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Patient values and preferences on valve replacement for aortic stenosis: a systematic review

Anja Fog Heen ,[1] Lyubov Lytvyn,[2] Michael Shapiro,[3] Gordon Henry Guyatt,[2] Reed Alexander Cunningham Siemieniuk,[2] Yuan Zhang,[2] Veena Manja,[4,5] Per Olav Vandvik,[6] Thomas Agoritsas[2,7]

ABSTRACT

The review aims to summarise evidence addressing patients' values, preferences and practical issues on deciding between transcatheter aortic valve insertion (TAVI) and surgical aortic valve replacement (SAVR) for aortic stenosis. We searched databases and grey literature until June 2020. We included studies of adults with aortic stenosis eliciting values and preferences about treatment, excluding medical management or palliative care. Qualitative findings were synthesised using thematic analysis, and quantitative findings were narratively described. Evidence certainty was assessed using CERQual (Confidence in the Evidence from Reviews of Qualitative Research) and GRADE (Grading of Recommendations Assessment, Development and Evaluation). We included eight studies. Findings ranged from low to very low certainty. Most studies only addressed TAVI. Studies addressing both TAVI and SAVR reported on factors affecting patients' decision-making along with treatment effectiveness, instead of trade-offs between procedures. Willingness to accept risk varied considerably. To improve their health status, participants were willing to accept higher mortality risk than current evidence suggests for either procedure. No study explicitly addressed valve reintervention, and one study reported variability in willingness to accept shorter duration of known effectiveness of TAVI compared with SAVR. The most common themes were desire for symptom relief and improved function. Participants preferred minimally invasive procedures with shorter hospital stay and recovery. The current body of evidence on patients' values, preferences and practical issues related to aortic stenosis management is of suboptimal rigour and reports widely disparate results regarding patients' perceptions. These findings emphasise the need for higher quality studies to inform clinical practice guidelines and the central importance of shared decision-making to individualise care fitted to each patient.

INTRODUCTION

Severe aortic stenosis is a common valvular disease occurring among approximately 3% of people over 75 years old that results in significant morbidity and mortality.[1] With increasing severity of stenosis, patients often experience chest pain, syncope and heart failure.[2] Treatment options include surgical aortic valve replacement (SAVR) or a minimally invasive approach, transcatheter aortic valve insertion (TAVI). Benefits of TAVI include shorter hospital stay and quicker recovery; however, long-term outcome data are scarce but emerging.[3]

In 2016 a BMJ Rapid Recommendations guideline (BMJ RapidRecs) was published regarding the choice of TAVI versus SAVR for patients with aortic stenosis at low to intermediate surgical risk.[4] To inform the guideline, a systematic review addressing patient values and preferences was conducted.[5] Since 2016, new trials with longer follow-up have been published,[6 7] requiring updated evidence synthesis and guidance. This article is an update of the previous review of patient values and preferences about TAVI versus SAVR.[5]

METHODS

We followed the MOOSE (Meta-analyses Of Observational Studies in Epidemiology) checklist (online supplemental appendix 1). The protocol was registered at PROSPERO (International Prospective Register of Systematic Reviews) (CRD42016041907).

Search strategy

We searched MEDLINE, EMBASE and PsycINFO via OVID, using a combination of keywords and subject headings for 'aortic stenosis' and 'valve replacement', as well as a validated methodological search filter for values and preferences studies.[8] We updated the previous search until 16 June 2020 (online supplemental appendix 2), without language or publication status restrictions. We searched for grey literature via relevant conference abstracts, theses and dissertations (using the keywords 'aortic stenosis' and 'preference' or 'experience'), and the reference lists of eligible studies.

Study selection

We included studies with participants ≥18 years with aortic stenosis whose values and preferences related to the decision to undergo TAVI or SAVR were elicited. We considered values and preferences as 'the relative importance patients placed on the outcomes' for treatment decisions.[9] We excluded studies not reporting original data, case reports, studies reporting health-related quality of life before and after treatment, and studies that transformed quality of life measures into utility values, because quality of life was assessed in the associated systematic review of treatment effectiveness informing the BMJ RapidRecs.[3] Our initial review[5] did not include studies reporting values and preferences focused solely on medical management or

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[1]Department of Medicine, Innlandet Hospital Trust Gjøvik Hospital, Brumunddal, Norway
[2]Department of Health Research Methods, Evidence, and Impact, McMaster University Faculty of Health Sciences, Hamilton, Ontario, Canada
[3]Chicago, Illinois, USA
[4]Department of Surgery, University of California Davis, Sacramento, California, USA
[5]Department of Medicine, Veterans Affairs Northern California Health Care System, Mather, California, USA
[6]Institute of Health and Society, University of Oslo, Oslo, Norway
[7]Division of General Internal Medicine, Department of Medicine, University Hospitals of Geneva, Geneva, Switzerland

Correspondence to
Dr Anja Fog Heen, Dept. of Medicine, Innlandet Hospital Trust Gjøvik Hospital, 2819 Gjøvik, Norway; anjaheen@gmail.com

AFH and LL contributed equally.

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palliative care of aortic stenosis. We therefore did not include them in this update and focused solely on TAVI and SAVR.

Data collection and synthesis

Two authors (AFH, LL) independently screened titles and abstracts using prespecified criteria after conducting calibration exercises. The authors reviewed full-text articles independently and in duplicate and resolved disagreements by discussion or consultation with a third reviewer (TA). We contacted the authors of two abstracts that were ultimately excluded and corresponded with two authors of included studies for further information.

Two reviewers (AFH, LL) independently abstracted participant demographics, clinical characteristics, methods and findings. We conducted thematic analysis on qualitative results,[10] coding and synthesising primary quotations from study participants and author-reported summaries and themes. Across eligible studies, we also abstracted patient-important practical issues (ie, how a treatment can affect patients' daily life) related to decisions to undergo treatment and categorised findings using a developed generic framework, described elsewhere.[11] The review authors resolved disagreements through discussion or by consulting a third party (TA).

Quality assessment

For studies reporting qualitative outcomes, we assessed study quality using the qualitative research checklist of the Critical Appraisal Skills Programme.[12] For studies reporting quantitative outcomes, we assessed risk of bias using the instrument developed by Zhang *et al*,[13] appraising the following domains: study population, measurement and data analysis.

Certainty of evidence

Beyond quality assessments of each study, we assessed the overall certainty of evidence using Grading of Recommendations Assessment, Development and Evaluation (GRADE) for quantitative findings[13 14] and Confidence in the Evidence from Reviews of Qualitative Research (CERQual) for qualitative findings.[15] We rated certainty of evidence as high, moderate, low or very low for each finding. Findings started at high certainty and rated them down if there were concerns in one or more domains.[16] For CERQual, certainty could be rated down for methodological limitations, coherence, adequacy and relevance.[15] For GRADE, certainty could be rated down for risk of bias, inconsistency, indirectness, imprecision and publication bias.[13 14]

Incorporation into BMJ RapidRecs

The BMJ RapidRecs are developed in a collaboration between the not-for-profit MAGIC Evidence Ecosystem Foundation[17] and The BMJ.[18] Recommendations and associated reviews are updated given potentially practice-changing new evidence,[4] and this update is part of this process. Findings will be appraised by an independent guideline panel, without conflict of interests, including patient partners, front-line clinicians and methodologists working together to translate emerging research to user-friendly and trustworthy recommendations, evidence summaries and tools for shared decision-making.[4 19]

RESULTS

We identified 1230 unique titles and abstracts and reviewed 51 in full text (figure 1). Eight studies, reported in ten articles, were deemed eligible, with new six studies since the original review.[20–25] Study findings are described narratively and include exemplar quotes from patients in the primary studies when available. Quantitative results are presented in table 1. Further details of the qualitative results are reported in online supplemental appendix table 5.

