Does the Use of a Decision Aid Improve Decision Making in Prosthetic Heart Valve Selection?

A Multicenter Randomized Trial

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Background—A Dutch online patient decision aid to support prosthetic heart valve selection was recently developed. A multicenter randomized controlled trial was conducted to assess whether use of the patient decision aid results in optimization of shared decision making in prosthetic heart valve selection.

Methods and Results—In a 5-center randomized controlled trial, patients were allocated to receive either standard preoperative care (control group) or additional access to the patient decision aid (intervention group). Legally capable adult patients accepted for elective isolated or combined aortic and mitral valve replacement were included. Primary outcome was preoperative decisional conflict (Decisional Conflict Scale); secondary outcomes included patient knowledge, involvement in valve selection, anxiety and depression, (valve-specific) quality of life, and regret. Out of 306 eligible patients, 155 were randomized (78 control and 77 intervention). Preoperative decisional conflict did not differ between the groups (34% versus 33%; P=0.834). Intervention patients felt better informed (median Decisional Conflict Scale informed subscore: 8 versus 17; P=0.046) and had a better knowledge of prosthetic valves (85% versus 68%; P=0.004). Intervention patients experienced less anxiety and depression (median Hospital Anxiety and Depression Scale score: 6 versus 9; P=0.015) and better mental well-being (mean Short Form Health Survey score: 54 versus 50; P=0.032). Three months postoperatively, valve-specific quality of life and regret did not differ between the groups.

Conclusions—A patient decision aid to support shared decision making in prosthetic heart valve selection does not lower decisional conflict. It does result in more knowledgeable, better informed, and less anxious and depressed patients, with a better mental well-being.

Clinical Trial Registration—http://www.trialregister.nl. Unique identifier: NTR4350.

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For heart valve replacement, 2 types of valve substitutes are available: mechanical and biological valves. Mechanical valves are designed to last a lifetime but require lifelong anticoagulation because of their increased thrombogenicity, resulting in an increased bleeding risk and increased risk of complications during pregnancy. Biological valves do not require long-term anticoagulation, unless another indication is present. However, they are subject to valve deterioration over time, and patients may require one or more reoperations later in life. The European Society of Cardiology Guidelines on the management of cardiovascular diseases during pregnancy state that a desire for pregnancy is considered an indication for a biological valve.[1] Given the different nature of mechanical versus biological prosthetic valve-related risks and benefits and the fact that the choice for either of the prosthetic heart valves is often highly value sensitive,[2] current clinical practice guidelines recommend shared decision making (SDM) and explicit consideration of patient preferences in prosthetic

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WHAT IS KNOWN

- Prosthetic heart valve selection is often highly value sensitive.
- Current clinical practice guidelines recommend explicit consideration of patient preferences in prosthetic heart valve selection.
- Many patients experience decisional conflict and suboptimal involvement in prosthetic valve selection and have limited knowledge of the advantages and disadvantages of mechanical and biological valves.

WHAT THE STUDY ADDS

- A patient decision aid in the setting of prosthetic heart valve selection does not reduce decisional conflict.
- It does improve the quality of decision making by better informing patients, reducing anxiety and depression, and improving mental health before the operation.

heart valve selection.[3,4] In a previous study, we have shown that many patients experience decisional conflict and suboptimal involvement in prosthetic valve selection and have limited knowledge of the advantages and disadvantages of mechanical and biological valves.[5]

Because no tools to support SDM are available in this setting, an online patient decision aid (PDA) to support prosthetic heart valve selection was recently developed in the Netherlands. The PDA informs patients about the available treatment options, encourages participation in decision making, and helps patients to assess their prosthetic valve preferences in relation to their values and goals in life, so they are optimally prepared to participate in prosthetic valve selection with their treating physician.[6]

We tested in a multicenter randomized controlled trial the hypothesis that the use of the PDA results in an improved quality of decision making in prosthetic heart valve selection compared with standard preoperative care in patients accepted for aortic and mitral valve replacement. Quality of decision-making measures included decisional conflict (primary outcome measure), patient knowledge, patient participation in decision making, anxiety and depression, health-related quality of life (QoL), valve-specific QoL, and patient regret.

Methods

Trial Design

A prospective, 1:1 randomized, open, parallel-design clinical trial was conducted in 5 Dutch hospitals between May 2014 and May 2016.

Participants

Eligible participants were adult patients who were accepted for elective isolated or combined aortic valve replacement and mitral valve replacement. Patients who were legally incapable were excluded. Eligible patients were contacted by phone, several weeks before their valve replacement surgery, and asked to participate. If a patient was willing to participate, he/she received an information letter, and written informed consent was obtained. Participants were recruited from 5 Dutch hospitals; 4 academic centers and 1 nonacademic hospital.

The study was approved by the institutional review board of all 5 participating centers (Erasmus MC MEC no 2013–569). The study is reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines for cluster-randomized trials.

