Evidence-based surgery: Dissemination, communication, decision aids

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The effects of a decision aid regarding treatment options for patients with an asymptomatic abdominal aortic aneurysm: a randomized clinical trial

ABSTRACT

Introduction: Abdominal aortic aneurysm patients tend to be informed inconsistently and incompletely about their disorder and the treatment options open to them. A decision aid may address these challenges. The objective of this trial was to evaluate whether these patients are better informed and experience less decisional conflict regarding their treatment options after viewing a decision aid.

Methods: A six-centre, randomised clinical trial comparing a decision aid versus regular information from the surgeon. Patients included had been recently diagnosed with an asymptomatic abdominal aortic aneurysm of at least 4 cm in diameter. The decision aid consisted of an interactive CD-ROM elaborating on elective surgery versus watchful waiting. Generally, the decision aid advised patients with aneurysms <5.5 cm to agree with watchful waiting, for larger aneurysms the decision aid provided insight into the balance of benefit and harm of a surgical and conservative approach, taking age, co morbidity and size of the aneurysm into account. The primary outcome was patient decisional conflict measured at one month follow-up. Secondary outcomes were patient knowledge, anxiety and satisfaction.

Results: In total, 178 abdominal aortic aneurysm patients were included. Decisional conflict scores did not differ significantly between the decision aid and the regular information groups (22 vs. 24 on a 0-100 scale; p=0.33). Patients in the decision aid group had significantly better knowledge (10.0 vs. 9.4 out of 13 points; p=0.04), while anxiety levels (4.4 and 5.0 on a 0-21 scale; p=0.73) and satisfaction scores (74 and 73 on a 0-100 scale; p=0.81) were similar in both groups.

Conclusion: In addition to regular patient-surgeon communication, a decision aid helps to share treatment decisions with abdominal aortic aneurysm patients by increasing their knowledge about the disorder and available treatment options without raising anxiety levels; however, it does not reduce decisional conflict, nor does it improve satisfaction.
INTRODUCTION

Most abdominal aortic aneurysms are found coincidentally during ultrasonography or CT scanning, after which patients will consult a surgeon for further information and advice. The rupture of these aneurysms entails a high mortality rate, but the majority of patients remain asymptomatic and will eventually die from another disease. Therefore, the patient’s risk of rupture during watchful waiting should be weighed against the benefits and risks of elective aneurysm repair.

In addition to the legal imperative to inform patients about their health, surgeons have an ethical obligation to share important decisions with their patients. This has been formulated in a recent statement on the role patients should play in healthcare decisions. In daily practice, however, aneurysm patients tend to be informed inconsistently about their disorder and available treatment options, while the amount of information given is often less than is legally required. Moreover, patients who have undergone elective abdominal aneurysm repair or have declined surgery reported being unaware of their options when making the treatment decision.

A decision aid, used in conjunction with regular patient-surgeon communication, may address these limitations by informing and involving patients in the decision making process. Decision aids typically contain information on treatment options and outcomes relating to the patient’s health status and explore patient preferences and values. Evidence from a recent systematic review shows that decision aids in general can help increase the patient’s knowledge about the disease, reduce their decisional conflict and improve patient-clinician communication.

We had previously developed a decision aid considering elective surgery and watchful waiting for patients with an asymptomatic abdominal aortic aneurysm. The aim of the current study was to evaluate whether patients recently diagnosed with an asymptomatic abdominal aortic aneurysm benefit from using this decision aid in addition to regular information from their surgeon. Benefit was primarily defined in terms of less decisional conflict regarding treatment options. Furthermore, we evaluated whether patients who used the decision aid were better informed about the disorder, less likely to be anxious, and more satisfied in terms of their communication with the surgeon. Final treatment choice and health outcomes, such as aneurysm rupture, post-operative mortality and morbidity and physical quality of life, were also documented.

