA ($P = 0.05$)	Full: 19 Partial: 4 Not: 2 N/a: 1

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Table 3 *Continued*

Study details	Study design	Methods, sample, and setting	Results	No. of SUNDAE items met
Scalia *et al.*,[51] 2018, USA	Cross-sectional observational study to evaluate whether Option Grid PtDAs change treatment preferences and which items of the PtDA are most important to users PtDA: **Angina treatment options Option Grid**[50]	Audit data collected from users of Option Grid PtDAs who had an account on the Option Grid website, over a 19-month period (June 2015 onwards). User responses in the PtDAs were collected from the top 5 most-used PtDAs. The Angina PtDA was accessed and fully completed by 88 users (47% female; 11% Hispanic, 46% not Hispanic, 43% ethnicity not stated; age range: 11% 20–30 years, 16% 31–40 years, 18% 41–50 years, 17% 51–60 years, 10% ≥60 years, 27% not stated).	For Angina treatment options: no significant preference shift between medical management and stenting; P = 0.200.	Full: 16 Partial: 6 Not: 2 N/a: 2

*Statistical significance (P < 0.05)

**Sum of scores on three-item questionnaire, max score, 12; lower values indicate higher health literacy.

↔: no change; ↑: higher value/score; ↓: lower value/score.

AS, aortic stenosis; CAD, coronary artery disease; CSE, cardiac self-efficacy; DAOH, days alive and out of hospital; DCS, decisional conflict scale; DM, diabetes mellitus; GAD-7, generalized anxiety disorder-7; IPDAS, International Patient Decision Aid Standards; NS, not significant (P > 0.05); OMT, optimal medical therapy; PCI, percutaneous coronary intervention; PtDA, patient decision aid; RCT, randomized controlled trial; SD, standard deviation; SDM, shared decision-making; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement; UC, usual care.

completion of questions about what matters to them and their concerns.[53] Five PtDAs invited patients to indicate their preferred treatment.[53,55,58,61,62] A personalized summary of patients' responses could be generated in two web-based PtDAs.[53,62] The readability level was not stated within any PtDA, although associated publications for two PtDAs reported the target reading age as eighth grade (age 13–14 years).[54,56] Development information was published, in varying detail, for some PtDAs,[53,55,58,61] two omitted this information,[49,57] whilst brief details about the development of clinical content were described for the remainder on the developers' websites.[62]

Quality of patient decision aids for coronary artery disease

Five PtDAs[49,53,55,57,62] were included for quality appraisal (two 'encounter PtDAs' were excluded[58,61]; *Table 2*). Three PtDAs[53,55,62] completely fulfilled the six IPDAS 'qualify' criteria (see Supplementary material online, *Table S10*). In total, the five PtDAs fulfilled between 42% and 100% (median 75%) of all 12 IPDAS criteria. Two PtDAs[53,62] fully or partially achieved all 12 IPDAS criteria but are not currently publicly available to patients. The IPDAS criteria least fulfilled across the PtDAs were 'providing information about the funding source', 'the updated policy', and 'the level of uncertainty around outcome probabilities'.

Overview of included studies

Table 3 provides an overview of the 10 studies included in the review (full details in Supplementary material online, *Table S1*). One study was conducted in the UK[54] and the remainder in the USA. Three reported on PtDA development and acceptability testing,[35,54,59] and seven evaluated PtDA effectiveness in either an RCT[42,60] or a quasi-experimental design.[20,40,51,56,63]

Studies reporting the development/acceptability of patient decision aids

One study[35] described the development of a PtDA for AS (TAVI vs. SAVR[34]) that is no longer available, and two studies[54,59] described the development and acceptability of PtDAs for chronic CAD (PCI vs. medicines only; PCI Choice[58,61] and CONNECT[53]). The systematic method of PtDA development recommended by IPDAS was implemented in the two CAD PtDA studies,[54,59] but only the CONNECT development study[54] cited a theory underpinning the methodology (i.e. Ottawa Decision Support Framework[65]). Patients and/or healthcare professionals were involved in either providing feedback or user testing PtDAs across all development studies.[35,54,59] Methods included semi-structured interviews,[35] cognitive interviews,[54] video and teleconference calls,[35,54] focus groups,[54,59] and observations.[59] Participant demographics were only reported in the CONNECT PtDA study, which was the only study that assessed health literacy levels with 71% of participants scoring 'adequate' on the Brief Health Literacy Screen.[54]