Intervention

The PDA was developed in a Delphi process according to the International Patient Decision Aids Standards.[7] In October 2012, a steering group, consisting of 2 cardiothoracic surgeons, 2 cardiologists, 2 patient representatives, and an epidemiologist, was formed, and the scope and purpose of the PDA were determined. α and β testing were performed to investigate comprehensibility, acceptability, and usability of the PDA by patients and clinicians. Based on this information, a draft of the PDA was developed by the steering group. Next, the comprehensibility and acceptability of the PDA by patients and clinicians was assessed. After that, the PDA was again reviewed by the steering group, and field tests were performed with patients and clinicians to assess usability. The steering group reviewed the test results, and the PDA was finalized. For a more detailed description of the development of the PDA, see Appendix I in the Data Supplement.

The final PDA is an online tool (www.hartklepkeuze.nl) and contains 2 sections: an information section on heart function, heart valve disease, available heart valve prostheses, the operation, living with a heart valve prosthesis, and hyperlinks for further information; and the actual PDA, which is made up of 7 parts: (1) introduction and personal information (patients may optionally enter age and sex), (2) information on the 2 options (mechanical or biological valve), (3) a comparison of the options (if patient has entered age and sex, then age- and sex-specific estimates of the lifetime risk of bleeding with a mechanical prosthesis and reoperation with a biological valve are displayed), (4) exploration of personal feelings about the 2 options, (5) a knowledge quiz, (6) exploration of patient preference, and (7) a summary of the results of the PDA that can be printed or e-mailed for use in the doctor's office.[7]

The clinical pathway for patients who are referred for heart valve replacement at the participating centers is as follows: referral letters and required patient information are sent to the secretariat of the department of cardiothoracic surgery. A heart team next discusses each patient, and a decision is made whether to pursue surgery or an alternative treatment strategy. After the patient is accepted for surgery, an invitation from the preoperative outpatient clinic is sent to the patient. At this point in time, the patient was invited to participate in the trial. Patients in the intervention group received a username and password to gain access to the PDA before the preoperative consultation. From that moment on, they had free access to the PDA and were able to visit the PDA as often as they preferred. Next, the patient was seen in the preoperative outpatient clinic, and the prosthetic valve choice was discussed. Physicians who performed the preoperative consultation were informed about the trial and were able to answer questions of the patient with regard to the PDA. Most often, the patient was seen by the surgeon before surgery, and then, the definitive choice for a prosthetic valve was made.

Outcomes

Patients completed 2 questionnaires, one preoperatively after surgical workup (including the preoperative consultation) and the other 3 months postoperatively.

Demographic questions included sex, age, and education. Highest educational level was assessed with a multiple choice question, which consisted of the following categories: college graduate or higher, high school graduate, less then high school, and other. Other baseline questions included assessment of which clinician (surgeon, cardiologist, both, or other) performed the preoperative consultation, whether a friend or family member was involved in prosthetic valve choice, and patient opinion on the amount of time available for prosthetic valve choice. Three months postoperatively, self-reported New York Heart Association Class was assessed through a multiple choice question.

Primary Outcome

Decisional Conflict

The Decisional Conflict Scale (DCS) was used preoperatively to measure degree of uncertainty about which course of action to take (in this case prosthetic valve selection) and the main modifiable factors contributing to uncertainty. It is a 16-item questionnaire with 5 subscales: uncertainty, informed, values clarity, support, and effective decision. Total scores <25 are associated with no decisional conflict and implementation of decision. Scores exceeding 25 are associated with decisional conflict. Scores ≥37.5 are associated with decision delay or feeling unsure about implementation.[8]

Secondary Outcomes

Patient Knowledge

Preoperatively and 3 months postoperatively, basic knowledge concerning prosthetic valves and patient self-perceived sufficiency of knowledge concerning prosthetic heart valves were assessed by multiple choice questions and a 1 to 5 Likert Scale.[9]

Patient (Preference for) Involvement in Prosthetic Valve Selection

Preoperative and 3 months postoperative patient perceived experience with involvement in prosthetic valve selection and preferences for involvement in prosthetic valve selection, and final decision for a prosthetic valve were assessed with multiple choice questions and the Control Preferences Scale.[10,11]

Anxiety and Depression

The Hospital Anxiety and Depression Scale was used to assess preoperative and 3 months postoperative symptoms and severity of anxiety and depression.[12,13]

Health-Related QoL

Health-related QoL was assessed preoperatively and 3 months postoperatively with the Dutch version of the Short Form Health Survey (SF-36).[14,15]

Valve-Specific QoL

Valve-specific QoL was assessed 3 months postoperatively with 7 valve-specific questions.[16,17]

Patient Regret

Patient regret with regard to prosthetic valve selection was assessed 3 months postoperatively with the Decision Regret Scale. A score of 0 means no regret; a score of 100 means high regret.[18]

Sample Size

The sample size calculation was based on our primary outcome, decisional conflict. In total, 140 patients were needed to detect an effect size of 0.35 on the DCS (2-tailed, power 80%, α=0.025).[19]

Randomization

Patients were randomly assigned (1:1) to standard preoperative care (control group) or standard preoperative care plus additional use of the PDA (intervention group) with permuted block sizes of 10, stratified by center.

The randomization sequence was generated by an independent statistician using a random number generator. Allocations were placed in serially numbered, opaque, sealed envelopes by 2 independent research assistants. The investigators were unaware of allocation sequence to ensure allocation concealment. They selected the next randomization envelope in sequence, and outcome was noted in a randomization and identification log.

