Title

Impact of Decision Aid on Decision-making of Patients With Severe Aortic Stenosis: Randomized Pilot Study.

Journal

Journal of the Society for Cardiovascular Angiography & Interventions, 1(2)

Authors

Valentine, K
Marques, Felisha
Selberg, Alexandra
et al.

Publication Date

2022

DOI

10.1016/j.jscai.2022.100025

Peer reviewed

Journal of the Society for Cardiovascular Angiography & Interventions 1 (2022) 100025

Contents lists available at ScienceDirect

Journal of the Society for Cardiovascular Angiography & Interventions

journal homepage: www.jscai.org

Original Research

Impact of Decision Aid on Decision-making of Patients With Severe Aortic Stenosis: Randomized Pilot Study

K.D. Valentine, PhD [a], Felisha Marques, MPH [a], Alexandra Selberg, MA [b], Laura Flannery, MD [b], Nathaniel Langer, MD [c], Ignacio Inglessis, MD [b], Jonathan Passeri, MD [b], Thoralf Sundt, MD [c], Karen Sepucha, PhD [a,*,#], Sammy Elmariah, MD, MPH [b,*,#]

[a] Department of General Internal Medicine, Massachusetts General Hospital, Boston, Massachusetts
[b] Division of Cardiology, Massachusetts General Hospital, Boston, Massachusetts
[c] Division of Cardiac Surgery, Massachusetts General Hospital, Boston, Massachusetts

A B S T R A C T

Background: Clinical guidelines recommend patients with aortic stenosis (AS) being considered for transcatheter aortic valve implantation or surgical aortic valve replacement to participate in shared decision-making (SDM) with a heart valve team (HVT). Data supporting these recommendations are limited. This project gathered data on feasibility and preliminary efficacy of a decision aid (DA) in decision-making for patients with severe AS deciding between transcatheter aortic valve implantation and surgical aortic valve replacement.

Methods: This institutional review board-approved randomized pilot trial assigned eligible patients to receive either the American College of Cardiology's DA for patients with AS or usual care. Patients were surveyed after their visit regarding knowledge, treatment-preference concordance, SDM (SDM process and CollaboRATE Scales), and decisional conflict. Patients were followed for 3 months to collect data on treatment received.

Results: Of 62 patients approached, 59 (95%) consented and participated. The average age of participants was 72 years, they were 100% white, and 32% of them were female. Intervention patients had higher knowledge scores (75.6 vs 65.5) and more frequently reported CollaboRATE top scores (67% vs 33%) than usual care patients. No other group comparisons reached significance. Patients who saw both members of the HVT before survey completion reported higher SDM process scores than those who saw only 1 specialist (3.1 vs 2.4).

Conclusions: The study exceeded enrollment targets, indicating feasibility. Results suggest the American College of Cardiology's DA improved patient knowledge and communication scores. Patients who met with both members of the HVT reported higher SDM. These observations highlight the importance of SDM and multidisciplinary HVT assessment in the management of severe AS.

Introduction

Treatment choice for severe aortic stenosis is complex. Patients and physicians must weigh tradeoffs between surgical aortic valve replacement (SAVR), a more invasive but established treatment with known, long-term durability and outcomes, and transcatheter aortic valve replacement (TAVR), a newer, less invasive procedure that has more uncertainty surrounding durability of the valve prosthesis and long-term complications but provides easier and faster procedural recovery. The Centers for Medicare and Medicaid Services (CMS) have therefore mandated that patients considering TAVR be evaluated by a multidisciplinary heart valve team (HVT).[1,2] Societal guidelines similarly endorse HVT evaluation and recommend shared decision-making for all patients in whom aortic valve intervention is being considered.[1,3]

Despite societal guideline and CMS mandates, implementation of shared decision-making has been limited.[4] Decision aids (DAs) have been utilized to facilitate and improve shared decision-making.[5] The use of the DA sponsored by the American College of Cardiology for high to prohibitive surgical risk patients deciding between medical management and TAVR, titled "The Severe Aortic Stenosis Decision Aid," has been found to improve shared decision-making and patient-centered outcomes,[6] but the American College of Cardiology's DA for patients with intermediate to high surgical risk deciding between TAVR and SAVR has not yet been evaluated.[7] We therefore sought to examine feasibility and preliminary effectiveness of the American College of Cardiology's DA