METHODS

Trial design

We conducted a six-centre, randomised clinical trial in the Netherlands (DECAID-trial; registered as NTR1524) comparing an additional decision aid versus regular information as
provided by the surgeon regarding elective surgery and watchful waiting for asymptomatic abdominal aortic aneurysms. The study was approved by the local medical ethics review board of each participating centre. The trial was designed, conducted and described according to the revised CONSORT statement.\textsuperscript{11}

**Intervention: decision aid in addition to regular information**

The intervention consisted of an interactive computer program provided on a CD-ROM. This program presents up-to-date, evidence-based information about abdominal aortic aneurysms and its treatment options i.e. elective aneurysm surgery and watchful waiting and the pros and cons of those treatment options, as is required by European law.\textsuperscript{2} In the decision aid patients with aneurysms <5.5 cm were advised to agree with watchful waiting, in keeping with available evidence from randomised clinical trials at that time.\textsuperscript{12,13} For patients with aneurysms $\geq 5.5$ cm the decision aid provided a comprehensive insight into the balance of benefit and harm of a surgical (open and endovascular) and a conservative approach, taking age, co-morbidity and size of the aneurysm into account. The program also includes a number of questions that invite the patient to clarify his or her preferences. (For example: To what extent would you be anxious or worried if you do not get surgical treatment?) Patients with aneurysms $\geq 5.5$ cm were not advised towards a certain treatment option. Finally, the only decision to be considered by the patient was about whether to perform elective surgery or watchful waiting. This decision aid meets the quality criteria for patient decision support technologies developed by the International Patient Decision Aids Standards Collaboration.\textsuperscript{8} The development and content of the decision aid have been described in detail elsewhere.\textsuperscript{10}

**Participants**

Eligible patients were identified between November 2008 and June 2011 at the outpatient clinics of the participating centres. Inclusion criteria were: patients of at least 18 years of age, with an asymptomatic abdominal aortic aneurysm who were visiting the outpatient clinic for the first time with an aneurysm diameter of at least 4.0 cm as confirmed by ultrasonography or CT scanning. Patients also had to understand Dutch well enough so as to be able to participate in the study. Exclusion criteria were: estimated life expectancy of less than a year or lack of the physical or mental capacity needed in order to provide informed consent.

**Eligibility**

During their first contact, the consulting surgeon briefly informed the patients, thereby fulfilling the inclusion criteria and asking for their verbal consent to participate in the study. Patients then received a brochure about the study and a baseline questionnaire to take home. If favourably disposed towards trial participation, they provided written informed
consent and returned the baseline questionnaire to the research centre in a pre-paid envelope.

Randomisation

Computer-generated randomisation (ALEA v. 2.2, NKI-AVL, Amsterdam, the Netherlands) was performed by one of the investigators after the patient’s informed consent form was received or confirmed by a phone call from one of the recruiting centres. Given that aneurysm size and operative risk may influence the extent of decisional conflict, minimisation was applied to ensure a well-balanced distribution of patients. In patients with an aneurysm diameter of less than 5.5 cm, surgery is not considered to be beneficial according to available evidence.\textsuperscript{12-16} The Glasgow Aneurysm Score predicts surgery outcome based on the patient’s age, preoperative renal function, cerebrovascular events and cardiac events. Validated cut-off levels classify patients into those with a low-risk and those with a high-risk of post-operative complications and death.\textsuperscript{17,18} The minimisation algorithm therefore contained the following factors: (1) aneurysm diameter either below 5.5 cm or at least 5.5 cm; and (2) either low or high operative risk, i.e. Glasgow Aneurysm Score below 81 or at least 81. Although more recent validation studies advocate other predictive models,\textsuperscript{19-22} the Glasgow Aneurysm Score was applied here as it guided treatment decision making and surgeons’ communication with the patient considering elective aneurysm repair at the time of the study.

Procedures

After randomisation, patients in the control group did not receive any intervention apart from the regular information provided by their surgeon. Patients allocated to the decision aid were invited to the outpatient clinic within three weeks or, if applicable, before their second outpatient consultation. The decision aid was viewed in a private room. A research assistant was present in order to ensure that the patient viewed the decision aid and that the program functioned properly. The research assistant was available to the patient for technical support only. If participants were unable to come to the outpatient clinic, they viewed the decision aid at their home in the presence of the research assistant. All other aspects of care for aneurysm patients in both the intervention and control groups (diagnostic work-up, watchful waiting, (endo)vascular procedures) were performed according to the Dutch national guideline on abdominal aortic aneurysm treatment.\textsuperscript{23}

Patients, investigators and research assistants could not be blinded after group assignment, a factor which is inherent to the intervention and the design of the study. Surgeons and nurses involved in the outpatient care of the participants were blinded to the patient’s allocation group, although patients were not prohibited from sharing their allocation with the care providers.
Follow-up

Patients received additional questionnaires during the follow-up period which they were invited to return by mail. This took place 1, 4 and 10 months after the date of randomisation.