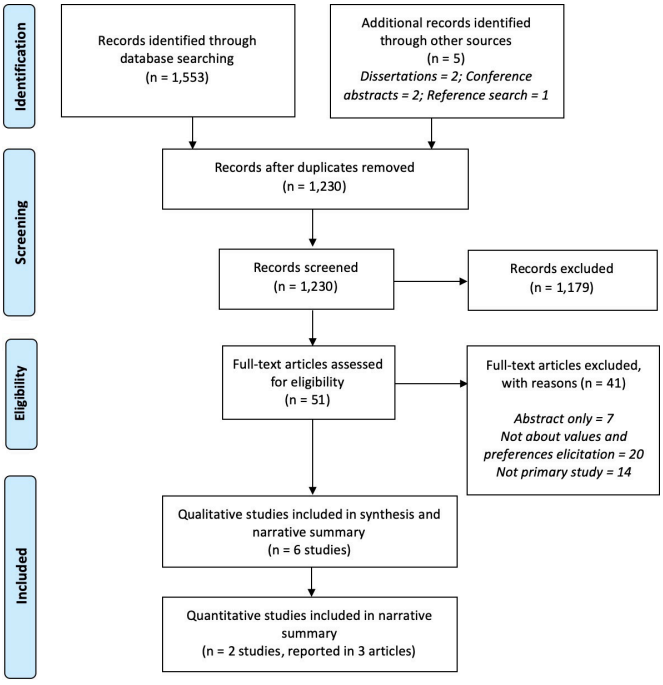

Figure 1 PRISMA study flow diagram. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Study characteristics

Studies were conducted in Canada, Norway, Sweden and USA (table 2). Of the quantitative studies, the sample sizes were 219[25] and 439.[26] Of the qualitative studies, one study included 333 participants,[20] while the others ranged from 10 to 46 participants.[21–24 27] Authors' conflicts of interest and study funding were variably reported. Two studies reported funding from a TAVI valve manufacturer (online supplemental appendix table 2).[20 25] All but one study included participants with confirmed severe aortic stenosis,[20–24 26 27] and the remaining included participants with self-reported diagnosis without specifying severity.[25] Participants were balanced in sex and were on average between 75 and 86 years old, except one study with 26% of participants aged 19–59 years old.[25] Surgical risk was variable across studies,[21 23 24 26 27] unknown or unspecified.[20 22 25]

Study quality and certainty of evidence

Most of the qualitative studies had methodological limitations,[20–22 24 27] the most common issues being inappropriate or unclear sampling and recruitment strategy, limited description of data analysis and strategies to enhance study rigour (online supplemental appendix table 3). For the quantitative studies, there were limitations in almost all domains, with the most concern being about participant selection, outcome presentation and data analysis (online supplemental appendix table 4). The certainty of findings ranged from low to very low (table 1, online supplemental appendix 1). The majority of studies assessed values and preferences on one intervention alone.

Table 1 GRADE summary of findings

Health state/outcome **(timeframe)**	Study design **(n=participants)**	Estimate of effect, **mean (SD) unless otherwise stated**	Certainty of evidence	Interpretation of finding
Mortality (30 days)	Adaptive swing weighting (109*)	Maximum acceptable increase in risk in exchange from SAVR to TAVI =3.7% (3.0)†.	Very low§¶**	The risk willingness of trading a reduction in mortality risk (30 days) for a less invasive procedure was uncertain and highly variable.
Mortality and aortic stenosis-related symptoms and concerns (lifetime)	Standard gamble (429)	Median risk willingness=25% (IQR 25%–50%). No risk (0%)=104 (23%). Low risk (0%–8%)=26 (6%). High risk (>8%–50%)=224 (51%). Prohibitive risk (>50%–95%)=68 (15%). 95%–100%=17 (4%).	Low§¶	The risk willingness of trading a reduction in mortality risk for full health with the procedure is highly variable among participants and across risk groups.
Disabling non-fatal stroke (30 days)	Adaptive swing weighting (110*)	Maximum acceptable increase in risk in exchange from SAVR to TAVI=6.7% (5.7)†.	Very low§¶**	The risk willingness of trading a reduction in risk of disabling stroke for a less invasive procedure was uncertain and highly variable.
Independence (30 days)	Adaptive swing weighting (131*)	Maximum acceptable reduction in benefit in exchange from SAVR to TAVI=13.9% (11.8)†.	Very low§¶**	The risk willingness of trading an increase of independence for a less invasive procedure was uncertain and highly variable.
Requirement for dialysis (1 year)	Adaptive swing weighting (132*)	Maximum acceptable increase in risk in exchange from SAVR to TAVI=6.2% (5.6)†.	Very low§¶**	The risk willingness of trading a reduction in the requirement for dialysis at 1 year for a less invasive procedure was uncertain and highly variable.
New permanent pacemaker (1 year)	Adaptive swing weighting (131*)	Maximum acceptable increase in risk in exchange from SAVR to TAVI=7.0% (5.7)‡.	Very low§¶**	The risk willingness of trading a reduction in permanent pacemaker insertion for a less invasive procedure was uncertain and highly variable.
Time over which the procedure has been proven to work	Adaptive swing weighting (131*)	Maximum acceptable decrease in duration that the procedure is known to work in exchange from SAVR to TAVI=17.4 years (16.9)‡.	Very low§¶**	The risk willingness of trading the expected duration or a new valve for a less invasive procedure was uncertain and highly variable.

*The total sample size was 219 participants, but they were not presented with all outcomes.
†Minimum acceptable reduction in benefit in exchange for reducing procedure invasiveness from 'invasive' to 'minimally invasive'.
‡Maximum acceptable increase in risk in exchange for reducing procedure invasiveness from 'invasive' to 'minimally invasive'.
§Serious risk of bias.
¶Serious imprecision.
**Serious indirectness.
GRADE, Grading of Recommendations Assessment, Development and Evaluation; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve insertion.

Values and preferences regarding outcomes of treatment

None of the studies presented participants' values and preferences based on a comprehensive assessment of the beneficial and adverse outcomes related to SAVR versus TAVI, nor did any studies report patient preferences about choosing between TAVI versus SAVR. Instead, studies focused on preferences about a selection of attributes in isolation. None of the studies addressed the lifelong management of treatment of valve failure.

Durability and valve reintervention

No study directly addressed how participants valued valve failure nor the risk and timing of reintervention. One study provided very low certainty of evidence regarding preferences about durability, illustrating considerable variability in patients' willingness to accept a shorter duration of the effectiveness of TAVI compared with SAVR.[25] A subgroup analysis suggested this variability may be partly explained by the fact that participants under 60 years old were more concerned with valve duration than those over 60.[25]

Mortality and risk willingness related to the decision to undergo treatment

All studies addressed mortality.[20–23 26 27] Studies did not explicitly distinguish between perioperative mortality, mortality from natural progression of disease or all-cause mortality. Participants viewed declining treatment to be worse than accepting the risk related to the procedure,[23] and thus were commonly willing to accept a high perioperative mortality risk. The importance of mortality can be illustrated by the following participant quote:

> And if I would have turned it [TAVI assessment] down, I mean, who knows how long I would last? Not much longer, probably, you know.[27]

Risk willingness varied considerably.[26] Overall, participants were willing to accept a higher mortality risk than current evidence suggests for TAVI, regardless of the fact that actual mortality risk is lower with TAVI than SAVR.[6 7 25]

For some participants, increasing life expectancy was more commonly a preference expressed by their families than by themselves,[23 24] as exemplified by the following quote:

> We did not discuss it too much the physician and I either. (…) He just asked if I wanted (the treatment) and I accepted. (…) I did it for the others' sake as well.[23]

Quality of life as reasons to undergo treatment

All but one study[26] reported improvements in health-related quality of life domains (eg, physical function, emotional well-being) as reasons to undergo treatment.[20 21 23–25 27] Common themes were desire for symptom relief and improved function. Respondents often described improved quality of life as the ability to do a specific activity, to regain or maintain independence,[21–24 27] to return to activities they had given up and to reconnect with their social network.[27] A participant's perspective was:

> We belong to a walking club […], but I've quit that in the last probably 3 or 4 months because I just couldn't keep up with them. They'd go and I said, "Well, I'll go half way" and they still got back before I did, so I said, "I guess I'll quit because it just hinders you guys."[27]

The desire to achieve the best possible health was closely intertwined with participants' ability to fulfil obligations towards family and friends and day-to-day activities when deciding on treatment.[20 21 23 24 27] Participants expressed not wanting to be a burden to relatives.[20 23 27] A participant noted the effect of their declining health on their partner, expressing:

> And this is passed on to my wife, of course. If I can't take [wife] to dance, she doesn't get to go either, you know what I mean?[27]

Concerns of pain

Pain was a concern with SAVR. One participant stated:

> Quite a bit of pain in the chest area, having your chest cracked open.[22]