Keywords: Aortic stenosis; shared decision-making; decision aid implementation; aortic valve replacement.
* Corresponding authors.
E-mail addresses: KSepucha@mgh.harvard.edu (K. Sepucha), selmariah@mgh.harvard.edu (S. Elmariah).
# Authors contributed equally.

https://doi.org/10.1016/j.jscai.2022.100025
Received 20 December 2021; Received in revised form 27 January 2022; Accepted 28 January 2022

within a randomized pilot trial. Specifically, we evaluated the impact of the American College of Cardiology DA on knowledge scores, the likelihood of patients receiving their preferred treatment, shared decision-making, and decisional conflict. Additionally, we explored whether these outcomes differed for patients who had seen a single member of the HVT compared with for those who had seen both cardiology and cardiac surgery HVT specialists.

Methods

Patients

Eligible patients had severe aortic stenosis, spoke English, were aged 55-85 years, were considered to be at low to intermediate risk based on clinician perceptions, and were scheduled for a visit to discuss their candidacy for TAVR or SAVR. Patients were ineligible if they had concomitant severe valvular, aortic, or coronary artery disease requiring surgical intervention or if they possessed a relative contraindication to either procedure. Study staff screened the outpatient clinics of all members of the HVT for eligible patients. These outpatient clinics include TAVR/SAVR follow-up visits, moderate aortic stenosis, patients older than 85 years, and other valvular/structural heart disease patients, which resulted in many ineligible patients. Study staff approached consecutive eligible patients for enrollment. The study was funded through internal departmental funds, approved by the Mass General Brigham Institutional Review Board. Full trial protocol can be accessed by contacting the corresponding authors.

Design

The study design was registered at ClinicalTrials.gov (#NCT04103931). The design involved recruitment at 2 sites. Due to challenges caused by the COVID-19 pandemic, the second site was unable to recruit patients and terminated the study early. We only present data from 1 site here.

The study was a randomized controlled trial. Prior to enrollment, study IDs were created and randomly assigned to intervention or control arm using a random number generator. Assuming 70% response rate and aiming for minimum 20 patients per arm, we expected to randomize 60 patients. Eligible patients were recruited by staff when they arrived for their visit prior to being seen by an HVT specialist. After agreeing to participate, patients were assigned a study ID in consecutive numerical order (and thus randomized) and given appropriate materials for the assigned study arm. All patients received a survey to be completed after the visit and returned via mail to study staff. Patients were recruited from September 2019 until February 2020; data regarding clinical visits with the HVT were collected until November 2020. Median time between patient visits and survey completion was 7 days (interquartile range 10.5 days). Consent was implied by return of the survey.

Intervention patients received the American College of Cardiology DA, "Treatment Options for Severe Aortic Stenosis for Patients Deciding Between TAVR and Surgery at Intermediate or High Surgical Risk." The DA can be found in the Supplement. The 7-page paper version includes a description of the decision, of aortic stenosis, information on the benefits and risks of each procedure, and patient stories.[7] Intervention patients were told that the DA was an information pamphlet that presents benefits and risks of treatment options to help patients and their doctors determine which treatment might be best. Other than the DA, intervention patients received usual care. Although the DA used in this study was designed for patients at intermediate or high surgical risk, we enrolled patients at low to intermediate surgical risk. Guidelines had recently indicated that TAVR was a viable option for low surgical risk patients,[8] and although there was no corresponding DA for these patients at the time, we still felt these patients could be aided by the information provided in the DA.

Control patients received usual care, which varied from provider to provider but usually consisted of in-clinic discussion of the treatment options, risks, and benefits, as well as showing the patient an animation of the TAVR procedure. Education regarding treatment options is provided by the clinicians directly. No formal written materials or DAs are provided as part of usual care. Patients have 2 separate clinic visits to complete the HVT evaluation; 1 with a valve team cardiologist, and 1 with a cardiac surgeon. At the center, patients tend to meet with the cardiology team first, followed by the cardiac surgery team. Visits are scheduled on different days, and cardiology and cardiac surgery clinicians discuss patient cases at a weekly multidisciplinary HVT meeting after both visits, and necessary diagnostic tests are completed. Patients are called either by the clinician or by the valve coordinator nurse after this meeting to confirm final treatment plan and to book a procedure.