Blinding

Because of the nature of the intervention, it was not possible to blind investigators and patients to the allocation.

Statistical Methods

All outcomes were analyzed according to the intention-to-treat principle.[20] Continuous variables are displayed by the mean and SD if normally distributed and by the median and range if there was no normal distribution. The distribution of the continuous variables was tested using the Kolmogorov–Smirnov test. Categorical variables are displayed as counts and percentages. Group comparison was done using the unpaired *t* test for continuous data with a normal distribution. In case of ordinal data or data with no normal distribution, we used the Mann–Whitney *U* test or the χ^2 test. To compare preoperative and postoperative group responses, the paired *t* test or Wilcoxon signed-rank test was used where appropriate. Multiple imputations (5 iterations) were used to impute missing DCS values. For the imputation, we used the 16 items of the DCS. In 2 patients, the DCS was completely missing, so we did not impute these data. In 18 patients, one or more items were missing, and in 90% of these cases, it concerned 1 question. We performed post hoc sensitivity analyses to assess the potential influence of imbalances in baseline characteristics on the effect of the use of the PDA on the primary outcome DCS by performing ordinal regression analyses. For some of the questions, patients had the option to choose I don't know or not applicable as an answer. These 2 options were omitted from the group comparisons.

All tests were 2-sided, and a $P \leq 0.05$ was considered statistically significant. All statistical analyses were performed using IBM-SPSS 20 (IBM Corp, Armonk, NY).

Results

Between May 2014 and March 2015, 306 patients were accepted for elective aortic valve replacement and mitral valve replacement in 1 of the 5 participating centers. The follow-up period lasted until June 2015, and study closure was in May 2016. Of these 306 eligible patients, 155 patients provided written informed consent and were randomized, of whom 78 received standard preoperative care and 77 received standard preoperative care and additional access to the PDA. One hundred and thirty-eight patients (71 allocated to the control group and 67 allocated to the intervention group) completed the preoperative questionnaire (Figure 1). Main reasons for declining informed consent, besides one patient who declined to participate, were the absence of a computer at home, a language barrier, or a postponed operation.

Patient characteristics, other baseline data, and the patient-reported implanted heart valve type are presented in Table 1. As there seemed to be potential imbalances in the baseline characteristics preoperative consultation and involved in prosthetic valve choice, we first performed an ordinal regression analysis to assess the effect of the use of the DA on the primary outcome DCS without correction for these potential imbalances, and next, a multivariable ordinal regression analysis with the 2 baseline characteristics included. There was no influence of the 2 baseline characteristics on the effect of the use of the PDA on the DCS (uncorrected exp β=0.90; *P*=0.38; corrected exp β= 0.94; *P*=0.63).

Table 2 presents the results for the primary outcome, preoperative decisional conflict. Figure 2 presents preoperative (preference for) involvement in prosthetic valve selection. Postoperatively, there were some minor changes in (preference for) involvement in prosthetic valve selection in comparison to the preoperative results: a larger proportion of patients totally agreed that they were involved in prosthetic valve choice (*P*=0.061); and in the intervention group postoperatively, a larger proportion of patients was of the opinion that it is important to be involved in prosthetic valve choice