Studies evaluating the effectiveness of patient decision aids

Three AS PtDAs[39,41,43] and seven PtDAs for chronic CAD[50,55,58,61,62,64] were evaluated across seven studies.[20,40,42,51,56,60,63] Sample size ranged from 12 to 203 participants. Most participants were White and had an advanced level of education (i.e. completed college). A variety of decision-making processes and decisional quality outcomes were assessed, including, patient satisfaction, treatment preference, patient-centred communication, involvement in SDM, decisional conflict, and knowledge level. Two[20,56] out of four studies that measured the SDM process (via the OPTION Scale[66] or Control Preferences Scale[67]) showed a significant improvement after using a PtDA for AS (TAVI or symptom management/palliative care[43]) and CAD (PCI, medical therapy, or CABG[55]). High scores for patient satisfaction, patient-centred communication (measured using

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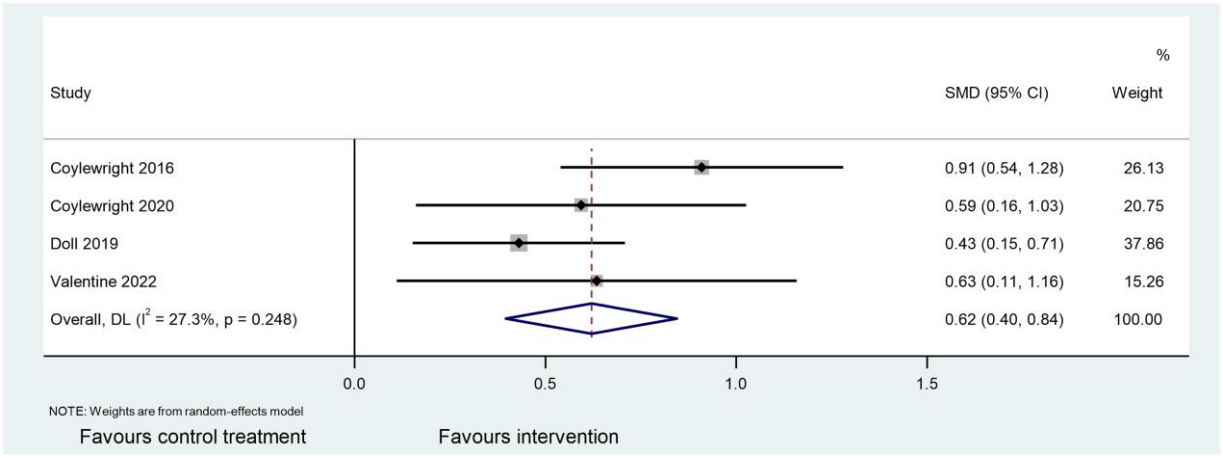

Figure 2 Forest plot for the meta-analysis of patient knowledge scores.