Table 2 Study and participant demographics

Study	Country	Study design	Sample size	Patient population	Previous TAVI/SAVR	Age (years), mean (SD)	Sex (male), n (%)	Surgical risk STS score, median (IQR)	Heart failure symptoms NYHA class*, n (%)	Quality of life, symptoms, function, n
Quantitative studies										
Marsh *et al*[34]	USA	Adapted swing weighting	219†	Self-reported aortic stenosis; received treatment within 10 years or experiencing limitations in their physical activity due to aortic stenosis.	Undergone aortic stenosis treatment (unspecified)=80.4%	19–39=26.5%; 40–59=33.8%; 60–74=25.1%; 75–89=13.2%; 90+=1.4%	91 (41.6)	NR	Class I=78 (35.6%); class II=101 (46.1%); class III=40 (18.3%)	General health (past week): very good=55; good=85; fair=65; poor=13; very poor=1
Hussain *et al*[26]	Norway	Standard gamble	439	Severe aortic stenosis; referred for aortic valve treatment.	NR	75 (11)	264 (60)	11.9% (7.50%–17.10%)	Class I=11 (13%); class II=43 (50%); class III/IV=46 (53%)‡	SF-36§¶ physical component score=38 (10); mental component score=49 (10)
Qualitative studies										
Coylewright *et al*[24]	USA	Interview	46	Severe aortic stenosis; assessed for aortic valve treatment.	NR	68–74=5; 75–89=29; 90+=12	25 (54.3)	9% (4.9%)§	NR	KCCQ-12¶** 36 (4–76)
Olsson *et al*[21]	Sweden	Interview	24	Severe aortic stenosis.	NR	80.7 (7.4)	15 (62.5)	NR	Class III=11 (46%); class IV=13 (54%)	NR
Skaar *et al*[23]	Norway	Interview	10	Severe aortic stenosis.	NR	70–79=3; 80–89=7	4 (40)	Logistic EuroSCORE <10=2; 10–20=7; >20=1	Class I=1 (10%); class II=7 (70%); class III=2 (20%)	SPPB fit=3; intermediate=6; frail=1
Lauck *et al*[27]	Canada	Interview	15	Severe symptomatic aortic stenosis.	Undergone cardiac surgery (unspecified)=6	86 (75–92)††	9 (60)	6.4% (2.6%–16.3%)	Class II=11 (73%), *others not specified*	All but one participant were able to complete all activities of daily living.
Ontario Health Technology Assessment Series[22]	Canada	Interview	10	Aortic stenosis.	Undergone TAVI=9, undergone SAVR=1	NR	NR	NR	NR	NR
Frank *et al*/Styra *et al*[20 35]	Canada	Interview	333	Patients with aortic stenosis considering treatment options.	None	80.5 (52–97)††	181 (54.5)	NR	NR	NR

*NYHA class I=no symptoms and no limitation in ordinary physical activity; class II=mild symptoms and slight limitation during ordinary activity; class III=marked limitation in activity due to symptoms, even during less than ordinary activity, comfortable only at rest; class IV=severe limitations, experiences symptoms even while at rest, mostly bedbound patients.
†Baseline variables reported for 219 participants, but outcome data are for 109–132 participants (ie, not all participants were asked about all outcomes).
‡NYHA classification only reported for 86 of 439 participants. Class III and IV grouped together but only 2% were class IV.
§Mean, SD.
¶Maximum score=100.
**Median, range.
††Mean, range.
KCCQ-12, Kansas City Cardiomyopathy Questionnaire; NR, not reported; NYHA, New York Heart Association; SAVR, surgical aortic valve replacement; SF-36, Short-Form 36; SPPB, Short Physical Performance Battery; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve insertion.

Those who had TAVI described minimal pain, with a participant saying:

> And I didn't have any pain afterwards at all. I didn't even know that I'd had incisions in my groin. I just didn't know it was there. It was amazing.[22]

Acute kidney injury and stroke

Two studies addressed acute kidney injury.[24 25] One addressed the possibility of dialysis as a patient concern related to potential TAVI complications.[24] The other study provided evidence regarding patients' willingness to accept the risk of needing dialysis within 1 year after the procedure.[25] Patients in one study frequently expressed that they were afraid of the possibility of a stroke.[21]

Practical issues related to valve replacement

Several studies addressed participants' concerns regarding practical issues, such as invasiveness, length of hospital stay and recovery time.[21 22 25] Regarding TAVI, one participant stated:

> It's easy by comparison to an open-heart surgery. That is just a big plus. Can you imagine having your chest cut right open and taking months to recover?[27]

Overall, patients reported the longer hospital stay and recovery time with SAVR, compared with TAVI, as a major concern.[22] None of the studies mentioned the need for—and accessibility to—cardiac rehabilitation after SAVR or TAVI.

Decision-making process and support

Respondents perceived physicians as essential sources of information and decision-making guidance and as facilitators of referral for TAVI, and participants stressed the importance of a trusting relationship with their physician(s).[21 23] The experience of receiving rigorous advice from their physician was important in decision-making, illustrated by the following participant quote:

> When I'm with my doctor, I believe he is competent enough just to see what my problem is and how it can be treated.[27]

A number of studies, however, reported the possibility that physicians might not act in a trustworthy way, which motivated participants to seek a second opinion.[21 23 27] Overall, participants took into account a variety of medical, functional and social factors in their decision-making.[20–24 27]

Accessibility and cost of the procedure

Participants who lived away from hospitals that offered the procedure reported greater difficulty accessing TAVI.[22] Several studies reported participants' concern about burden of personal cost due to travel, meals and accommodation,[22 27] exemplified by the following participant quote:

> My family wanted to be there when I had the surgery, so there was … overnight accommodation … and meals, and so on. And someone to help with the driving … It was basically … personal expenses.[22]

Given the expected shorter length of hospital stay with TAVI, some patients perceived these costs to be much lower than with SAVR.[22]

DISCUSSION

Our search identified eight studies that examined patients' values, preferences and practical issues related to aortic stenosis treatment.[20–25] They provided limited evidence regarding how participants explicitly value and balance benefits and harms associated with TAVI and SAVR.[20–27] Most studies addressed only TAVI, and those that addressed both TAVI and SAVR did not specify the information they had provided to participants about the relative merits and burdens of the two procedures. Study participants were concerned about treatment complications, and willingness to accept procedural risk varied considerably. Participants of the qualitative studies rarely reported perspectives regarding specific outcomes (eg, stroke), but rather highlighted and valued fast return to function, independence, and social and daily activities. In terms of decision-making in general, trust in physicians and medical teams was very important in the decision. For practical issues, accessibility of the procedure and associated costs (eg, travel for themselves and their caregivers) were commonly reported.

Recent randomised trials,[28 29] as well as previously published trials with longer follow-up,[6 7] have added up to the current body of evidence comparing TAVI and SAVR.[3] Taken together, this evidence tends to show substantial short-term benefits of TAVI on outcomes important to patients with severe aortic stenosis at low and intermediate preoperative surgical risk, along with a substantially reduced burden of treatment.

However, valve durability with TAVI remains uncertain over the longer term due to limited follow-up compared with SAVR. An important concern is that TAVI might require valve reintervention much earlier than SAVR. This issue is particularly crucial for younger populations, as their life expectancy puts them at higher risk of needing one—or more—reinterventions. Unfortunately, our systematic review provides limited evidence on how patients may value differing valve durability and the risk of reinterventions. Indeed, only one study reported on patients' perceptions about willingness to accept a shorter duration of effectiveness of TAVI compared with SAVR, showing important variability. This study had methodological limitations and was funded by a valve device company.[25]

Another issue that varies with age is how the relative effects of TAVI translate in terms of absolute differences: because patients present a higher baseline mortality, TAVI is likely going to result in larger absolute reductions in deaths among older rather than younger patients. The balance of benefits and harms of TAVI versus SAVR will thus highly depend on age—as a proxy of life expectancy—as well as comorbidities.[4] The age or baseline risk threshold at which patients would consider the balance between benefits, harms and burden (including the risk of reintervention) in favour of either TAVI or SAVR remains thus far insufficiently explored. Current inference on these issues is further limited by the fact that several studies asked patients to trade off outcomes without basing the options on current best evidence. For example, they present unrealistic outcome risk options that were beyond the range of actual risks reported in trials.[4 6 7] The trade-off of outcomes may thus be misinformed or even misguided in such studies. Even less explored are patients' values and preference regarding the possible sequence of valve interventions.

Strengths and limitations

Our review has several strengths. First, we prospectively registered the protocol and followed study reporting criteria. Second, we conducted a comprehensive search, including grey literature, up to June 2020. Third, we assessed study quality using recommended instruments,[9 12 15] as well as using standardised methods to address the overall certainty of evidence for both quantitative and qualitative findings.[13 14 30] Fourth, the inclusion of a

patient partner as a coauthor enriched the framework used for thematic analysis. Finally, we abstracted data regarding patient-important practical issues, which shed light on areas important for decision-making that are rarely included when developing guidelines.