Primary outcome

The primary outcome was decisional conflict as measured by the validated Decisional Conflict Scale at baseline and after one month follow-up.\textsuperscript{24,25} This 16-item scale expresses the degree of uncertainty within an individual about which course of action to undertake. Scores range from 0 (none at all) to 100 (severe decisional conflict). The one-month time interval was chosen because, by then, patients were supposed to have made their treatment decision while elective surgery would probably not have been performed yet. Decisional conflict assessment was repeated at 4 months and 10 months after the date of randomisation.

Secondary outcomes

Patient knowledge of the disorder and treatment options was assessed by means of 13 items of the Dutch multiple-choice Aneurysm Knowledge Questionnaire at baseline and after the one-month follow-up.\textsuperscript{26} The score ranges between 0 (no understanding at all) and 13 points (complete understanding). Levels of anxiety were measured at baseline and at the 1-month, 4-month and 10-month follow-ups, using the validated Hospital Anxiety and Depression Scale. Employing the items which question anxiety on this scale, the anxiety score ranges from 0 to 21.\textsuperscript{27,28}

Patient satisfaction with respect to the conversation with the surgeon at the outpatient clinic was assessed by means of the Patient Satisfaction Questionnaire at baseline and after the one month follow-up. The questionnaire consists of five visual analogue scales, anchored at 0 and 100; the Dutch translation of the questionnaire has been validated in a previous study.\textsuperscript{29-31} Physical quality of life was measured with the widely used and validated Medical Outcomes Study 12-Item Short-Form Health Survey at baseline and after all follow-up events.\textsuperscript{32} The scale renders a score ranging from 0-100 points.

The other outcomes were retrieved from medical records 10 months after the date of randomisation: final treatment choice, aneurysm rupture, possible date of surgery, and postoperative mortality and major morbidity. Major morbidity was defined as postoperative complications interfering with everyday activities in the long term, such as re-operation in the event of bowel ischemia or peripheral ischemia, renal failure requiring dialysis, pulmonary embolus, stroke and myocardial infarction or arrhythmia requiring resuscitation.\textsuperscript{33}
Sample size

In order to estimate the necessary group size, a previous study on a decision aid for benign prostatic hypertrophy patients was chosen because of the similarity of the study and the likely similarities of the sex and age distribution of the participants. A pre-study power analysis showed that a group size of 85 would allow us to detect a significant difference of 7.5 points on the 100-point Decisional Conflict Scale between groups at one month after inclusion with a power of 90% and at a significance level of 0.05, assuming a mean decisional conflict score of 32.5 in patients assigned to the decision aid group and a standard deviation of 15. Allowing for attrition of 5% during the first month, we planned to include a total of 178 asymptomatic abdominal aortic aneurysm patients.

Data collection and analysis

The total number of eligible patients was determined in retrospect by examining the medical records of all patients who had been documented with an abdominal aortic aneurysm-related code when entering the outpatient clinic during the inclusion period.

The following information was collected from patients’ medical records at baseline: aneurysm diameter, smoking status, hypertension, hypercholesterolemia, diabetes, stroke, transient ischemic attack, myocardial infarction, angina pectoris, heart failure and chronic or acute kidney failure.

Exclusion of study participants with missing values on one or more items can cause biased results and decreases statistical efficiency. For this reason, missing values in our dataset were completed by multiple imputation analysis. This method uses all available data to impute the missing values based on the correlation between variables with missing values and all other variables. If one of the outcome measures of a patient had more than 25% missing values, that particular outcome measure of said patient was excluded from the analyses.