Measures and outcomes

Patient survey consisted of:

- Knowledge: 6 multiple-choice items about the treatment options and outcomes adapted from previous work[9]; correct responses received 1 point and were scaled to create a knowledge score (0-100%).
- Preferred treatment: 1 item with responses of SAVR, TAVR, no treatment, or not sure.
- Shared decision-making process[10]: 6 items assessing whether options, pros, cons, and preferences were discussed (total scores range from 0 to 4; higher scores indicating greater shared decision-making).
- CollaboRATE[11]: 3-item measure of patient-centered communication that is reported as the percentage earning the top score, indicating good communication.
- SURE[12]: 4-item measure of decisional conflict that is reported as the percentage earning the top score, indicating no decisional conflict.
- Stage of decision-making[13]: 1 item asks how far along patients are in their decision.
- DA usage (intervention arm only): Patients reported how much of the DA they reviewed (all, most, some, a little, or none).

Staff reviewed patient charts and Society of Thoracic Surgeons and Transcatheter Valve Therapy registries to identify treatment received (TAVR, SAVR, neither) and Society of Thoracic Surgeons Risk Scores within approximately 3 months of the visit. However, some patients saw clinicians in early 2020 meaning that their treatment could have been delayed due to the COVID-19 pandemic and resultant surgical shutdowns. Given this limitation, chart and registry review was conducted up to June 2021 to ensure all procedures were captured. Procedures occurred between 15 days after recruitment up until just a year after recruitment (384 days); the average time between recruitment and treatment was 124 days (standard deviation [SD] = 99 days). Registry review was also used to identify clinical indicators including, history of hypertension, diabetes mellitus, renal replacement therapy, lung disease requiring O_2, prior myocardial infarction, and creatinine. Patient age, sex, and creatinine values were input into the Chronic Kidney Disease Epidemiology Collaboration formula for estimated glomerular filtration rate. Staff kept records of the patient's visit with the HVT member when they were recruited and reviewed patient charts to identify dates of visits with other HVT members approximately 3 months after the visit.

Two measures were calculated: preference concordance and informed, patient-centered decision.[9] Patients were said to make preference-concordant decisions if they received their preferred treatment. Patients preferring SAVR and receiving SAVR, preferring TAVR and receiving TAVR, and preferring no treatment and receiving no treatment were considered concordant; all others were considered discordant. The informed, patient-centered decision is a composite variable generated using the knowledge score and preference concordance. Patients are considered to have made an informed, patient-centered decision only if they are both informed (knowledge score $\geq$60%) and

received their preferred treatment; all other patients were considered to have made an uninformed, patient-centered decision. See the Supplement for full survey.

Statistical analyses

We used *t* tests (age) and χ^2 analyses (sex, education) to test for differences in these patient characteristics between arms, DA usage, and extent of exposure to the HVT (ie, meeting with both HVT specialists versus meeting with only 1 HVT specialist by the time our questionnaire was completed). *t* Tests explored differences between arms for continuous variables (knowledge, shared decision-making process); χ^2 analyses were used for discrete variables (CollaboRATE, SURE, informed, patient-centered decisions). When exploring treatment leaning and treatment choice by arm, Fisher exact tests were required given small samples. As the pilot was not powered to detect differences, we calculated effect sizes to be used to adequately power future studies. A 2-proportions z-test was used to test for feasibility to identify if we met our desired 70% response rate.

Similar techniques were used for all χ^2 sensitivity analyses of DA usage, which were completed to identify if there were differences on all outcome measures between patients in the intervention arm who reviewed all the DAs and those who reported reviewing none, some, or most of the DAs. Similar methods were also employed to identify if exposure to the HVT was related to differences on all outcome measures. For all analyses, missing data were excluded pairwise. All analyses were completed in RStudio version 1.1.447 using R version 19.6.0.[14,15]

Results

Of 62 eligible patients approached for participation, 60 agreed to participate and were randomized. Surveys were returned by 59 patients (28/29 control; 31/31 intervention), yielding a 95% (59/62) consent rate. This consent rate exceeded our desired rate of 70% ($\chi^2(1) = 11.95$, $P < .001$), indicating feasibility. See Figure 1 for the Consolidated Standards of Reporting Trials (CONSORT) diagram.[16] We did not analyze for nonresponder bias as the small number of nonresponders (n = 3) makes this bias negligible. Baseline patient characteristics were comparable across study arms (Table 1; $P > .05$ for all). Average patient age was 72 years (SD = 7), 32% of the sample were women, most (52%) had a college degree or more, all identified as white, and had median Society of Thoracic Surgeons-predicted mortality risk scores of 1.4 (SD = 1.7). For patients in the intervention arm, most (68%) reported reviewing all of the DA.