Our review has also limitations. First, we excluded studies looking at health-related quality of life for patients with aortic stenosis before and after therapy because these studies do not directly report on patient preferences. Second, due to the considerable heterogeneity of the types of studies included, we were not able to explore potential differences in values and preferences for subgroups of participants. Finally, our review highlights limitations of current evidence in the field, and particularly the lack of data on key outcomes and practical issues which guideline panels and patients need to inform decision-making.

CONCLUSION AND AVENUES FOR FUTURE RESEARCH

In parallel to new evidence on the effectiveness and durability of interventions, we need higher quality evidence on patients' values and preferences on all key outcomes, as well as better insight on what practical issues matter most to them. Future studies should be conducted in a broad and representative array of patients with severe, symptomatic aortic stenosis with variable risk profiles and comorbidities. They should also be informed by current best evidence on benefits and harms, rather than hypothetical (or even implausible) effects. Evidence from real-life decision-making, for example by using encounter decision aids, may better capture actual values and preferences to inform stakeholders such as guideline developers.[19 31]

Another priority should be to identify key practical issues for decision-making. New frameworks have been proposed to better structure searching, evidence synthesis and inclusion in the guideline-making process of patient-important practical issues.[19 32 33] Indeed, in highly preference-sensitive decisions such as whether to undergo TAVI or SAVR, practical issues related to each intervention and how they may affect patients' daily life may dominate shared decision-making conversations.[9]

Key messages

What is already known on this subject?

- Transcatheter aortic valve insertion (TAVI) is increasingly offered as an alternative treatment option to surgical aortic valve replacement (SAVR) for severe, symptomatic aortic stenosis, but its long-term durability remains uncertain.
- There is limited evidence on values, preferences and practical issues that are important to patients with aortic stenosis regarding the trade-offs of benefits and harms of TAVI compared with SAVR.

What might this study add?

- We provide a critical appraisal of empirical evidence on values and preferences related to aortic stenosis treatment.
- Current evidence suggests there is considerable variability among patients' values and preferences regarding the outcomes associated with TAVI or SAVR, as well as regarding the duration that the procedure has been proven to be effective.
- To improve their health status, participants were willing to accept higher mortality risk than current evidence suggests for either procedure, although this evidence was of low to very low certainty.
- Overall, participants preferred minimally invasive procedures with a shorter hospital stay and recovery time and also reported concerns regarding postsurgical pain and costs.
- An important limitation of this evidence is that no study presented participants current best evidence on all benefits and risks for both procedures, including valve durability, when enquiring for their preferred option.

How might this impact on clinical practice?

- Discussions regarding individual patients' values and preferences, focusing on the key outcomes and practical issues identified in this paper, can support shared decision-making about the best aortic stenosis treatment option for patients.
- This evidence can also inform the updates of health technology assessment and clinical practice guidelines on TAVI and SAVR.

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Contributors AFH led and coordinated the project. TA and POV provided supervision. AFH, LL and TA screened the studies for eligibility. AFH and LL extracted the data, assessed study risk of bias and synthesised the data. AFH, LL and TA assessed the quality of the body of evidence. All study authors were involved in the interpretation and discussion of the results. AFH and LL drafted the manuscript, and all authors critically revised the manuscript. All authors approved the final version of the article. AFH is the guarantor.

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Patient and public involvement statement Outcomes of interest included for this review were established by a multidisciplinary guideline panel that included three patient partners. One patient partner (MMS) from the guideline panel was included as a coauthor of this study. MMS was involved in the interpretation of study results and provided feedback on the manuscript.

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ORCID iD

Anja Fog Heen http://orcid.org/0000-0002-8873-7028

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Appendix 1. MOOSE Checklist for Meta-analyses of Observational Studies

Item No	Recommendation	Reported on Page No
Reporting of background should include		
1	Problem definition	3
2	Hypothesis statement	N/A
3	Description of study outcome(s)	4
4	Type of exposure or intervention used	4
5	Type of study designs used	4
6	Study population	4
Reporting of search strategy should include		
7	Qualifications of searchers (e.g., librarians and investigators)	3,4
8	Search strategy, including time period included in the synthesis and key words	3, 25-27
9	Effort to include all available studies, including contact with authors	3,4
10	Databases and registries searched	4
11	Search software used, name and version, including special features used (e.g., explosion)	N/A
12	Use of hand searching (e.g., reference lists of obtained articles)	4
13	List of citations located and those excluded, including justification	16, 28-30
14	Method of addressing articles published in languages other than English	N/A
15	Method of handling abstracts and unpublished studies	4
16	Description of any contact with authors	4
Reporting of methods should include		
17	Description of relevance or appropriateness of studies assembled for assessing the hypothesis to be tested	5
18	Rationale for the selection and coding of data (e.g., sound clinical principles or convenience)	5
19	Documentation of how data were classified and coded (e.g., multiple raters, blinding and interrater reliability)	5

20	Assessment of confounding (e.g., comparability of cases and controls in studies where appropriate)	N/A
21	Assessment of study quality, including blinding of quality assessors, stratification or regression on possible predictors of study results	5
22	Assessment of heterogeneity	N/A
23	Description of statistical methods (e.g., complete description of fixed or random effects models, justification of whether the chosen models account for predictors of study results, dose-response models, or cumulative meta-analysis) in sufficient detail to be replicated	N/A
24	Provision of appropriate tables and graphics	16-22
Reporting of results should include		
25	Graphic summarizing individual study estimates and overall estimate	N/A
26	Table giving descriptive information for each study included	17
27	Results of sensitivity testing (e.g., subgroup analysis)	N/A
28	Indication of statistical uncertainty of findings	N/A
Reporting of discussion should include		
29	Quantitative assessment of bias (e.g., publication bias)	N/A
30	Justification for exclusion (e.g., exclusion of non-English language citations)	N/A
31	Assessment of quality of included studies	33, 34
Reporting of conclusions should include		
32	Consideration of alternative explanations for observed results	12-14
33	Generalization of the conclusions (i.e., appropriate for the data presented and within the domain of the literature review)	14
34	Guidelines for future research	14
35	Disclosure of funding source	16

From: Stroup DF, Berlin JA, Morton SC, et al, for the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) Group. Meta-analysis of Observational Studies in Epidemiology. A Proposal for Reporting. *JAMA*. 2000;283(15):2008-2012. doi: 10.1001/jama.283.15.2008

Appendix 2. Search strategy example – MEDLINE.

Database searched = OVID Medline Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

1. *Attitude to Health/
2. *Patient Participation/
3. preference*.ti,ab.
4. *Patient Preference/
5. choice.ti.
6. choices.ti.
7. value*.ti.
8. health state values.ti,ab.
9. valuation*.ti.
10. expectation*.ti,ab.
11. attitude*.ti,ab.
12. acceptab*.ti,ab.
13. knowledge.ti,ab.
14. point of view.ti,ab.
15. user participation.ti,ab.
16. users participation.ti,ab.
17. users' participation.ti,ab.
18. user's participation.ti,ab.
19. patient participation.ti,ab.
20. patients' participation.ti,ab.
21. patients participation.ti,ab.
22. patient's participation.ti,ab.
23. patient perspective*.ti,ab.
24. patients perspective*.ti,ab.
25. patients' perspective*.ti,ab.

26. patient's perspective*.ti,ab.
27. patient perce*.ti,ab.
28. patients perce*.ti,ab.
29. patients' perce*.ti,ab.
30. patient's perce*.ti,ab.
31. health perception*.ti,ab.
32. user view*.ti,ab.
33. users view*.ti,ab.
34. users' view*.ti,ab.
35. user's view*.ti,ab.
36. patient view*.ti,ab.
37. patients view*.ti,ab.
38. patients' view*.ti,ab.
39. patient's view*.ti,ab.
40. or/1-39
41. patient*.ti.
42. user*.ti.
43. men.ti.
44. women.ti.
45. or/41-44
46. exp *Decision Making/
47. decision mak*.ti,ab.
48. decisions mak*.ti,ab.
49. decision*.ti.
50. mak*.ti.
51. 49 and 50
52. avoidance learning/
53. 46 or 47 or 48 or 51 or 52
54. 45 and 53
55. discrete choice.ti,ab.
56. decision board*.ti,ab.