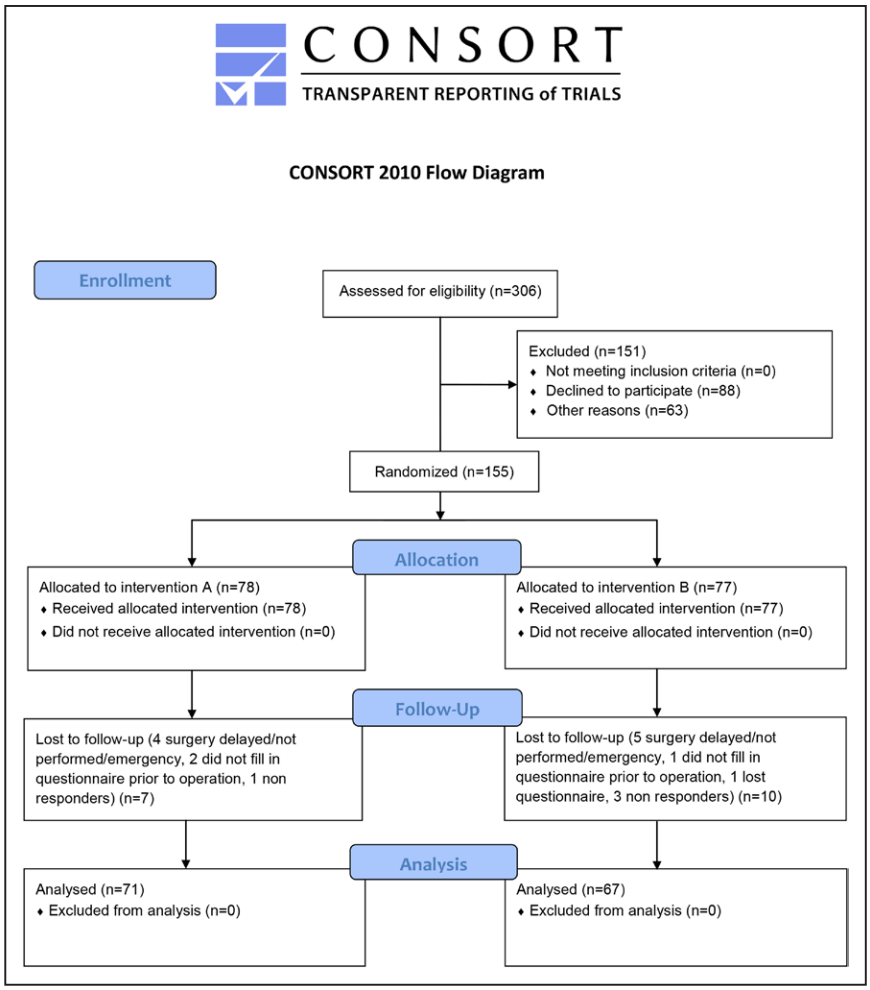

Figure 1. Flowchart.

(*P*=0.066). Table 3 shows preoperative and 3 months postoperative patient knowledge. Table 4 presents preoperative and postoperative anxiety and depression (Hospital Anxiety and Depression Scale) and health-related QoL (SF-36). Three months postoperatively, 84% of patients were in New York Heart Association class I or II. Table 5 presents valve-specific QoL 3 months postoperatively. Three months postoperative regret with regard to prosthetic valve choice ranged from 0 to 55, with no statistical difference between the intervention and control groups. The majority of patients in the intervention and control groups did not experience any regret (70% versus 64%, respectively; *P*=0.513). Patients who were more involved in prosthetic valve choice experienced less regret 3 months postoperative (*P*=0.001).

Discussion

For most patients, there is no right or wrong choice in prosthetic valve selection. Therefore, for this trial, it was decided to evaluate the effect of the PDA on the quality of decision making, patient knowledge, and patient anxiety and QoL, rather than its potential effect on prosthetic valve selection and clinical outcomes. The most important findings of the trial are that, although it fails to show an effect on the primary outcome measure, preoperative decisional conflict, a PDA to support SDM in the setting of prosthetic heart valve selection results before surgery in more knowledgeable, better informed, and less distressed patients with a better patient mental well-being.

Preoperative decisional conflict was common: one third of patients experienced decisional conflict, and 1 out of 6 patients to such an extent that they felt unsure about the prosthetic valve choice. There was relatively no effect of the PDA on preoperative decisional conflict. According to the DCS subscales, intervention patients felt more informed. Both groups scored relatively low, indicating that they felt good informed. However, the magnitude of the difference between the groups is impressive, namely, 9 (intervention group 8 and control group 17). Intervention patients felt more informed but also seemed a bit more uncertain, which may explain why the PDA failed to improve decisional conflict. It seems that the underlying assumption that more knowledge about a topic will automatically lead to more certainty in judgment may not be necessarily true. Also, the quantity of information needed to be comfortable in the decision-making process may show strong individual differences. Eventually, it may be that we just have to accept a certain level of decisional conflict and support our patients herein only by recognition of this problem. What remains then is to concentrate on the optimum quantity and quality of information and maybe personalize this for different types of people.[21] It is also possible that the failure of improving decisional conflict is in part because of the fact that the PDA is not yet implemented into the clinical

Table 1. Patient Characteristics and Other Baseline Data

	Intervention Group (n=67)	Control Group (n=71)
Age, y, median (range)	66 (22–82)	68 (31–84)
Male sex, n (%)	51 (76)	53 (75)
Patient-reported educational level, n (%)		
<High school	13 (19)	19 (27)
High school graduate	34 (51)	31 (44)
College graduate	18 (28)	16 (23)
Other	2 (3)	4 (6)
Missing	0	1 (1)
Patient-reported implanted prosthesis type*, n (%)		
Mechanical valve	16 (24)	15 (21)
Biological valve	37 (55)	42 (59)
Other	1 (2)	2 (3)
Do not know	6 (9)	4 (6)
Missing	7 (10)	8 (11)
Preoperative consultation by, n (%)		
Surgeon	27 (40)	20 (28)
Cardiologist	26 (39)	36 (51)
Other	14 (21)	15 (21)
Involved in prosthetic valve choice, n (%)		
Family member	26 (39)	38 (54)
Friend	1 (2)	0
Other	10 (15)	4 (6)
No one else	30 (45)	27 (38)
Missing	0	2 (3)
Enough time available for prosthetic valve choice, n (%)		
Yes	48 (72)	43 (61)
No	2 (3)	3 (4)
I do not know	2 (3)	2 (3)
I did not have to make a decision	15 (22)	20 (29)
Missing	0	3 (4)

*This is the patient-reported prosthesis type that the patient received. It was assessed postoperatively.