All analyses were made on an intention to treat basis. For group comparisons of continuous variables (decisional conflict, knowledge, anxiety, satisfaction and physical quality of life), we used analysis of covariance (ANCOVA), using the baseline value as a covariate in order to reduce residual variance in our comparisons and to correct for possible differences in the corresponding measure at baseline. For group comparisons of categorical variables, we used the Chi-square test or Fisher’s exact test in the event of an expected count below 10. A p-value <0.05 was considered to indicate a significant difference. We used SPSS for Windows, version 19.0 (IBM SPSS, Armonk, NY, USA).

In terms of the primary outcome, two subgroup analyses were planned: one for patients with aneurysms larger than 5.5 cm, given that these patients were expected to experience high levels of decisional conflict and could therefore benefit more from the decision aid; and the second for patients with an aneurysm measuring less than 5.5 cm, given that they were expected to experience less decisional conflict due to the presence of clear-cut evidence to support performing watchful waiting at this stage.
RESULTS

Out of 1,072 patients documented with an abdominal aortic aneurysm-related code during the inclusion period, 718 appeared ineligible for reasons displayed in Figure 1. Another 176 patients were not randomised because of the following reasons: they were not asked to participate, they declined to participate, their co-morbidity threatened their life expectancy so that a 10-month follow-up was likely not to be completed, or for other reasons. Eventually, 178 asymptomatic abdominal aortic aneurysm patients participated in the study. Patients included were predominantly male and on average just over 70 years of age with a mean aneurysm diameter of 5.4 cm (Table 1). At baseline, about half of the patients stated to prefer elective surgical repair; about a third preferred watchful waiting and a minority indicated to be unsure.

Of the included patients, 176 (99%) actually received the intervention they had been allocated to, i.e. regular information from the surgeon or additional viewing of the decision aid (Figure 1). Outcomes at one month of follow-up were available for 166 (93%).

**Figure 1. Flowchart**

Assessed for eligibility (n=1072)

- Ineligible (n=718)
  - No abdominal aortic aneurysm (n=126)
  - Patient not newly diagnosed (n=253)
  - Elective surgery performed already (n=143)
  - Aneurysm < 4 cm (n=165)
  - Symptomatic aneurysm suspected (n=31)

- Not randomised (n=176)
  - Language barrier (n=4)
  - Physically or mentally unable (n=10)
  - Life expectancy < 1 year (n=18)
  - 2nd opinion (n=17)
  - Missed inclusion (n=89)
  - Declined to participate (n=38)

Randomized (n=178)

Allocated to decision aid group (n=91)
  - Received allocated intervention (n=89)
  - Did not receive allocated intervention: elective aneurysm repair shortly after randomisation (n=2)

Allocated to control group (n=87)
  - Received allocated intervention (n=87)

Loss to follow-up (n=10)
  - Life expectancy < 1 year (n=2)
  - Too nervous concerning aneurysm (n=1)
  - Language barrier for questionnaire (n=1)
  - Lost to follow up (n=6)

Follow-up at one month (n=81)
  - Excluded from analysis (n=0)

Follow-up at one month (n=85)
  - Excluded from analysis (n=0)
Table 1. Baseline characteristics of patients in both randomization arms.