Intervention arm patients had higher knowledge scores (mean [M] = 75.6, SD = 15) than the control arm, with a moderate effect size (M = 65.5, SD = 16.9; t(56) = 2.4, $P = .02$, d = 0.6). The intervention arm also had higher CollaboRATE scores than the control arm (67% vs 33%; χ^2 (1) = 5.1, $P = .025$, $\varphi = 0.3$). See Figure 2.

The shared decision-making process scores (intervention: M = 2.8, SD = 0.9; control: M = 2.6, SD = 1.1; $P = .643$, d = 0.1) and SURE top scores (intervention: 74%, control: 75%; $P > .99$, $\varphi < 0.1$) did not differ by arms. Arms were also similar in decision stage, with 61% stating that they had made a choice in each arm.

Preferred treatments were similar between arms; both arms preferred TAVR most often (61% in the intervention arm; 44% in the control arm), followed by SAVR (23% in the intervention arm; 26% in the control arm), less than a quarter stated they were unsure (13% in the intervention arm; 22% in the control arm), and only a handful reported not wanting treatment (3% in the intervention arm; 7% in the control arm). Treatment received was also similar between arms, with most patients receiving TAVR (52% in the intervention arm; 50% in the control arm); however, control arm patients received neither TAVR nor SAVR (21%) more often than intervention arm patients (3%), while intervention arm patients received SAVR (45%) more often than control arm patients (29%).

Preference-concordance was similar between arms, with just over half of patients receiving concordant care (61% in the intervention arm; 54% in the control arm). Although the rates of informed, patient-centered decisions were higher in the intervention arm than those in the control arm (intervention: 57%, control: 33%), this difference did not reach statistical significance ($P = .13$, $\varphi = 0.2$; Table 2, $P > .13$).

Of the 44 patients who had documented visits with both members of the HVT in our hospital system during the study period, more than half (59% [26/44]) of patients completed the study questionnaire after interacting with 1 HVT member, and the rest (41% [18/44]) competed it

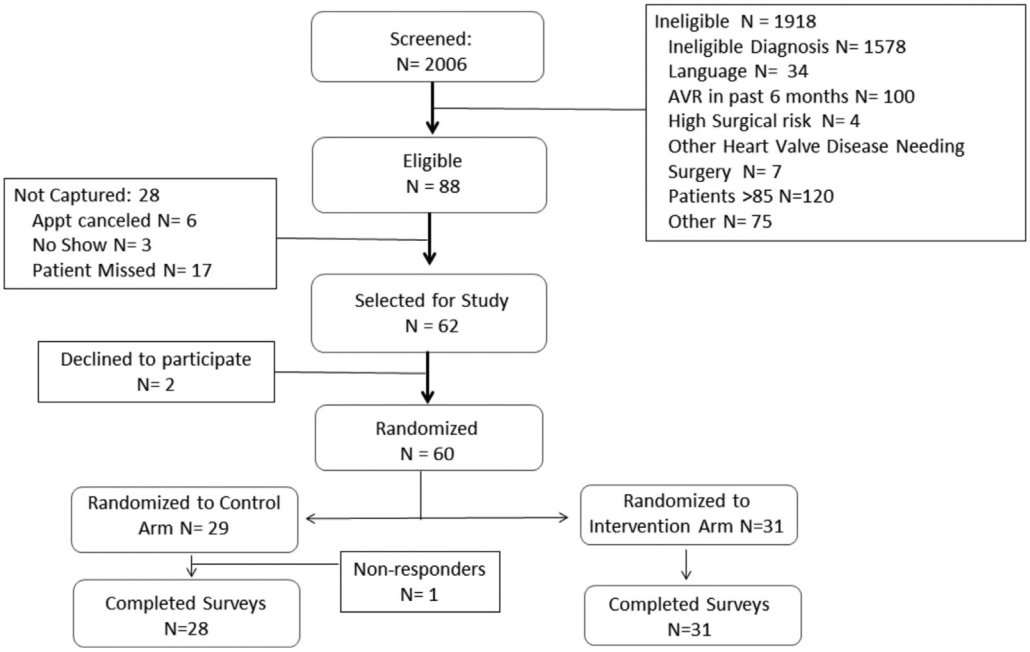

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram. Appt, Appointment; AVR, aortic valve implantation or aortic valve replacement.