Table 2. Preoperative Decisional Conflict

	Intervention Group (n=66)	Control Group (n=70)
Decisional conflict, n (%)		
>25	22 (33)	24 (34)
>37.5	11 (16)	13 (18)
Total score, median (range)	24 (0–69)	24 (0–72)
Informed subscale*	8 (0–100)	17 (0–100)
Clarity subscale	28 (0–72)	27 (0–93)
Support subscale	25 (0–78)	25 (0–72)
Uncertainty subscale	40 (0–92)	33 (0–100)
Effectiveness subscale	6 (0–100)	6 (0–100)

*$P<0.05$ intervention vs control group.

care path. The PDA helped patients to prepare for choosing a particular valve prosthesis, and also the treating physician needs to be prepared to engage into SDM. Participating patients sometimes were informed by a physician who stated that a choice was already made by the heart team or that there was no choice. One can imagine that this will have led to an increase in decisional conflict, in particular, more uncertainty. Therefore, besides refinement of the PDA and formal implementation of the PDA in the care path (including a change in healthcare policy that rewards SDM), education of the treating physicians will be necessary, and hopefully, this will result in reduction of decisional conflict.

Interestingly, intervention patients did not only feel more informed but also they actually had better preoperative knowledge with regard to prosthetic heart valves. It, therefore, seems that the PDA is an important source of information for patients who are facing a heart valve replacement. This is in line with a previous systematic review on PDAs in a wide variety of diseases, which showed that PDAs improve patient knowledge.[22] As improved patient knowledge is associated with improved therapy compliance and reduced healthcare costs, the use of this PDA might also help healthcare cost containment.[23,24]

This trial also shows that most patients prefer to participate in decision making and indicate that prosthetic heart valve selection should be a joint decision of the patient and the physician. However, about a quarter of the patients felt that they did not have a choice, and 20% were of the opinion that one was not involved in prosthetic valve selection. A considerable part of the patients was of the opinion that they did not have to make a decision with regard to prosthetic valve choice. In other words, their doctor made the decision. It is not clear whether prosthetic valve choice was actually not possible or SDM was not applied. We have shown in a previous study that although Dutch cardiologists and cardiothoracic surgeons consider patient involvement in prosthetic valve selection, it seems that there is room for improvement in its practical application.[2] To better serve patient needs with regard to participation in decision making, SDM should be implemented in the medical curriculum and tools to support SDM such as information portals and PDAs should be implemented in the care path.

We additionally investigated whether use of the PDA reduces anxiety and depression and improves QoL because it has been shown that patient participation in clinical decision making may improve QoL in a variety of medical conditions.[25,26] The current trial confirms these observations as intervention patients had a better mental QoL preoperatively compared with control patients. Not surprisingly, use of the PDA has no effect on the physical QoL, which is severely influenced by the heart valve disease for which surgical treatment is needed. Furthermore, as can be expected, physical QoL was evidently better 3 months postoperatively compared with preoperatively in both the intervention and control groups, illustrating the relief of symptoms by the surgical treatment. Intervention patients experienced less preoperative