<table>
<thead>
<tr>
<th></th>
<th>Decision aid group (n=91)</th>
<th>Control group (n=87)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>80 (88%)</td>
<td>75 (86%)</td>
</tr>
<tr>
<td>Age in years (SD)</td>
<td>74 (8)</td>
<td>72 (9)</td>
</tr>
<tr>
<td>Aneurysm diameter in cm (SD)</td>
<td>5.3 (1.0)</td>
<td>5.4 (1.1)</td>
</tr>
<tr>
<td>Glasgow Aneurysm Score (SD)</td>
<td>76 (11)</td>
<td>75 (11)</td>
</tr>
<tr>
<td>Cerebrovascular comorbidity (%)</td>
<td>14 (15%)</td>
<td>11 (13%)</td>
</tr>
<tr>
<td>Impaired kidney function (%)</td>
<td>5 (5%)</td>
<td>9 (10%)</td>
</tr>
<tr>
<td>Cardiac comorbidity (%)</td>
<td>29 (32%)</td>
<td>32 (37%)</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>12 (13%)</td>
<td>21 (24%)</td>
</tr>
<tr>
<td>Treated for hypertension (%)</td>
<td>46 (51%)</td>
<td>26 (30%)</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>12 (13%)</td>
<td>15 (17%)</td>
</tr>
<tr>
<td>Heart failure (%)</td>
<td>4 (4%)</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Dyslipidemia (%)</td>
<td>35 (38%)</td>
<td>31 (36%)</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease (%)</td>
<td>7 (8%)</td>
<td>15 (17%)</td>
</tr>
<tr>
<td>Smoking (%)</td>
<td>33 (36%)</td>
<td>29 (33%)</td>
</tr>
<tr>
<td>Having a partner (%)</td>
<td>70 (77%)</td>
<td>68 (78%)</td>
</tr>
<tr>
<td>Having children at home (%)</td>
<td>7 (8%)</td>
<td>10 (11%)</td>
</tr>
<tr>
<td>Employment</td>
<td>Employed (%)</td>
<td>Unemployed (%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retired (%)</td>
</tr>
<tr>
<td></td>
<td>8 (9%)</td>
<td>15 (18%)</td>
</tr>
<tr>
<td></td>
<td>64 (70%)</td>
<td>57 (66%)</td>
</tr>
<tr>
<td>Education</td>
<td>Basic education (%)</td>
<td>Secondary education (%)</td>
</tr>
<tr>
<td></td>
<td>49 (54%)</td>
<td>16 (18%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>22 (24%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19 (22%)</td>
</tr>
</tbody>
</table>

SD=standard deviation

that time, 26 patients had already undergone elective aneurysm repair: 10 patients in the control group and 16 patients in the decision aid group. The proportion of values missing varied from 2% to 9% per outcome measure.

At baseline, patients experienced less decisional conflict than was anticipated in the sample size calculation, reflected by the low decisional conflict scores (Table 2). At one-month follow-up, decisional conflict scores had decreased in both randomisation arms, but without a significant difference between the decision aid group and the control group: 22 versus 24 respectively; p=0.33 (Table 2).

After viewing the decision aid, patients had greater knowledge concerning their disorder and the available treatment options when compared to patients allocated to the control group (10.0 vs. 9.4; p=0.04) (Table 2). Patient anxiety levels did not differ between the decision aid and control group at one month follow-up (4.4 and 5.0, respectively; p=0.73). All patients expressed being satisfied with the information and conversation with the surgeon at the outpatient clinic, with no differences between the groups (73 and 73,
respectively; \( p=0.81 \). Physical quality of life scores did not differ between patients in the decision aid group and those in the control group (52 and 53, respectively; \( p=0.27 \)).

The number of patients that eventually underwent elective aneurysm repair was similar in both arms: 39 in the decision aid group and 36 in the control group; \( p=0.84 \) (Table 3). Postoperative mortality and major morbidity was low and did not differ significantly between patients who had versus those who had not viewed the decision aid. The rate of aneurysm rupture during watchful waiting appeared equal in both groups after a 10 month follow-up.

In the subgroup of patients with an aneurysm of 5.5 cm or more (Table 4), decisional conflict scores did not differ significantly between randomisation arms at one-month follow-up (15 in decision aid group versus 15 in control group; \( p=0.93 \)). In patients with an aneurysm of below 5.5 cm, baseline decisional conflict levels appeared to be higher

### Table 2. Results of the outcome measures per treatment arm at baseline and follow-up. Values are given in means (standard deviations).