57. decision analy*.ti,ab.
58. decision-support.ti,ab.
59. decision tool*.ti,ab.
60. decision aid*.ti,ab.
61. discrete-choice*.ti,ab.
62. decision*.ti,ab.
63. 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62
64. 45 and 63
65. 54 or 64
66. decision support techniques/
67. (health and utilit*).ti.
68. gamble*.ti,ab.
69. prospect theory.ti,ab.
70. preference score.ti,ab.
71. preference elicitation.ti,ab.
72. health utilit*.ti,ab.
73. (utility and (value* or score* or estimate*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
74. health state.ti,ab.
75. feeling thermometer*.ti,ab.
76. best-worst scaling.ti,ab.
77. best worst scaling.mp.
78. best worst.ti,ab.
79. TTO.ti,ab.
80. time trade-off.ti,ab.
81. probability trade-off.ti,ab.
82. or/66-81
83. Choice Behavior/

84. or/66-83

85. preference based.ti,ab.

86. preference score.ti,ab.

87. multiattribute.ti,ab.

88. multi attribute.mp.

89. EuroQoL 5D.mp.

90. EuroQoL5D.ti,ab.

91. EQ5D.mp.

92. EQ 5D.ti,ab.

93. SF6D.ti,ab.

94. SF 6D.ti,ab.

95. HUI.ti,ab.

96. 15D.ti,ab.

97. or/85-96

98. SF36.ti,ab.

99. SF 36.ti,ab.

100. SF12.ti,ab.

101. SF 12.mp.

102. HRQoL.ti,ab.

103. QoL.ti,ab.

104. quality of life.ti,ab.

105. "Quality of Life"/

106. or/98-105

107. 40 or 65 or 84 or 97 or 106

108. Aortic Stenosis.mp. or exp Aortic Valve Stenosis/

109. (aortic valve implantation or TAVR or transcatheter or transfemoral or transapical or transaxillary or SAVR or heart valve replacement or surgical aortic valve replacement or surgical AVR or SAVR or TAVI or aortic valve replacement or transvascular).af.

110. 107 and 108 and 109

111. limit 110 to humans

Appendix Table 1. Excluded studies, with reasons.

#	Title	First author	Year	Reason for exclusion
1	Toronto Aortic Stenosis Quality of Life Scale (TASQ): Development and quality of life in aortic stenosis and TAVI patients	Styra	2019	Abstract only
2	Rapid-cycle development of decision support tools for patients with symptomatic aortic stenosis	Knoepke	2018	Abstract only
3	Risk willingness and survival in patients with severe aortic stenosis	Hussain	2019	Abstract only
4	A learning curve for shared decision making: The impact of physician experience on decision aid efficacy in severe aortic stenosis	Coylewright	2018	Abstract only
5	Subjective preferences and goal among the patients treated with transaortic valvular replacement	Sugiura	2019	Abstract only
6	Patients and their physicians do not agree on shared decision making in transcatheter aortic valve replacement	Coylewright	2016	Not about values and preferences elicitation
7	Is it worth it? A collaborative clinical decision making exercise using an old-school debate	Wright	2016	Not about values and preferences elicitation
8	The medically managed patient with severe symptomatic aortic stenosis in the TAVR era: Patient characteristics, reasons for medical management, and quality of shared decision making at heart valve treatment centers	Dharmarajan	2017	Not about values and preferences elicitation
9	Patients' Decision Making About Undergoing Transcatheter Aortic Valve Implantation for Severe Aortic Stenosis	Olsson	2016	Not about values and preferences elicitation
10	Determinants and Outcome of Decision Making Among Patients with Severe Aortic Stenosis	Hussain	2017	Not about values and preferences elicitation

11	Patients' self-reported function, symptoms and health-related quality of life before and 6 months after transcatheter aortic valve implantation and surgical aortic valve replacement	Olsson	2017	Not about values and preferences elicitation
12	Self-reported health status, treatment decision and survival in asymptomatic and symptomatic patients with aortic stenosis in a Western Norway population undergoing conservative treatment: a cross-sectional study with 18 months follow-up	Oterhals	2017	Not about values and preferences elicitation
13	[ANMCO/SIC/SICI-GISE/SICCH Consensus document: Risk stratification in elderly patients undergoing cardiac surgery and transcatheter aortic valve implantation]	Pulignano	2016	Not about values and preferences elicitation
14	Patients and informal caregivers' experience of surgical and transcatheter aortic valve replacement: Real-world data contributing to establish value-based medicine in Denmark	Rosseel	2019	Not about values and preferences elicitation
15	Current decision making and short-term outcome in patients with degenerative aortic stenosis: the Pooled-RotterdAm-Milano-Toulouse In Collaboration Aortic Stenosis survey	Van Mieghem	2016	Not about values and preferences elicitation
16	Factors influencing the choice between transcatheter and surgical treatment of severe aortic stenosis in patients younger than 80 years: Results from the OBSERVANT study	Tarantini	2020	Not about values and preferences elicitation
17	Transforming the experience of aortic valve disease in older patients: A qualitative study	Kirk	2019	Not about values and preferences elicitation
18	Long-term outcomes of transcatheter versus surgical aortic valve replacement in low risk, elderly patients with severe aortic stenosis	Kang	2019	Not about values and preferences elicitation

19	Reasons for choosing conservative management in symptomatic patients with severe aortic stenosis - Observations from the CURRENT AS registry	Ishii	2019	Not about values and preferences elicitation
20	Patient disposition and clinical outcome after referral to a dedicated TAVI clinic	Gorecka	2019	Not about values and preferences elicitation
21	Validation of a Heart Team Performance for Patients with Severe Aortic Stenosis	D'Aronco	2019	Not about values and preferences elicitation
22	The Learning Curve for Shared Decision-making in Symptomatic Aortic Stenosis	Coylewright	2020	Not about values and preferences elicitation
23	Pilot Study of a Patient Decision Aid for Valve Choices in Surgical Aortic Valve Replacement	Anaya	2019	Not about values and preferences elicitation
24	Exploring the experience of early discharge after transcatheter aortic valve implantation for older adults and their informal caregivers (Dissertation)	Knoll	2018	Not about values and preferences elicitation
25	Living with Aortic Stenosis: A Phenomenological Study of Patients' Experiences and Subsequent Health Choices (Dissertation)	Hagen-Peter	2015	Not about values and preferences elicitation
26	Low Gradient Aortic Stenosis: Who Benefits From Intervention?	Baumgartner	2019	Not primary study
27	TAVR in Patients With End-Stage Renal Disease and Critical Aortic Stenosis: Hard Choices	Bayliss	2019	Not primary study
28	Quality of life after transcatheter aortic valve replacement	Bonow	2017	Not primary study
29	TAVR: A Good Fix, But It Cannot Fix Everything	Carabello	2016	Not primary study
30	Treating of aortic valve stenosis in real-life: A multifaceted decision-making challenge	Franken	2017	Not primary study
31	Are transcatheter procedures the treatment of choice for all patients with severe aortic stenosis?	Hernandez-Vaquero	2017	Not primary study

32	The less complex the case is, the more complex is it to choose? The case of lower risk patients with aortic valve stenosis	Lemos	2018	Not primary study
33	Elevating Aortic Stenosis Treatment?	McCabe	2018	Not primary study
34	Transcatheter aortic valve implantation in patients with severe aortic stenosis: Does lower-risk profile mean a young patient?	Michel	2019	Not primary study
35	Transcatheter aortic valve replacement: Suitable for all?	Minakata	2018	Not primary study
36	Aortic stenosis: Treat the patient not the numbers	Otto	2018	Not primary study
37	Surgical or transcatheter aortic-valve replacement	Reyes	2017	Not primary study
38	From knowledge to wisdom	Sousa-Uva	2018	Not primary study
39	TAVR - The future of aortic stenosis management	Ullah	2016	Not primary study

Appendix Table 2. Additional study and participant demographics.

Study	Data collection period	Setting	Funding source	Conflicts of interest
Quantitative studies				
Marsh 2020	July-August 2018	Not applicable (online survey)	Edwards Lifesciences	Two authors are employees of Edwards Lifesciences. Three studies are employees of Evidera. Evidera received funding from Edwards Lifesciences to conduct the study and develop the manuscript.
Hussain 2016	May 2010-April 2014	Large university hospital	Norwegian Health Association and Inger and John Fredriksen	No conflict of interest
Qualitative studies				
Coylewright 2015	June 2012-August 2014	Tertiary academic medical institution	No funding sources	No conflict of interest
Olsson 2016	May 2010-June 2011	Large university hospital	Vasterbotten's County Council, Umea˚University, and The Heart Foundation of Northern Sweden	No conflict of interest
Skaar 2017	February 2014-April 2015	Large university hospital	Grieg Foundation, Department of Heart Disease, Haukeland University Hospital and Kavli Research Centre for Geriatrics and Dementia, Haraldsplass Deaconess Hospital, Bergen.	NR
Lauck 2016	NR	Provincial cardiac TAVI center	Providence Health Care Nursing Research Competition	Four authors are consultants to Edward Lifesciences. One author is a consultant for Edward Lifesciences, St. Jude Medical and Abbott Inc., HearthWare, and Norvasc.
Ontario Health Technology Assessment Series 2018	NR	Not applicable (phone interview)	Health Quality Ontario	NR

Frank 2019/Styra 2019	2015-2017	Tertiary academic medical institution	Partially funded from Edwards Lifesciences (manufacturer of TAVI valves)	NR

NR = Not reported.