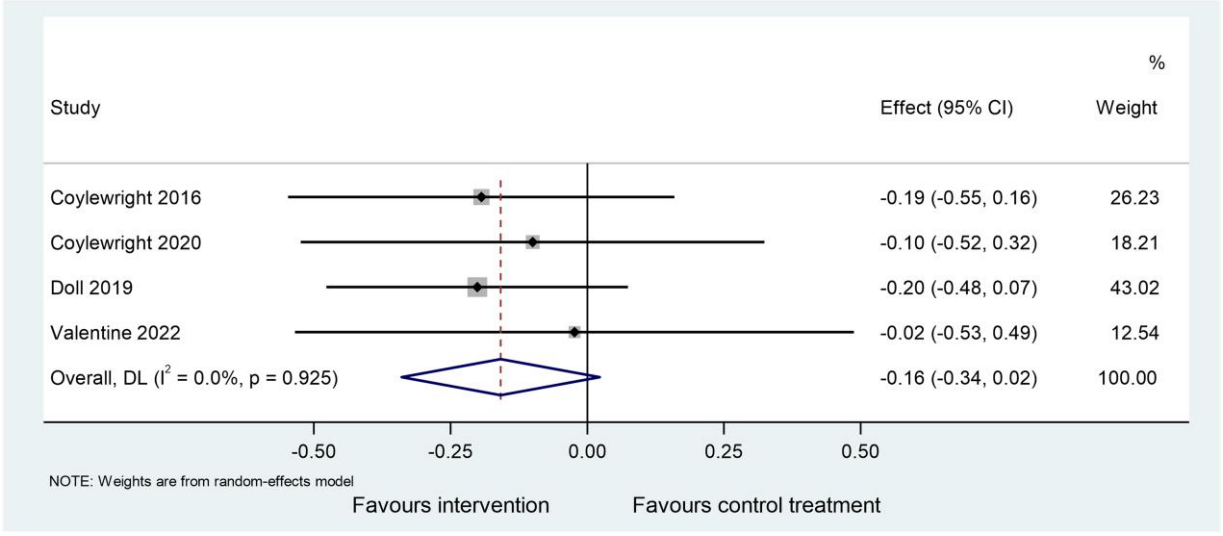

Figure 3 Forest plot for meta-analysis of decisional conflict scores.

CollaboRATE[68]), and the Preparation for Decision-making Scale[69] were reported after PtDA use for both AS and chronic CAD treatments.[20,40,42,63] Patients' treatment preference, treatment delivered, or treatment concordance with patient preferences did not significantly change in any study.[42,51,56] Cardiologists in two studies felt that they already performed SDM consistently and that PtDAs were poorly understood by patients and negatively impacted on consultations.[20,60] Most patients preferred a DVD- or booklet-formatted PtDAs than web-based formats.[56,63]

Quality of studies

The 26-item SUNDAE checklist was used to evaluate the quality of reporting for all included studies, with results summarized in *Table 3* (full evaluation in Supplementary material online, *Table S12*). Across the studies, between 50% and 89% (median 73%) of the SUNDAE criteria were completely fulfilled. Two of the three development studies either fully, or partially, satisfied all applicable SUNDAE.[54,59] No evaluation study achieved all 26 criteria. One criterion (Item 18) was only fully achieved by one study,[40] because the other six evaluation studies used a bespoke patient knowledge questionnaire, which had not undergone psychometric testing. Nine SUNDAE criteria were achieved by all studies. The criteria least consistently achieved were those related to the methods and results sections (e.g. 'description of the development process', 'PtDA fidelity', 'process evaluation', and 'theories/models used to guide the study design and selection of evaluation measures').

Meta-analyses

All six evaluation studies were assessed for inclusion in meta-analyses. Usable post-test data for patient knowledge and decisional conflict scores were obtained from four studies, with a total sample of 476 participants,[20,42,56,60] evaluating two PtDAs for AS[39,41] and three for

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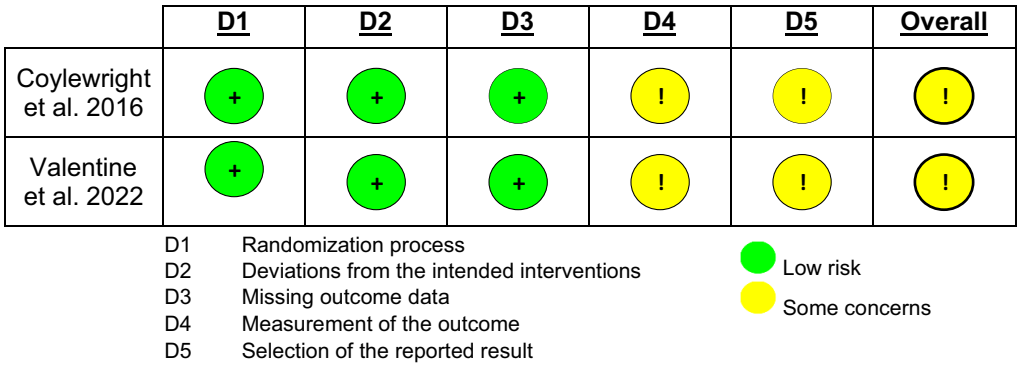