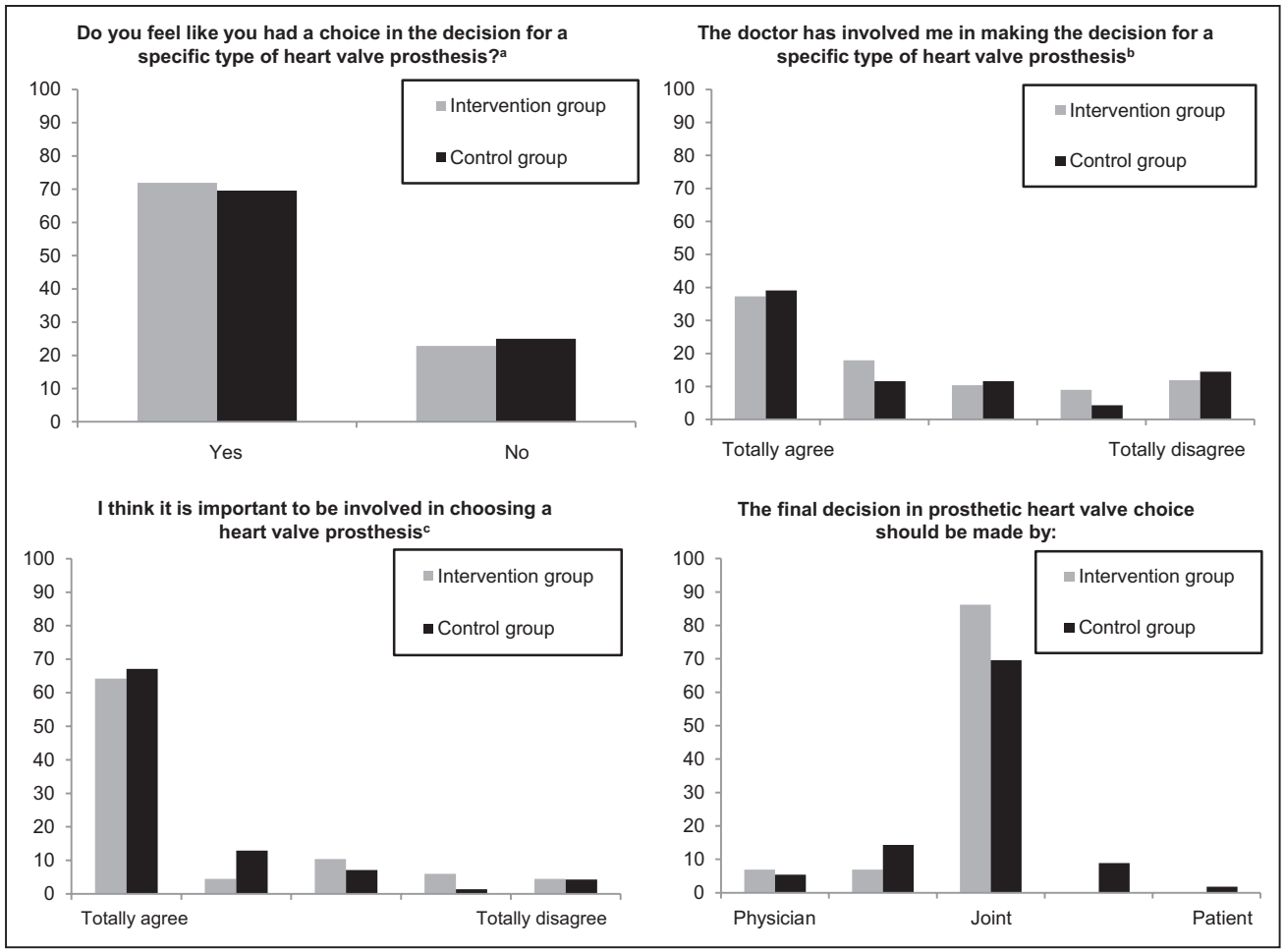

Figure 2. Preoperative patient (preference for) involvement in prosthetic valve selection. [a]Percentages of patients in the intervention and control groups who answered "I do not know" (5.3% and 5.4%, respectively). [b]Percentages of patients in the intervention and control groups who answered "I do not know" (1.5% and 4.3%, respectively) and "not applicable" (11.9% and 14.5%, respectively). [c]Percentages of patients in the intervention and control groups who answered "I do not know" (1.5% and 1.4%, respectively) and "not applicable" (9% and 5.7%, respectively).

anxiety and depression. It can be debated whether anxiety is an appropriate measure to evaluate a PDA, because it is known from the literature that anxiety can be associated with more effective decision making. Furthermore, the heart valve replacement itself can cause a raised level of anxiety.[27] In our randomized trial, the PDA did reduce anxiety. The reason

Table 3. Patient Knowledge

	Preoperative		Postoperative	
Basic knowledge, n (%)	Intervention Group	Control Group	Intervention Group	Control Group
What type of aortic valve prosthesis is the most durable?	63 (94)	59 (83)	58 (94)	56 (86)
Which type of aortic valve prosthesis has the highest risk of causing blood clots?*,†	57 (85)	51 (72)	55 (89)	51 (79)
With which type of aortic valve prosthesis does one have to use lifelong anticoagulation?†	61 (91)	58 (82)	57 (92)	55 (85)
All questions correct*	57 (85)	48 (68)	51 (82)	48 (74)
2 questions correct	4 (6)	10 (14)	7 (11)	7 (11)
1 question correct	2 (3)	3 (4)	3 (5)	4 (6)
0 questions correct	3 (5)	9 (13)	1 (2)	5 (8)
Missing	1 (2)	1 (1)	0	1 (2)
Patient self-perceived sufficiency of knowledge	49 (73)	44 (62)	54 (87)	49 (77)

*$P<0.05$ intervention vs control group preoperatively.
†$P<0.05$ intervention vs control group postoperatively.

Table 4. HADS and SF-36 Outcomes

	Preoperative		Postoperative	
	Intervention Group	Control Group	Intervention Group	Control Group
HADS, median (range)*,†	6 (0–33)	9 (0–41)	3 (0–38)	4 (0–21)
Anxiety, n (%)†				
Normal (0–7)	20 (30)	17 (24)	49 (79)	56 (86)
Mild (8–10)	31 (46)	38 (54)	2 (3)	2 (3)
Moderate (11–14)	13 (19)	9 (13)	5 (9)	4 (6)
Severe (15–21)	3 (5)	7 (10)	1 (2)	0
Missing	0	0	5 (8)	3 (5)
Depression, n (%)†				
Normal (0–7)	0	0	49 (79)	60 (92)
Mild (8–10)	16 (24)	16 (23)	5 (8)	2 (3)
Moderate (11–14)	51 (76)	55 (78)	2 (3)	1 (2)
Severe (15–21)	0	0	2 (3)	0
Missing	0	0	4 (7)	2 (3)
Quality of life, mean (SD)				
PCS†	41 (11)	39 (11)	44 (10)	44 (10)
MCS*	54 (9)	50 (11)	54 (10)	53 (10)
Physical functioning†	63 (24)	57 (26)	74 (23)	75 (22)
Role physical*	50 (42)	35 (43)	50 (42)	52 (43)
Bodily pain	74 (24)	74 (24)	76 (24)	78 (21)
General health†	61 (20)	56 (22)	68 (20)	68 (19)
Vitality†	58 (22)	56 (22)	67 (24)	66 (20)
Social functioning*	81 (22)	70 (26)	77 (27)	78 (22)
Role emotional*	81 (34)	67 (40)	80 (37)	80 (33)
Mental health†	80 (16)	73 (21)	82 (17)	81 (16)

*$P<0.05$ intervention vs control group preoperatively.