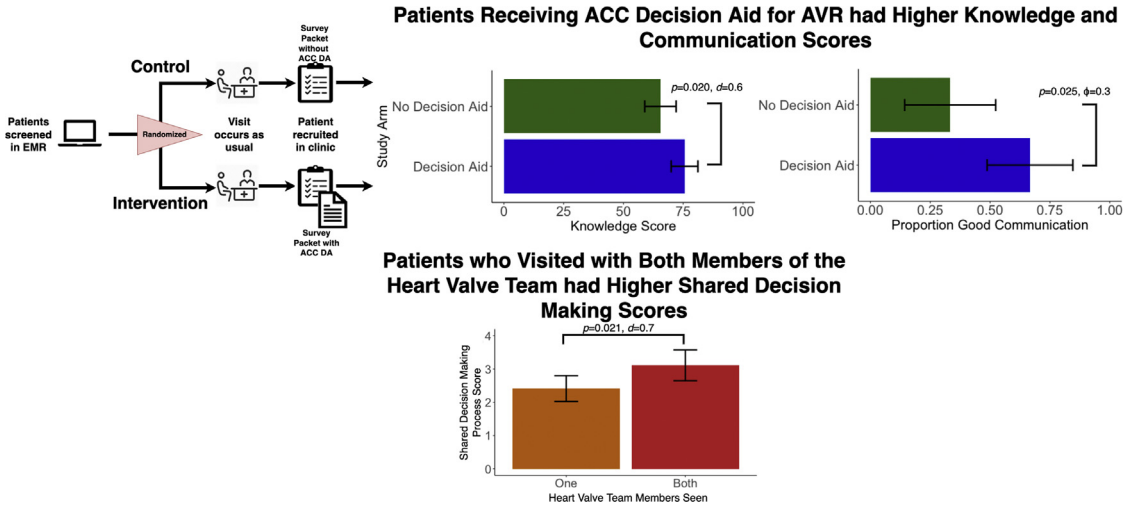

Figure 2. A randomized pilot study of patients with severe aortic stenosis receiving the American College of Cardiology decision aid versus usual care.

after meeting with both members. Patients who completed the questionnaire after visits with both HVT members had higher shared decision-making process scores (M = 3.1, SD = 0.9) than those who had only seen 1 HVT specialist (M = 2.4, SD = 1.0; t(42) = 2.4, $P = .021$, d = 0.7; Fig. 2). Knowledge; SURE top scores; CollaboRATE top scores; informed, patient-centered decisions; preference match; decision stage; treatment preference; and treatment received did not differ between those who completed the questionnaire after visits with both HVT members and those who completed the questionnaire after a visit with only 1 HVT member ($Ps > .18$; Table 3).

Discussion

Clinical practice guidelines and CMS each recommend the use of shared decision-making and HVT assessments for patients being evaluated for SAVR or TAVR in order to encourage the appropriate use of each procedure, to enhance patient education and understanding of each treatment modality, and to facilitate team-based care for managing patients through the preprocedural and postprocedural phases of care. This randomized pilot study is the first to examine the impact of these recommendations on low- to intermediate-risk aortic stenosis patients being evaluated for TAVR and SAVR and also to investigate the efficacy of the American College of Cardiology DA for intermediate- to high-surgical-risk patients with aortic stenosis. We found that the DA was associated with greater knowledge and higher communication ratings in patients considering TAVR or SAVR. The DA did not appear to impact decisional conflict or the likelihood of patients receiving their preferred treatment. Additionally, we found that patients who met with both cardiology and cardiac surgery members of the HVT had higher shared decision-making process scores than those who had only met with 1 member. Our pilot study demonstrates the feasibility of enrolling patients with severe aortic stenosis in a randomized trial to evaluate a DA intervention.

Table 1. Characteristics of study population.