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>1 month</th>
<th>ANCOVA*</th>
<th>4 months</th>
<th>10 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decisional Conflict score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision aid group</td>
<td>31 (20)</td>
<td>22 (17)</td>
<td>( p=0.33 )</td>
<td>19 (14)</td>
<td>21 (17)</td>
</tr>
<tr>
<td>Control group</td>
<td>29 (18)</td>
<td>24 (17)</td>
<td></td>
<td>22 (17)</td>
<td>18 (17)</td>
</tr>
<tr>
<td>Knowledge about disorder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision aid group</td>
<td>9.0 (2.5)</td>
<td>10.0 (2.2)</td>
<td>( p=0.04 )</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Control group</td>
<td>8.8 (2.3)</td>
<td>9.4 (2.1)</td>
<td></td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Anxiety level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision aid group</td>
<td>4.9 (4.2)</td>
<td>4.4 (3.6)</td>
<td>( p=0.73 )</td>
<td>4.2 (4.0)</td>
<td>4.3 (4.2)</td>
</tr>
<tr>
<td>Control group</td>
<td>5.7 (4.0)</td>
<td>5.0 (4.0)</td>
<td></td>
<td>4.6 (3.7)</td>
<td>4.5 (4.3)</td>
</tr>
<tr>
<td>Satisfaction level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision aid group</td>
<td>77 (13)</td>
<td>74 (16)</td>
<td>( p=0.81 )</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Control group</td>
<td>75 (15)</td>
<td>73 (19)</td>
<td></td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Physical quality of life</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision aid group</td>
<td>45 (10)</td>
<td>44 (10)</td>
<td>( p=0.80 )</td>
<td>43 (11)</td>
<td>44 (11)</td>
</tr>
<tr>
<td>Control group</td>
<td>44 (10)</td>
<td>43 (10)</td>
<td></td>
<td>43 (11)</td>
<td>42 (11)</td>
</tr>
</tbody>
</table>

* Analysis of covariance test analyzed differences between decision aid group and control group at 1 month follow-up, corrected for baseline values.
NA= not applicable

### Table 3. Additional clinical outcomes

<table>
<thead>
<tr>
<th></th>
<th>Decision aid group (n=91)</th>
<th>Control group (n=87)</th>
<th>Chi(^2) test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective aneurysm repair performed</td>
<td>39 (43%)</td>
<td>36 (41%)</td>
<td>( p=0.84 )</td>
</tr>
<tr>
<td>Elective aneurysm repair &lt; 5.5 cm</td>
<td>6/52 (12%)</td>
<td>8/51 (16%)</td>
<td>( p=0.56 )</td>
</tr>
<tr>
<td>Elective aneurysm repair ≥ 5.5 cm</td>
<td>33/39 (85%)</td>
<td>28/36 (78%)</td>
<td>( p=0.56 )</td>
</tr>
<tr>
<td>Post-operative mortality</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>NA</td>
</tr>
<tr>
<td>Post-operative major morbidity</td>
<td>0 (0%)</td>
<td>2 (6%)</td>
<td>( p=0.23^* )</td>
</tr>
<tr>
<td>Rupture during watchful waiting</td>
<td>0 (0%)</td>
<td>3 (8%)</td>
<td>( p=0.12^* )</td>
</tr>
</tbody>
</table>

NA= not applicable
* Fisher’s exact test
in contrast to baseline levels of the other patients included (Table 4). At the one-month follow-up, there was no statistically significant difference in decisional conflict levels between randomisation arms for patients with an aneurysm of below 5.5 cm (28 and 30, respectively; \( p=0.19 \)).

**DISCUSSION**

This study shows that a treatment decision aid provided to patients recently diagnosed with an abdominal aortic aneurysm did not significantly reduce decisional conflict when used in addition to regular patient-surgeon communication. Patients receiving the decision aid showed greater knowledge of their disorder and available treatment options without being more anxious. However, the decision aid did not increase patient satisfaction or health outcomes.

As opposed to previous reviews on decision aids in surgery,\(^7,9\) in our study no significant reduction in patients’ decisional conflict was found. Moreover, decisional conflict levels appeared to be lower than we anticipated. This may have several explanations. Firstly, elective aneurysm surgery differs from other types of surgery in that patients are asymptomatic at the time of making the decision whilst they have to consider the risk of fatal aneurysm rupture. Therefore, it is a commonly accepted practice to extensively inform patients about the surgical procedure, potential complications, prognosis and alternative treatment options. If necessary, patients are invited for a second consultation at the outpatient clinic.

Secondly, this study was powered to detect a significant difference of 7.5 points on the 100-point Decisional Conflict Scale. The fact that we failed to find a significant effect does not preclude that smaller differences from using a decision aid exist in this application. However, one could question the clinical relevance of slight reductions in decisional conflict. It is unknown to what extent decisional conflict scores need to be lowered in order to find an improvement that is, besides statistically significant, also relevant to the patient.\(^{35,36}\)

The subgroup of patients with aneurysms of 5.5 cm or more did not seem to experience higher decisional conflict levels. Our unexpected finding that patients with a small

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**Table 4.** Decisional Conflict Scale scores for subgroups of patients per treatment arm at baseline and follow-up. Values are given in means (standard deviations).