Appendix Table 3. Qualitative study quality.

Study	Coylewright 2016	Ontario Health Technology Assessment Series 2018	Lauck 2015	Olsson 2019	Skaar 2019	Styra/Frank 2019
1. Was there a clear statement of the aims of the research?	Yes	Yes	Yes	Yes	Yes	Yes
2. Is a qualitative methodology appropriate?	Yes	Yes	Yes	Yes	Yes	Yes
3. Was the research design appropriate to address the aims of the research?	Yes	Yes	Yes	Yes	Yes	Yes
4. Was the recruitment strategy appropriate to the aims of the research?	No	Can't tell	No	Yes	Yes	Yes
5. Was the data collected in a way that addressed the research issue?	Yes	Yes	Yes	Yes	Yes	Can't tell
6. Has the relationship between researcher and participants been adequately considered?	Can't tell	No	No	No	Yes	No
7. Have ethical issues been taken into consideration?	Yes	Can't tell	Yes	Yes	Yes	Yes
8. Was the data analysis sufficiently rigorous?	No	Can't tell	Yes	Yes	Yes	Can't tell
9. Is there a clear statement of findings?	Yes	Yes	Yes	Yes	Yes	Yes
Overall methodological limitations	Moderate	Serious	Moderate	No or very minor	No or very minor	No or very minor

Appendix Table 4. Quantitative study quality.

Risk of bias criteria		**Hussain 2016**	**Marsh 2020**
Selection of participants into the study	Was an appropriate study sample selected from the sampling frame?	Moderate risk of bias	Serious risk of bias
Completeness of data	Was the attrition sufficiently low to minimize the risk of bias?	Moderate risk of bias	Serious risk of bias
Measurement Instrument: Choice of the methodology	Was the instrument used for eliciting relative importance of outcomes valid and reliable?	Moderate risk of bias	Low risk of bias
Measurement Instrument: Administration of the methodology	Was the instrument administered in the intended way?	Low risk of bias	Moderate risk of bias
Measurement Instrument: Outcome presentation	Was a valid representation of the outcome (health state) utilized?	Moderate risk of bias	Serious risk of bias
Measurement Instrument: Understanding of the methodology	Did the researchers check the understanding of the instrument?	Moderate risk of bias	Low risk of bias
Data analysis	Were the results analyzed appropriately to avoid influence of bias and confounding?	Moderate risk of bias	Serious risk of bias

Appendix Table 5. Qualitative results - CERQual Summary of Findings

Summary of Qualitative Review Findings	**Reference**	**Explanation of CERQual assessment**
Values and preferences concerning perioperative mortality risk of procedure		
Patients with severe aortic stenosis viewed declining treatment to be worse than accepting the risk related to the procedure	[23]	Limited, thin data to support this finding, only one study that did address both TAVI and SAVR
Risk willingness varied considerably, but many patients were generally willing to accept a high perioperative mortality risk when undergoing aortic valve replacement	[21 23]	Limited, thin data to support this finding, not enough studies, not enough settings, and studies did not address both TAVI and SAVR.
Values and preferences concerning health-related quality of life when deciding on treatment		
Function/ activities of daily living		
Patients aimed for improved body function, better health and activities of daily living when deciding on treatment.	[21 27 23 22]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and all but one study did not address both TAVI and SAVR, and when it was reported it was separate
Patient-defined goals central to decision-making included specific activities and hobbies.	[21 27 23 24]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and studies did not address both TAVI and SAVR.
Patients emphasized importance of managing by oneself or be independent as reasons to undergo treatment.	[21 27 24 22]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and studies did not address both TAVI and SAVR.
Improve quality of life		
Patients hoped the procedure would improve their quality of life, and spoke of their desire to get back to 'normal', have a 'good life' or have a 'new lease on life' when deciding on treatment.	[27 22 23 24]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and studies and studies did not address both TAVI and SAVR
Maintaining independence/ obligations		
Patients reported their sense of responsibility to maintain the best possible health condition to be able to fulfill their obligations, including on financial management, maintaining one's home and participating in day-to-day activities.	[21 27 24 22]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and all but one study did not address both TAVI and SAVR, and when it was reported it was separate

Some patients reported that they felt an obligation to their relatives to accept a treatment that was recommended.	[27] [23]	Studies with methodological limitations, limited, thin data to support this finding, uncommon, but important finding, not enough studies, not enough settings and all but one study did not address both TAVI and SAVR, and when it was reported it was separate
Values and preferences concerning pain and risk of stroke		
Some patients were concerned about pain or getting a stroke after the procedure.	[22]	Study with methodological limitations, uncommon, but important finding, only one study and TAVI and SAVR was reported separately
Values and preferences related to decision-making guidance on treatment and practical issues		
Patients stressed the importance of a trusting relationship with their physician(s) as essential sources of information, decision-making guidance and facilitators of referral and decision-making	[21] [27] [23]	Studies with methodological limitations, thin data to support this finding, not enough studies, not enough settings and studies did not address both TAVI and SAVR, and when it was reported it was separate
There was a high degree of variability on the reliance on informal social support provided by family, friends and community members on their decision making.	[21] [27] [23]	Studies with methodological limitations, thin data to support this finding, not enough studies, not enough settings and studies did not address both TAVI and SAVR, and when it was reported it was separate
Patients and caregivers noted that the costs involved with travel and a longer hospital stay were an additional burden and a potential barrier to receiving SAVR.	[22] [21] [23] [27]	All but one study did not address both TAVI and SAVR, and when it was reported it was separate

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6	Study population	4
Reporting of search strategy should include		
7	Qualifications of searchers (e.g., librarians and investigators)	3,4
8	Search strategy, including time period included in the synthesis and key words	3, 25-27
9	Effort to include all available studies, including contact with authors	3,4
10	Databases and registries searched	4
11	Search software used, name and version, including special features used (e.g., explosion)	N/A
12	Use of hand searching (e.g., reference lists of obtained articles)	4
13	List of citations located and those excluded, including justification	16, 28-30
14	Method of addressing articles published in languages other than English	N/A
15	Method of handling abstracts and unpublished studies	4
16	Description of any contact with authors	4
Reporting of methods should include		
17	Description of relevance or appropriateness of studies assembled for assessing the hypothesis to be tested	5
18	Rationale for the selection and coding of data (e.g., sound clinical principles or convenience)	5
19	Documentation of how data were classified and coded (e.g., multiple raters, blinding and interrater reliability)	5

20	Assessment of confounding (e.g., comparability of cases and controls in studies where appropriate)	N/A
21	Assessment of study quality, including blinding of quality assessors, stratification or regression on possible predictors of study results	5
22	Assessment of heterogeneity	N/A
23	Description of statistical methods (e.g., complete description of fixed or random effects models, justification of whether the chosen models account for predictors of study results, dose-response models, or cumulative meta-analysis) in sufficient detail to be replicated	N/A
24	Provision of appropriate tables and graphics	16-22
Reporting of results should include		
25	Graphic summarizing individual study estimates and overall estimate	N/A
26	Table giving descriptive information for each study included	17
27	Results of sensitivity testing (e.g., subgroup analysis)	N/A
28	Indication of statistical uncertainty of findings	N/A
Reporting of discussion should include		
29	Quantitative assessment of bias (e.g., publication bias)	N/A
30	Justification for exclusion (e.g., exclusion of non-English language citations)	N/A
31	Assessment of quality of included studies	33, 34
Reporting of conclusions should include		
32	Consideration of alternative explanations for observed results	12-14
33	Generalization of the conclusions (i.e., appropriate for the data presented and within the domain of the literature review)	14
34	Guidelines for future research	14
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From: Stroup DF, Berlin JA, Morton SC, et al, for the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) Group. Meta-analysis of Observational Studies in Epidemiology. A Proposal for Reporting. *JAMA*. 2000;283(15):2008-2012. doi: 10.1001/jama.283.15.2008

Appendix 2. Search strategy example – MEDLINE.