Characteristic	Intervention n = 31	Control n = 28	Overall N = 59
Age, years	74 ± 6	71 ± 8	72 ± 7
Women	39 (12/31)	25 (7/28)	32 (19/59)
Education			
High school graduate or less	12 (3/28)	25 (7/28)	18 (9/56)
Some college	32 (9/28)	29 (8/28)	30 (17/56)
4-Year college graduate	18 (5/28)	18 (5/28)	18 (10/56)
More than 4-year degree	39 (11/28)	29 (8/28)	34 (19/56)
Reviewed all decision aids	68 (21/31)	NA	68 (21/31)
STS risk score	1.5 [2.7]	1.3 [1.3]	1.4 [1.7]
Hypertension[a]	88 (21/24)	88 (15/17)	88 (36/41)
Diabetes mellitus[a]	29 (7/24)	41 (7/17)	34 (14/41)
Renal replacement therapy[a]	4 (1/24)	6 (1/17)	5 (2/41)
Lung disease requiring O_2[a]	4 (1/24)	6 (1/17)	5 (2/41)
Prior myocardial infarction[a]	5 (1/21)	18 (3/17)	11 (4/38)
Estimated GFR, mL/min/1.73 m^2[a,b]	62.7 ± 25	71.9 ± 24	66.2 ± 25

Values are mean ± standard deviation, % (n/N), or median [interquartile range]. GFR, glomerular filtration rate; NA, not applicable; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement.

[a] Data only available for 41 of the patients who underwent TAVR, or SAVR, from registries.

[b] Data only available for 39 patients.

There is limited literature examining DAs in the context of aortic stenosis. Coylewright et al[6] found that the knowledge scores of patients with aortic stenosis choosing between TAVR and medical management were 13% higher for patients whose doctors used an in-visit DA than for usual care patients. Furthermore, they found that patient satisfaction was higher when an in-visit DA was used. However, similar to our study, they found low decisional conflict overall (only 4% of patients were conflicted) and no differences in decisional conflict between DA patients and usual care patients.

This pilot study has provided evidence of feasibility for conducting shared decision-making implementation research in this patient population, as well as preliminary data on efficacy for the American College of Cardiology DA. Our study protocol was simple and feasible within our clinical workflow; patients were provided the handout with a straightforward explanation by a nonclinician study staff. The results support the need for future, well-powered studies to investigate the effectiveness of DAs

The latest systematic review of patient DAs across a myriad of broad clinical scenarios found an overall increase in knowledge of about 13% across studies, which is similar to what we found here (10% increase in knowledge).[5] Although the analysis did not reach statistical significance, we also found that patients who received the DA were more likely to make informed, patient-centered decisions (24% higher rate), which is similar in magnitude to the effect reported in the systematic review. One key finding that differs from the larger literature is the lack of impact on decisional conflict. It is not entirely clear why the DA did not impact this outcome. However, as three-quarters of the usual care group felt unconflicted, it is possible that usual care at our site, or the HVT assessment, is sufficient to ensure most patients felt sure about their decision, thus making it difficult to demonstrate a marked improvement. A more detailed measure of decisional conflict (ie, the full decisional conflict scale[17] and not just the SURE subset of items) may be more sensitive to potential benefits of the DA.

Table 2. Descriptive statistics and test statistics for comparisons of study arms.

Measure	Intervention	Control	t(df) or χ^2 (df)	*P*	d or φ
Knowledge[a]	75.6 ± 15	65.5 ± 16.9	2.4 (56)	.02	0.6
SDM process[a]	2.8 ± 0.9	2.6 ± 1.1	0.5 (57)	.643	0.1
SURE top score	74 (23/31)	75 (21/28)	0 (1)	1	0.0
CollaboRATE top score	67 (20/30)	33 (9/27)	5.1 (1)	.025	0.3
IPC	57 (17/30)	33 (9/27)	2.2 (1)	.134	0.2
Preference concordance	61 (19/31)	54 (15/28)	0.1 (1)	.737	0
Decision stage			0.8 (3)	.851	0.1
Not thought about it	3 (1/31)	7 (2/28)			
Thinking about it	19 (6/31)	21 (6/28)			
Close to choosing	16 (5/31)	11 (3/28)			
Made a choice	61 (19/31)	61 (17/28)			
Treatment preference			2 (3)	.563	0.2
SAVR	23 (7/31)	26 (7/27)			
TAVR	61 (19/31)	44 (12/27)			
No treatment	3 (1/31)	7 (2/27)			
Unsure	13 (4/31)	22 (6/27)			
Treatment received within 3 mo of visit			5.2 (2)	.074	0.3
SAVR	45 (14/31)	29 (8/28)			
TAVR	52 (16/31)	50 (14/28)			
Neither[b]	3 (1/31)	21 (6/28)			

Values are mean ± standard deviation or % (n/N).
IPC, informed, patient-centered; SAVR, surgical aortic valve replacement; SDM, shared decision-making; TAVR, transcatheter aortic valve replacement.
[a] Indicates the use of *t* test.
[b] Neither here indicates that the patient did not receive TAVR or SAVR.