Figure 4 Risk of bias summary using the Cochrane RoB2 tool.

chronic CAD.[55,58,61] Variation in the PtDAs and the patient groups across the four studies necessitated the use of standardized measures in the meta-analyses. Leave-one-out sensitivity analyses revealed no individual study to be exerting excessive influence on either meta-analysis (see Supplementary material online).

Patient knowledge

Patient knowledge of treatment options was significantly greater in the PtDA groups compared with usual care in all four studies.[20,42,56,60] The meta-analysis determined that the synthesized estimate of the standardized mean difference in knowledge scores (PtDA—usual care) was 0.620 (95% CI 0.396–0.845), favouring the PtDA over usual care groups. A *Z*-test of the standardized mean effect indicated strong evidence at the 5% significance level for a non-zero effect ($Z = 5.42$; $P < 0.001$). Cochran's χ^2 test for heterogeneity indicated no evidence for statistical heterogeneity ($\chi^2_{(3)} = 4.12$; $P = 0.248$). The I^2 statistic was 27.3%, which may indicate low levels of heterogeneity. Data are summarized in *Figure 2*.

Decisional conflict

Decisional conflict (measured by the validated SURE score[70] or Decisional Conflict Scale[71]) was not significantly different between PtDA and usual care groups in all four studies.[20,42,56,60] However, the 'informed' subscale of the Decisional Conflict Scale score was significantly lower (i.e. favourable) in the PtDA groups compared with usual care.[56,60] The meta-analysis determined that the synthesized estimate of the standardized mean difference in decisional conflict (PtDA—usual care) was −0.159 (95% CI −0.339 to 0.022). A *Z*-test of the standardized mean effect revealed no evidence for a non-zero effect ($Z = -1.717$; $P = 0.086$). Cochran's χ^2 test for heterogeneity indicated no evidence for statistical heterogeneity ($\chi^2_{(3)} = 0.47$; $P = 0.925$). The I^2 statistic was 0.00%, indicating that heterogeneity might not be important. Data are summarized in *Figure 3*.

Risk of bias

The RoB2 tool[32] was used to evaluate potential bias in the two randomized controlled studies[42,60] with results indicating 'some concerns' (*Figure 4*). The two non-randomized studies[20,56] were evaluated using the NHLBI Quality Assessment of Controlled Intervention Studies and were rated as 'fair quality', indicating susceptibility to 'some bias'.[33]

Discussion

Patient decision aids are evidence-based tools known to be effective in improving the quality of SDM to help patients receive care that is 'right' for them. Patients who use PtDAs are more knowledgeable, informed, and involved, have more accurate risk perceptions, and are more confident in their treatment decision and clearer about their health goals and treatment preferences.[18] This benefits patients because those who are more active in making treatment decisions tend to have better health outcomes and are more satisfied with their care.[72] Within cardiology, many patients with AS and chronic CAD have unresolved decisional needs and require support when considering treatment with TAVI and planned PCI, respectively.[14–17] Patient decision aids offer a potential solution but cardiology teams' lack of awareness of available high-quality PtDAs is a barrier to implementation.[21]

To the best of our knowledge, this review makes a useful contribution to the research literature as the first study to systematically identify and evaluate the availability, characteristics, and quality of PtDAs used to support SDM for AS and chronic CAD. We also report on the effectiveness of TAVI PtDAs to improve decisional quality, which extends an existing meta-analysis on SDM in cardiology settings that did not include this common interventional procedure.[22] These findings, combined with our narrative summary of PtDA evaluation and development studies, provide a comprehensive international overview of AS and CAD PtDAs to inform cardiology practice.