Database searched = OVID Medline Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

1. *Attitude to Health/
2. *Patient Participation/
3. preference*.ti,ab.
4. *Patient Preference/
5. choice.ti.
6. choices.ti.
7. value*.ti.
8. health state values.ti,ab.
9. valuation*.ti.
10. expectation*.ti,ab.
11. attitude*.ti,ab.
12. acceptab*.ti,ab.
13. knowledge.ti,ab.
14. point of view.ti,ab.
15. user participation.ti,ab.
16. users participation.ti,ab.
17. users' participation.ti,ab.
18. user's participation.ti,ab.
19. patient participation.ti,ab.
20. patients' participation.ti,ab.
21. patients participation.ti,ab.
22. patient's participation.ti,ab.
23. patient perspective*.ti,ab.
24. patients perspective*.ti,ab.
25. patients' perspective*.ti,ab.

26. patient's perspective*.ti,ab.
27. patient perce*.ti,ab.
28. patients perce*.ti,ab.
29. patients' perce*.ti,ab.
30. patient's perce*.ti,ab.
31. health perception*.ti,ab.
32. user view*.ti,ab.
33. users view*.ti,ab.
34. users' view*.ti,ab.
35. user's view*.ti,ab.
36. patient view*.ti,ab.
37. patients view*.ti,ab.
38. patients' view*.ti,ab.
39. patient's view*.ti,ab.
40. or/1-39
41. patient*.ti.
42. user*.ti.
43. men.ti.
44. women.ti.
45. or/41-44
46. exp *Decision Making/
47. decision mak*.ti,ab.
48. decisions mak*.ti,ab.
49. decision*.ti.
50. mak*.ti.
51. 49 and 50
52. avoidance learning/
53. 46 or 47 or 48 or 51 or 52
54. 45 and 53
55. discrete choice.ti,ab.
56. decision board*.ti,ab.

57. decision analy*.ti,ab.
58. decision-support.ti,ab.
59. decision tool*.ti,ab.
60. decision aid*.ti,ab.
61. discrete-choice*.ti,ab.
62. decision*.ti,ab.
63. 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62
64. 45 and 63
65. 54 or 64
66. decision support techniques/
67. (health and utilit*).ti.
68. gamble*.ti,ab.
69. prospect theory.ti,ab.
70. preference score.ti,ab.
71. preference elicitation.ti,ab.
72. health utilit*.ti,ab.
73. (utility and (value* or score* or estimate*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
74. health state.ti,ab.
75. feeling thermometer*.ti,ab.
76. best-worst scaling.ti,ab.
77. best worst scaling.mp.
78. best worst.ti,ab.
79. TTO.ti,ab.
80. time trade-off.ti,ab.
81. probability trade-off.ti,ab.
82. or/66-81
83. Choice Behavior/

84. or/66-83

85. preference based.ti,ab.

86. preference score.ti,ab.

87. multiattribute.ti,ab.

88. multi attribute.mp.

89. EuroQoL 5D.mp.

90. EuroQoL5D.ti,ab.

91. EQ5D.mp.

92. EQ 5D.ti,ab.

93. SF6D.ti,ab.

94. SF 6D.ti,ab.

95. HUI.ti,ab.

96. 15D.ti,ab.

97. or/85-96

98. SF36.ti,ab.

99. SF 36.ti,ab.

100. SF12.ti,ab.

101. SF 12.mp.

102. HRQoL.ti,ab.

103. QoL.ti,ab.

104. quality of life.ti,ab.

105. "Quality of Life"/

106. or/98-105

107. 40 or 65 or 84 or 97 or 106

108. Aortic Stenosis.mp. or exp Aortic Valve Stenosis/

109. (aortic valve implantation or TAVR or transcatheter or transfemoral or transapical or transaxillary or SAVR or heart valve replacement or surgical aortic valve replacement or surgical AVR or SAVR or TAVI or aortic valve replacement or transvascular).af.

110. 107 and 108 and 109

111. limit 110 to humans

Appendix Table 1. Excluded studies, with reasons.

#	Title	First author	Year	Reason for exclusion
1	Toronto Aortic Stenosis Quality of Life Scale (TASQ): Development and quality of life in aortic stenosis and TAVI patients	Styra	2019	Abstract only
2	Rapid-cycle development of decision support tools for patients with symptomatic aortic stenosis	Knoepke	2018	Abstract only
3	Risk willingness and survival in patients with severe aortic stenosis	Hussain	2019	Abstract only
4	A learning curve for shared decision making: The impact of physician experience on decision aid efficacy in severe aortic stenosis	Coylewright	2018	Abstract only
5	Subjective preferences and goal among the patients treated with transaortic valvular replacement	Sugiura	2019	Abstract only
6	Patients and their physicians do not agree on shared decision making in transcatheter aortic valve replacement	Coylewright	2016	Not about values and preferences elicitation
7	Is it worth it? A collaborative clinical decision making exercise using an old-school debate	Wright	2016	Not about values and preferences elicitation
8	The medically managed patient with severe symptomatic aortic stenosis in the TAVR era: Patient characteristics, reasons for medical management, and quality of shared decision making at heart valve treatment centers	Dharmarajan	2017	Not about values and preferences elicitation
9	Patients' Decision Making About Undergoing Transcatheter Aortic Valve Implantation for Severe Aortic Stenosis	Olsson	2016	Not about values and preferences elicitation
10	Determinants and Outcome of Decision Making Among Patients with Severe Aortic Stenosis	Hussain	2017	Not about values and preferences elicitation

11	Patients' self-reported function, symptoms and health-related quality of life before and 6 months after transcatheter aortic valve implantation and surgical aortic valve replacement	Olsson	2017	Not about values and preferences elicitation
12	Self-reported health status, treatment decision and survival in asymptomatic and symptomatic patients with aortic stenosis in a Western Norway population undergoing conservative treatment: a cross-sectional study with 18 months follow-up	Oterhals	2017	Not about values and preferences elicitation
13	[ANMCO/SIC/SICI-GISE/SICCH Consensus document: Risk stratification in elderly patients undergoing cardiac surgery and transcatheter aortic valve implantation]	Pulignano	2016	Not about values and preferences elicitation
14	Patients and informal caregivers' experience of surgical and transcatheter aortic valve replacement: Real-world data contributing to establish value-based medicine in Denmark	Rosseel	2019	Not about values and preferences elicitation
15	Current decision making and short-term outcome in patients with degenerative aortic stenosis: the Pooled-RotterdAm-Milano-Toulouse In Collaboration Aortic Stenosis survey	Van Mieghem	2016	Not about values and preferences elicitation
16	Factors influencing the choice between transcatheter and surgical treatment of severe aortic stenosis in patients younger than 80 years: Results from the OBSERVANT study	Tarantini	2020	Not about values and preferences elicitation
17	Transforming the experience of aortic valve disease in older patients: A qualitative study	Kirk	2019	Not about values and preferences elicitation
18	Long-term outcomes of transcatheter versus surgical aortic valve replacement in low risk, elderly patients with severe aortic stenosis	Kang	2019	Not about values and preferences elicitation

19	Reasons for choosing conservative management in symptomatic patients with severe aortic stenosis - Observations from the CURRENT AS registry	Ishii	2019	Not about values and preferences elicitation
20	Patient disposition and clinical outcome after referral to a dedicated TAVI clinic	Gorecka	2019	Not about values and preferences elicitation
21	Validation of a Heart Team Performance for Patients with Severe Aortic Stenosis	D'Aronco	2019	Not about values and preferences elicitation
22	The Learning Curve for Shared Decision-making in Symptomatic Aortic Stenosis	Coylewright	2020	Not about values and preferences elicitation
23	Pilot Study of a Patient Decision Aid for Valve Choices in Surgical Aortic Valve Replacement	Anaya	2019	Not about values and preferences elicitation
24	Exploring the experience of early discharge after transcatheter aortic valve implantation for older adults and their informal caregivers (Dissertation)	Knoll	2018	Not about values and preferences elicitation
25	Living with Aortic Stenosis: A Phenomenological Study of Patients' Experiences and Subsequent Health Choices (Dissertation)	Hagen-Peter	2015	Not about values and preferences elicitation
26	Low Gradient Aortic Stenosis: Who Benefits From Intervention?	Baumgartner	2019	Not primary study
27	TAVR in Patients With End-Stage Renal Disease and Critical Aortic Stenosis: Hard Choices	Bayliss	2019	Not primary study
28	Quality of life after transcatheter aortic valve replacement	Bonow	2017	Not primary study
29	TAVR: A Good Fix, But It Cannot Fix Everything	Carabello	2016	Not primary study
30	Treating of aortic valve stenosis in real-life: A multifaceted decision-making challenge	Franken	2017	Not primary study
31	Are transcatheter procedures the treatment of choice for all patients with severe aortic stenosis?	Hernandez-Vaquero	2017	Not primary study