Table 3. Descriptive statistics and test statistics for comparisons of exposure to the heart team.

Measure	Both members	One member[a]	t(df) or χ^2(df)	*P*	d or φ
Knowledge[b]	71.3 ± 17	68.7 ± 13.9	0.6 (41)	.580	0.2
SDM process[b]	3.1 ± 0.9	2.4 ± 1.0	2.4 (42)	.021	0.7
SURE top score	67 (12/18)	77 (20/26)	0.2 (1)	.506	0.1
CollaboRATE top score	50 (9/18)	52 (13/25)	0 (1)	1	0.0
IPC	47 (8/17)	48 (12/25)	0 (1)	1	0.0
Preference match	56 (10/18)	62 (16/26)	0 (1)	.761	0.0
Decision stage			3.1 (3)	.363	0.3
Not thought about it	11 (2/18)	4 (1/26)			
Thinking about it	17 (3/18)	23 (6/26)			
Close to choosing	22 (4/18)	8 (2/26)			
Made a choice	50 (9/18)	65 (17/26)			
Treatment preference			2 (2)	.493	0.2
SAVR	6 (1/17)	19 (5/26)			
TAVR	76 (13/17)	62 (16/26)			
No treatment[c]	6 (1/17)	0 (0/26)			
Unsure	12 (2/17)	19 (5/26)			
Treatment received			1.5 (1)	.18	0.2
SAVR	17 (3/18)	42 (11/26)			
TAVR	72 (13/18)	58 (15/26)			
Neither[d,c]	11 (2/18)	0 (0/26)			

Values are mean ± standard deviation or % (n/N).
HVT, heart valve team; IPC, informed, patient-centered; SAVR, surgical aortic valve replacement; SDM, shared decision-making; TAVR, transcatheter aortic valve replacement.
[a] For those patients who were surveyed after interacting with 1 member of the heart team, 18 were from the intervention arm; 21 had seen only a valve team cardiologist. Although these analyses only contained 44 patients, sensitivity analyses that categorized all other patients as visiting with only one member of the HVT showed similar results, but we reported only on the smaller sample here for clarity.
[b] Indicates the use of *t* test.
[c] Given small sample sizes, this level of the variable was removed from the χ^2 analysis.
[d] Neither here indicates that the patient did not receive TAVR or SAVR.

across a diverse set of clinical sites. Importantly, future studies should be powered to not only test for efficacy of the DA but also use more complex multilevel models that allow researchers to adjust for the individual effects of particular physicians on patient's experiences. Furthermore, our study raises important implementation questions regarding when in the process the DA may be most helpful and effective.

This study provides objective evidence in support of the current CMS mandate for a multidisciplinary HVT assessment. Our results are the first to suggest that the HVT assessment may lead to patients experiencing greater shared decision-making. Although we were not able to determine the mechanism by which the HVT impacted shared decision-making, it is possible that patients were benefiting from hearing the clinical explanation multiple times, having multiple opportunities for questions, having additional time to process the information given to them, or perhaps the requirement to meet with 2 specialists emphasized to the patients that there was a decision to be made cooperatively. While our current sample was too small to analyze for interactions between the intervention and exposure to the HVT, future research should test if this interaction is present. As the multidisciplinary process leads to patients getting information at different time points, understanding this process will help us decipher the best time to give patients a DA.

Limitations

Our study must be interpreted in the context of several limitations. The pilot study had a small sample size and was not powered to detect differences between treatment groups. Because completion of the study survey was used to imply consent to participate in this pilot study, subjects were randomized prior to providing implicit consent. While this approach may result in an imbalance between randomly assigned study arms, only 3 patients in our study failed to complete the study survey. Formal informed consent may be considered in future larger studies prior to randomization to mitigate this risk. Ethnic and racial homogeneity of the study cohort limits the generalizability of our results and reflects previously identified disparities in the management of aortic stenosis.[18] Furthermore, a quarter of patients did not have documented visits with both HVT members during the 3-month study window. Delays in outpatient care relating to the COVID-19 pandemic may have slowed the evaluation and the visit with the second HVT member. It is also possible that the patient met with a cardiologist or cardiac surgeon outside of our hospital system. Patients aged 55-59 and 80-85 years may not have been considered strongly for both treatment modalities, limiting their perception of a decision.