†$P<0.05$ preoperative versus postoperative total group.

HADS indicates Hospital Anxiety and Depression Scale; MCS, Mental Component Scale; PCS, Physical Component Scale; and SF-36, Short Form Health Survey.

for this remains to be elucidated. This was the first randomized trial that evaluated a PDA in the field of prosthetic heart valve selection. It is possible that a PDA reduces anxiety in this particular field, also because SDM is not often applied.[5] Additionally, as can be expected, the surgical treatment resulted in a dramatic decrease in anxiety and depression. Of note, in contrast to the preoperative results, there were no differences 3 months postoperatively in anxiety, depression, and QoL between intervention and control patients. It, therefore, seems that a PDA to support prosthetic heart valve selection is particularly effective in preoperative reduction of anxiety and depression and improvement of patient mental well-being. Whether this is clinically meaningful can of course be debated, but given the consistent direction of these differences in favor of the use of the PDA, we think we can state that the use of the PDA has a positive effect on the mental well-being of patients at the time of decision making.

Patients who were more involved in prosthetic valve choice experienced less regret postoperatively. It is important to keep in mind that it is possible that patients who were more involved in decision making have different patient characteristics than patients who were less involved and that this is the reason for the observed difference. Overall regret, however, was low despite the suboptimal decision making in the current trial. It is possible that the phenomenon of choice closure contributed to this. Choice closure is the process by which people come to perceive a decision to be resolved and complete. As choice closure results in less regret, it can explain at least in part why the vast majority of patients did not have any regret with regard to their prosthetic valve choice.[28]

Three months postoperative valve-specific QoL did not differ between the groups and revealed that most common valve-related concerns among patients are valve sound and possible bleeding caused by anticoagulation therapy. It is known that patients sometimes experience fear of rare valve-specific limitations, despite the preoperative information they received.[29] We hypothesized that a PDA provides

Table 5. Three Months Postoperative Valve-Specific QoL

	Intervention Group, %	Control Group, %	*P* Value
If I had to do it over again, would I make the same decision to have surgery?			
Yes	93	90	0.717
I do not know	3	6	
No	…	2	
Missing	3	3	
Is there a valve sound that bothers me?			
Never/rarely	69	66	0.487
Occasionally	23	15	
Frequently/always	3	12	
Missing	5	6	
Following my valve surgery, the frequency of doctor visits and blood tests bothers me.			
Never/rarely	71	72	0.819
Occasionally	21	19	
Frequently/always	2	6	
Missing	7	3	
The possibility of complications due to my implanted valve concerns me.			
Never/rarely	78	68	0.116
Occasionally	11	28	
Frequently/always	6	2	
Missing	5	3	
I am concerned about possible bleeding caused by my anticoagulant medication.			
Never/rarely	66	63	0.235
Occasionally	27	23	
Frequently/always	2	11	
Missing	5	3	
I am afraid that my valve may fail.			
Never/rarely	84	85	0.668
Occasionally	10	11	
Frequently/always	2	2	
Missing	5	3	
I am afraid that I may need another valve operation.			
Never/rarely	77	80	0.187
Occasionally	18	17	
Frequently/always	…	…	
Missing	5	3	

understandable information that helps patients to clarify valve-specific limitations. Our results, however, did not endorse this hypothesis.

With regard to future research, it would be useful to consider a trial that looks into the effect of the use of a PDA on the prosthetic heart valve choice that is eventually made, now that we know that the quality of decision making is positively influenced by the use of a PDA.

Limitations

This study population represents Dutch cardiovascular clinical practice and may not be generalizable to other countries. Unfortunately, although every effort was made to recruit all eligible patients, patient recruitment was low (155/306). Main reasons were the absence of a computer at home, a language barrier (the Netherlands has an increasingly diverse population with many nationalities and cultural backgrounds), or a postponed operation. These reasons underline the importance of expanding the delivery modes (also provide a paper version) and language options of the PDA to improve uptake. Not all randomized patients completed the preoperative questionnaire, which may have resulted in selection bias. Because of privacy law regulations in the Netherlands, we are unable to register information of patients who were invited to participate in the trial but who declined to participate or did not fill in the preoperative questionnaire. Therefore, we are unable to report any details on those patients or to perform a sensitivity analysis to assess the degree of selection bias introduced by the missing preoperative questionnaires.

The results in this randomized trial are based on self-reported outcomes during a small time window (preoperatively and 3 months postoperatively). The potential longer-term effects of the use of the PDA remain unexplored.

Questionnaires were completed at home, and patients may have been influenced by family members or friends.

Patient age ranged from 22 through 84 years, and it may well be that particular age groups (eg, young adult patients) potentially benefit more from the use of a PDA than others. Given the limited sample size of this study, age sub groups were not analyzed but are worthwhile exploring in future studies.

Although the PDA was developed according to the International Patient Decision Aids Standards in a Delphi process including all stakeholders, it may be that the PDA is not yet optimally tailored to the needs of Dutch patients and the Dutch healthcare system. Continuous maintenance and further improvement of the PDA in a joint effort of all stakeholders is required to ascertain an effective and sustainable tool to support the SDM process in Dutch clinical practice.