32	The less complex the case is, the more complex is it to choose? The case of lower risk patients with aortic valve stenosis	Lemos	2018	Not primary study
33	Elevating Aortic Stenosis Treatment?	McCabe	2018	Not primary study
34	Transcatheter aortic valve implantation in patients with severe aortic stenosis: Does lower-risk profile mean a young patient?	Michel	2019	Not primary study
35	Transcatheter aortic valve replacement: Suitable for all?	Minakata	2018	Not primary study
36	Aortic stenosis: Treat the patient not the numbers	Otto	2018	Not primary study
37	Surgical or transcatheter aortic-valve replacement	Reyes	2017	Not primary study
38	From knowledge to wisdom	Sousa-Uva	2018	Not primary study
39	TAVR - The future of aortic stenosis management	Ullah	2016	Not primary study

Appendix Table 2. Additional study and participant demographics.

Study	Data collection period	Setting	Funding source	Conflicts of interest
Quantitative studies				
Marsh 2020	July-August 2018	Not applicable (online survey)	Edwards Lifesciences	Two authors are employees of Edwards Lifesciences. Three studies are employees of Evidera. Evidera received funding from Edwards Lifesciences to conduct the study and develop the manuscript.
Hussain 2016	May 2010-April 2014	Large university hospital	Norwegian Health Association and Inger and John Fredriksen	No conflict of interest
Qualitative studies				
Coylewright 2015	June 2012-August 2014	Tertiary academic medical institution	No funding sources	No conflict of interest
Olsson 2016	May 2010-June 2011	Large university hospital	Vasterbotten's County Council, Umea˚University, and The Heart Foundation of Northern Sweden	No conflict of interest
Skaar 2017	February 2014-April 2015	Large university hospital	Grieg Foundation, Department of Heart Disease, Haukeland University Hospital and Kavli Research Centre for Geriatrics and Dementia, Haraldsplass Deaconess Hospital, Bergen.	NR
Lauck 2016	NR	Provincial cardiac TAVI center	Providence Health Care Nursing Research Competition	Four authors are consultants to Edward Lifesciences. One author is a consultant for Edward Lifesciences, St. Jude Medical and Abbott Inc., HearthWare, and Norvasc.
Ontario Health Technology Assessment Series 2018	NR	Not applicable (phone interview)	Health Quality Ontario	NR

Frank 2019/Styra 2019	2015-2017	Tertiary academic medical institution	Partially funded from Edwards Lifesciences (manufacturer of TAVI valves)	NR

NR = Not reported.

Appendix Table 3. Qualitative study quality.

Study	Coylewright 2016	Ontario Health Technology Assessment Series 2018	Lauck 2015	Olsson 2019	Skaar 2019	Styra/Frank 2019
1. Was there a clear statement of the aims of the research?	Yes	Yes	Yes	Yes	Yes	Yes
2. Is a qualitative methodology appropriate?	Yes	Yes	Yes	Yes	Yes	Yes
3. Was the research design appropriate to address the aims of the research?	Yes	Yes	Yes	Yes	Yes	Yes
4. Was the recruitment strategy appropriate to the aims of the research?	No	Can't tell	No	Yes	Yes	Yes
5. Was the data collected in a way that addressed the research issue?	Yes	Yes	Yes	Yes	Yes	Can't tell
6. Has the relationship between researcher and participants been adequately considered?	Can't tell	No	No	No	Yes	No
7. Have ethical issues been taken into consideration?	Yes	Can't tell	Yes	Yes	Yes	Yes
8. Was the data analysis sufficiently rigorous?	No	Can't tell	Yes	Yes	Yes	Can't tell
9. Is there a clear statement of findings?	Yes	Yes	Yes	Yes	Yes	Yes
Overall methodological limitations	Moderate	Serious	Moderate	No or very minor	No or very minor	No or very minor

Appendix Table 4. Quantitative study quality.

Risk of bias criteria		**Hussain 2016**	**Marsh 2020**
Selection of participants into the study	Was an appropriate study sample selected from the sampling frame?	Moderate risk of bias	Serious risk of bias
Completeness of data	Was the attrition sufficiently low to minimize the risk of bias?	Moderate risk of bias	Serious risk of bias
Measurement Instrument: Choice of the methodology	Was the instrument used for eliciting relative importance of outcomes valid and reliable?	Moderate risk of bias	Low risk of bias
Measurement Instrument: Administration of the methodology	Was the instrument administered in the intended way?	Low risk of bias	Moderate risk of bias
Measurement Instrument: Outcome presentation	Was a valid representation of the outcome (health state) utilized?	Moderate risk of bias	Serious risk of bias
Measurement Instrument: Understanding of the methodology	Did the researchers check the understanding of the instrument?	Moderate risk of bias	Low risk of bias
Data analysis	Were the results analyzed appropriately to avoid influence of bias and confounding?	Moderate risk of bias	Serious risk of bias

Appendix Table 5. Qualitative results - CERQual Summary of Findings

Summary of Qualitative Review Findings	**Reference**	**Explanation of CERQual assessment**
Values and preferences concerning perioperative mortality risk of procedure		
Patients with severe aortic stenosis viewed declining treatment to be worse than accepting the risk related to the procedure	[23]	Limited, thin data to support this finding, only one study that did address both TAVI and SAVR
Risk willingness varied considerably, but many patients were generally willing to accept a high perioperative mortality risk when undergoing aortic valve replacement	[21 23]	Limited, thin data to support this finding, not enough studies, not enough settings, and studies did not address both TAVI and SAVR.
Values and preferences concerning health-related quality of life when deciding on treatment		
Function/ activities of daily living		
Patients aimed for improved body function, better health and activities of daily living when deciding on treatment.	[21 27 23 22]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and all but one study did not address both TAVI and SAVR, and when it was reported it was separate
Patient-defined goals central to decision-making included specific activities and hobbies.	[21 27 23 24]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and studies did not address both TAVI and SAVR.
Patients emphasized importance of managing by oneself or be independent as reasons to undergo treatment.	[21 27 24 22]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and studies did not address both TAVI and SAVR.
Improve quality of life		
Patients hoped the procedure would improve their quality of life, and spoke of their desire to get back to 'normal', have a 'good life' or have a 'new lease on life' when deciding on treatment.	[27 22 23 24]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and studies and studies did not address both TAVI and SAVR
Maintaining independence/ obligations		
Patients reported their sense of responsibility to maintain the best possible health condition to be able to fulfill their obligations, including on financial management, maintaining one's home and participating in day-to-day activities.	[21 27 24 22]	Studies with methodological limitations, limited, thin data to support this finding, not enough studies, not enough settings and all but one study did not address both TAVI and SAVR, and when it was reported it was separate

Some patients reported that they felt an obligation to their relatives to accept a treatment that was recommended.	[27] [23]	Studies with methodological limitations, limited, thin data to support this finding, uncommon, but important finding, not enough studies, not enough settings and all but one study did not address both TAVI and SAVR, and when it was reported it was separate
Values and preferences concerning pain and risk of stroke		
Some patients were concerned about pain or getting a stroke after the procedure.	[22]	Study with methodological limitations, uncommon, but important finding, only one study and TAVI and SAVR was reported separately
Values and preferences related to decision-making guidance on treatment and practical issues		
Patients stressed the importance of a trusting relationship with their physician(s) as essential sources of information, decision-making guidance and facilitators of referral and decision-making	[21] [27] [23]	Studies with methodological limitations, thin data to support this finding, not enough studies, not enough settings and studies did not address both TAVI and SAVR, and when it was reported it was separate
There was a high degree of variability on the reliance on informal social support provided by family, friends and community members on their decision making.	[21] [27] [23]	Studies with methodological limitations, thin data to support this finding, not enough studies, not enough settings and studies did not address both TAVI and SAVR, and when it was reported it was separate
Patients and caregivers noted that the costs involved with travel and a longer hospital stay were an additional burden and a potential barrier to receiving SAVR.	[22] [21] [23] [27]	All but one study did not address both TAVI and SAVR, and when it was reported it was separate