Conclusions

Within a randomized pilot study, we found that the American College of Cardiology DA for patients deciding between TAVR and SAVR increased knowledge and improved perceived communication. We also found that patients evaluated by both cardiology and cardiac surgery HVT specialists experienced greater shared decision-making, supporting the societal clinical practice guideline and CMS mandates for shared decision-making and multidisciplinary HVT assessment for patients being considered for AVR.

Declaration of competing interest

Dr Passeri has received institutional research support from Edwards Lifesciences; has been a speaker at an educational symposium sponsored

by Medtronic; and has received consulting fees from Medtronic. Dr Inglessis has received institutional research support from Medtronic, St. Jude Medical, and W.L. Gore and Associates and is a proctor for Medtronic and Edwards Lifesciences. Dr Elmariah has received research grants from Edwards Lifesciences, Medtronic, and Abbott and consulting fees from Edwards Lifesciences. All other authors have reported that they have no relationships to disclose.

Funding sources

The study was funded through internal departmental funds.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at https://doi.org/10.1016/j.jscai.2022.100025.

References

1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Transcatheter Aortic Valve replacement (TAVR)*(20.32)*; 2012. Accessed June 1, 2019. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=355.
2. Centers for Medicare & Medicaid Services. *Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R)*; 2019:150. Accessed June 1, 2019. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=293.
3. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2021;143(5):e35–e71. https://doi.org/10.1161/CIR.0000000000000923.
4. Légaré F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Educ Couns*. 2008;73(3):526–535. https://doi.org/10.1016/j.pec.2008.07.018.
5. Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2017;4(4):CD001431. https://doi.org/10.1002/14651858.CD001431.pub5.
6. Coylewright M, O'Neill E, Sherman A, et al. The learning curve for shared decision-making in symptomatic aortic stenosis. *JAMA Cardiol*. 2020;5(4):442–448.
7. CardioSmart, American College of Cardiology. A decision aid for treatment options for severe aortic stenosis for patient deciding between TAVR and surgery. 2017. Accessed June 1, 2019. https://www.cardiosmart.org/docs/default-source/assets/decision-aid/aortic-stenosis-tavr-surgery.pdf?sfvrsn=a59c08f5_1.
8. Waksman R, Rogers T, Torguson R, et al. Transcatheter aortic valve replacement in low-risk patients with symptomatic severe aortic stenosis. *J Am Coll Cardiol*. 2018;72(18):2095–2105. https://doi.org/10.1016/j.jacc.2018.08.1033.
9. Sepucha KR, Atlas SJ, Chang Y, et al. Informed, patient-centered decisions associated with better health outcomes in orthopedics: prospective cohort study. *Med Decis Making*. 2018;38(8):1018–1026. https://doi.org/10.1177/0272989X18801308.
10. Valentine KD, Vo H, Fowler FJ, Brodney S, Barry MJ, Sepucha KR. Development and evaluation of the shared decision making process scale: a short patient-reported measure. *Med Decis Making*. 2021;41(2):108–119. https://doi.org/10.1177/0272989X20977878.
11. Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G. The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. *J Med Internet Res*. 2014;16(1):e2. https://doi.org/10.2196/jmir.3085.
12. Légaré F, Kearing S, Clay K. Are you SURE? Assessing patient decisional conflict with a 4-item screening test. *Can Fam Physician*. 2010;56(8):e308–e314.
13. O'Connor A. User manual - measures of decision/choice predisposition. 1996. Accessed June 1, 2019. https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_ChoicePredisposition_Decision.pdf.
14. RStudio Team. RStudio: integrated development for R. 2016. Accessed August 1, 2016. http://www.rstudio.com/.
15. R Core Team. R: A language and environment for statistical computing. 2018. Accessed August 1, 2016. https://www.r-project.org/.
16. Montgomery P, Grant S, Mayo-Wilson E, et al. Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 extension. *Trials*. 2018;19:407. https://doi.org/10.1186/s13063-018-2733-1.
17. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15(1):25–30. https://doi.org/10.1177/0272989X9501500105.
18. Alkhouli M, Holmes DR, Carroll JD, et al. Racial disparities in the utilization and outcomes of TAVR: TVT registry report. *JACC Cardiovasc Interv*. 2019;12(10):936–948. https://doi.org/10.1016/j.jcin.2019.03.007.