With regard to patient experience with involvement in prosthetic valve selection patients had the option to choose not applicable in the questionnaire. This term may have been misinterpreted by patients because several patients chose not applicable because their doctor made the decision with regard to prosthetic valve type. This also applies to the questions concerning information provision. It is recommended that the option not applicable is not added to future questionnaires.

Conclusions

A PDA in the setting of prosthetic heart valve selection does not reduce decisional conflict. It does improve the quality of decision making by better informing patients, reducing anxiety and depression, and improving mental health before the operation. Effective implementation of the PDA in the care path of patients who require aortic and mitral valve replacement is the

next major step forward in improving clinical decision making and will hopefully help to lower overall decisional conflict.

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Disclosures

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Does the Use of a Decision Aid Improve Decision Making in Prosthetic Heart Valve Selection?: A Multicenter Randomized Trial

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SUPPLEMENTAL MATERIAL

Appendix 1

The PDA was developed in a Delphi process according to the International Patient Decision Aids Standards (IPDAS). [1]

First, a survey among 117 cardio-thoracic surgeons and cardiologists was conducted, to assess and compare their opinion on (1) patient involvement, (2) risk conveyance in aortic valve selection, and (3) aortic valve preferences. Most respondents agreed that patients should be involved in decision-making, with surgeons more leaning toward patient involvement (always: 83% versus 50% respectively; $p<0.01$) than cardiologists. Most respondents found that ideally doctors and patients should decide together, with cardiologists more leaning toward taking the lead compared to surgeons ($p<0.01$). Major risks of the therapeutic options were usually discussed with patients, and less common complications to a lesser extent. A wide variation in valve preference was noted with cardiologists more leaning toward mechanical prostheses, while surgeons preferred bioprostheses more often ($p<0.05$). The conclusion of this survey was that patient involvement and risk conveyance in aortic valve selection was considered important by cardiologists and cardio-thoracic surgeons. Medical profession influenced attitude with regard to aortic valve selection and patient involvement, and preference for a valve substitute. The variation in valve preference suggested that in most patients both valve types are suitable and aortic valve selection may benefit from evidence-based informed shared decision-making. [2]

Second, a prospective multicenter cohort study was set up. Aim of the study was to assess among adult patients accepted for aortic valve replacement (AVR): (1) experience with current clinical decision-making regarding prosthetic valve selection, (2) preferences for SDM and risk presentation, and (3) prosthetic valve knowledge and numeracy. Patients were surveyed preoperatively and 3 months postoperatively. Preoperatively 132 patients (89 males/43 females; mean age 67 years (range 23-86)) responded. Decisional conflict was observed in 56% of patients, and in 25% to such extent that it made them feel unsure about the decision. Sixty-eight percent wanted to be involved in decision-making, whereas 53% agreed they actually were. Sixty-nine percent were able to answer three basic knowledge questions concerning prosthetic valves correctly. Fifty-six percent were able to answer three basic numeracy questions correctly. Three months post-surgery 90% (n=110) were satisfied with their aortic valve prosthesis, with no difference between mechanical and bioprosthetic valve recipients. This cohort study showed that in current clinical practice many AVR patients experience decisional conflict, suboptimal involvement in prosthetic valve selection, and exhibit impaired knowledge concerning prosthetic valves and numeracy. Given the broad support for SDM among AVR patients and obvious need for understandable information, to-be-developed tools to support SDM in the setting of prosthetic valve selection will help to improve quality of decision-making, better inform and actively involve patients, and reduce decisional conflict.

In addition to the studies among clinicians and patients, a steering group, consisting of two cardio-thoracic surgeons, two cardiologists, two patient representatives and an epidemiologist, was formed. Based on the information from the clinicians and patients study, the draft of the PDA was developed by the steering group. Next step was to check the comprehensibility and acceptability of the PDA by patients (alpha testing 1) and clinicians (alpha testing 2).

Alpha testing 1 was conducted by means of a focus group. We approached eight patients with a prosthetic heart valve and seven of them participated. Two main subjects were discussed: 1) differences between a mechanical and biological valve that are essential to make a choice, and 2)

other information that should be included in the PDA. Any additional information from the focus group meeting was incorporated in the PDA.
Alpha testing 2 was conducted by the steering group. We tried and tested the PDA on different devices. We also looked for errors in the text. After alpha testing 1 and 2, the PDA was again reviewed by the steering group. The PDA was modified according to the decisions from the steering group. After that field tests were performed with patients (beta testing 1) and clinicians (beta testing 2) to assess usability. We contacted eight clinicians (cardio-thoracic surgeons and cardiologists) and eleven patients who underwent an aortic valve replacement by e-mail. We sent the clinicians and patients a review form which contained the following questions: 1) what do you think is missing?, 2) what can be improved?, and 3) are there things unclear? Furthermore we asked the clinicians and patient to grade the following things: 1) lay-out, 2) user-friendliness, 3) speed, 4) comprehensibility, and 5) general impression. Seven patients and one clinician responded. After beta testing the steering group reviewed the test results, made changes to the PDA in case this was necessary and the PDA was finalized.

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