Patient decision aid availability and quality

Our findings on the availability of PtDAs (*Table 1*) provide a valuable reference for cardiology teams and make an important contribution to the international literature. For the first time, internationally accepted quality criteria were used to evaluate the quality of AS and CAD PtDAs. We identified 21 PtDAs, but only one AS[41] and one CAD PtDA[49] were less than 5 years old and currently publicly available for patient distribution. However, only the AS PtDA was rated as high-quality having fulfilled all quality criteria. Given that SDM is recommended in clinical guidelines and health policy,[5,6,9,10] this lack of publicly available high-quality AS and CAD PtDAs is a significant finding that has not previously been reported. Overall, PtDAs scored poorly on criteria that address potentially harmful bias, which is consistent with reviews of cancer PtDAs.[23] This highlights that information concerning the uncertainty of treatment options, funding sources and updated policies, requires improvement. Doctors may be reluctant to discuss uncertainties around treatment outcomes, as they believe this will be viewed as incompetence[73] and will reduce patient trust and satisfaction with care.[74] Yet, from a patient perspective, higher levels of trust in

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cardiologists are associated with feeling listened to and involved in decisions about their health and treatments.[75] Having an open and honest dialogue is valued by heart disease patients.[76] Increasing cardiology teams' awareness about patients' communication preferences and additional SDM skills may improve this important element of SDM.[77]

Patient decision aid accessibility

The PtDAs identified in this review had different designs, formats, and delivery approaches. There was a lack of consensus about the optimum characteristics for AS and CAD PtDAs. Potentially, this might be because patients' and cardiology teams' preferences varied; a view confirmed in this review.[54,56,63] A recent meta-analysis reported that the PtDA format (e.g. paper, computer, and web based) had no impact on effectiveness for improving SDM in cardiology settings.[22] Our results corroborate this finding; patient knowledge and some aspects of the SDM process (patient perception of SDM and integration of SDM in consultations) were significantly improved in two studies despite using PtDAs with different formats[20,56]: a printed one-page within-consultation 'encounter PtDA' for AS[43] and a web-based pre-consultation PtDA for CAD.[55] This suggests that a paper-based PtDA may be as effective as a more sophisticated digital version. However, additional research is required to corroborate this finding given the paucity of studies. We suggest that paper versions of PtDAs could be made routinely available, as a minimum, to support SDM for two reasons. First, 6–7% of adults in the USA[78] and the UK[79] have never used the internet. Second, it is recognized that the introduction of digital interventions can potentially widen health inequalities.[80]

The overall quality of reporting, in both AS and CAD PtDA development and evaluation studies, was good, according to the recommended SUNDAE criteria. The aims, rationale, explanation of the PtDA and study methods, and implications for practice and research were comprehensively described in most studies. However, most studies did not measure PtDA fidelity or explore potential mechanisms for their effect on decision outcomes. The demographics of patients involved in the development and/or evaluation studies were either unknown,[35,59] under-reported,[40,51] or predominantly White, English-speaking people educated to high school level or higher.[20,42,54,56,60,63] Furthermore, readability levels were not reported in any PtDA, although the target reading age for two CAD PtDAs was reported as 13–14 years in associated publications.[54,56] These findings are significant because it is unclear how relevant and accessible existing AS and CAD PtDAs are for under-represented populations, which makes it challenging for cardiology teams to evaluate their appropriateness and usefulness within their clinical setting. Since patient–healthcare professional communication has the potential to reduce or increase health disparities,[81] it is important that the development and testing of PtDAs involve patients from diverse backgrounds.

Comparisons with other meta-analyses

Our meta-analyses found significantly improved levels of patient knowledge following the use of two AS PtDAs[39,41] and three CAD PtDAs,[55,58,61] compared with usual care. This finding is consistent with a recent meta-analysis of cardiology PtDAs.[22] However, our meta-analysis found no significant difference in decisional conflict between PtDA and usual care groups, in contrast to other reviews.[18,22] There are several potential explanations for this finding. The five PtDAs[41,43,55,58,61] evaluated may have limited function in eliciting preferences. Decisional conflict may have already been low in participants at baseline and/or in usual care groups[7,47,64,75] or the measure may have a ceiling effect. Another explanation relates to educational attainment. A large proportion of participants across the four studies had achieved a high-school education level or higher, which is known to be associated with lower decisional conflict.[82]

Although not included in our meta-analysis due to heterogeneity of study designs, outcome measures indicating the quality of the decision-making process were significantly greater following the use of PtDAs across some[20,40,42,56,63] but not all studies,[51,60] and no negative outcomes were reported. The inconsistent findings might be explained by differences are study designs, outcomes, measurement instruments, and the PtDAs themselves. Given the wide variety of measures used to evaluate the quality of SDM, consensus on the most appropriate is recommended.

Implementation of patient decision aids in clinical practice

None of the PtDAs were evaluated in a large-scale randomized controlled trial that appeared to be sufficiently powered with a low risk of bias, possibly due to difficulties with recruitment and/or PtDA implementation. Several factors influence the successful implementation of PtDAs; a PtDA that is too complex or competes with existing practice is unlikely to be used.[77] Involvement and commitment from senior leadership and the clinical teams are an enabler to the use of PtDAs as is the engagement of the family and significant others.[77] Successful strategies to integrate PtDAs into clinical settings include training the entire cardiology team, linking PtDA outcomes with organizational priorities, proactively encouraging patients to engage with the PtDA, and reflecting on existing pathways to identify opportunities for PtDA use and SDM conversations.[77] The latter strategy could be particularly useful for elective PCI where the timing of PtDA delivery is challenging because diagnosis and treatment often occur together in the same procedure.[83] Providing PtDAs and seeking patients' treatment preferences and goals earlier in the severe AS pathway should be considered.[13]

Strengths and limitations

We comprehensively and systematically searched multiple databases, trial registers, and 30 online sources to identify AS and CAD PtDAs and their development and evaluation studies. However, we may not have identified all eligible PtDAs and six were not available so an evaluation of their characteristics and quality was not possible. The wide range of measurement instruments used to evaluate the quality of SDM limited the number of meta-analyses conducted and made cross study comparisons challenging. Nevertheless, this review provides a high-quality international review of AS and CAD PtDAs.

Conclusions

A diverse range of AS and CAD PtDAs has been developed over the past 16 years, but few are up to date and currently available. To increase the transparency around PtDA quality and effectiveness, information about the uncertainty of treatment outcomes, funding sources and future updates should be added. The 'voice' of underserved populations and those with low health literacy levels is needed in the development or evaluation of PtDAs as to date, this has been lacking. Paper-based versions of digital PtDAs should be available to avoid widening health inequalities associated with the digital divide. We recommend that cardiology teams use the most up-to-date and highest-quality PtDAs available. We concluded that patients who use PtDAs when considering treatments for AS or chronic CAD are likely to be better informed than those who do not.

Supplementary material

Supplementary material is available at *European Journal of Cardiovascular Nursing* online.

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Author contributions

E.H., F.A., and D.C.: conceptualization; E.H. and F.A.: methodology; E.H. and J.S.: formal analysis; E.H., F.A., A.B., D.C., A.-Y.C., and H.C.: investigation; E.H.: project administration; E.H., F.A., and J.S.: visualization; E.H., F.A., and J.S.: writing—original draft; and E.H., F.A., A.B., J.S., D.C., A.-Y.C., and H.C.: writing—review & editing.

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Data availability

The data underlying this review are available in the article and in its online supplementary material.

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