<table>
<thead>
<tr>
<th>Decision aid group</th>
<th>Control group</th>
<th>ANCOVA*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal aortic aneurysm &lt; 5.5 cm</td>
<td>35 (18)</td>
<td>28 (16)</td>
</tr>
<tr>
<td>Abdominal aortic aneurysm ( \geq ) 5.5 cm</td>
<td>26 (22)</td>
<td>15 (14)</td>
</tr>
</tbody>
</table>

* Analysis of covariance test analyzed differences between decision aid group and control group at 1 month follow-up, corrected for baseline values.
aneurysm experienced more decisional conflict could be explained by the fact that these patients tend to have shorter consultations with their surgeon.\textsuperscript{5} Moreover, patients with small aneurysms might not relish the idea of watchful waiting, i.e. postponing elective surgery while running the risk of rupture between follow-up visits.

Our findings of increased patient knowledge with unaltered anxiety levels, satisfaction or health outcomes are in keeping with systematic reviews evaluating previous studies on decision aids in surgery and other medical specialties.\textsuperscript{7,9} One could doubt the relevance of the rather marginal increase in knowledge, although the size of the effect does approach that of a recent systematic review on decision aids in surgery.\textsuperscript{7} In a previous pilot study, patients felt better informed and claimed the decision aid adds value in the decision making process.\textsuperscript{10}

A number of limitations of this study has to be discussed. A considerable number of patients could not be included, were not asked to participate or declined to participate. Based on the motives recorded for declining trial participation, we have no reason to assume that these patients systematically differ from the study participants; however selection bias may have occurred in patients that were not included.

The fact that both patients and surgeons were aware of the aim and subject of the study and could not be blinded to the allocation may have introduced performance bias in terms of altered communication styles. It is possible that surgeons in the contributing centres offered more than average information to their patients.

We also would like to note that the aneurysms in our patients were found coincidentally, mainly during ultrasonography or CT scanning. A screening program for abdominal aortic aneurysm is not currently applied in the Netherlands. It is therefore uncertain to what extent our results can be extrapolated to people whose aneurysm is found by screening.

Future research should focus on identifying specific subgroups of patients which may derive more benefit from the introduction of the decision aid than the entire population of abdominal aortic aneurysm patients. We observed a greater decline in decisional conflict with the decision aid in patients with a small aneurysm, but our study was not powered for evaluating such effects with sufficient precision in subgroups. Patients expressing the need for more explicit information or expressing high decisional conflict scores, and thereby overlooking the full range of consequences of treatment options, may also benefit more from a decision aid.\textsuperscript{35}

The actual use of decision aids in daily clinical practice poses some challenges.\textsuperscript{37} It is up to the surgeon to recognize situations of clinical uncertainty and to acknowledge the importance of sharing treatment decisions with patients. In doing so, some physicians in other medical specialties are reluctant to use decision aids as their use would prolong physician-patient communication.\textsuperscript{38,39} Yet, one could argue that when patients are informed about their condition and treatment options beforehand, actual consultation times might be reduced and interaction optimized, as this time can be focused on resolving remaining areas of uncertainty.
When considering the use of a decision aid, the surgeon also has to evaluate whether the patient would understand the information being provided.\textsuperscript{40,41} Some patients may not understand enough about their health and their condition to be able to make evidence-guided decisions, but such patients may be hard to identify.\textsuperscript{42}

Surgeons in clinical practice face the challenge of sharing aneurysm treatment decisions with patients. This study shows that it can be safe to use a decision aid in addition to regular surgeon patient communication for this purpose, as our use of the decision aid did not increase anxiety, nor did it affect health outcomes. In this way, patients can be provided with complete evidence-based information about their disease and the available treatment options, while their preferences are being elicited as well, irrespective of the hospital or surgeon visited. Nevertheless, the effects of the decision aid in terms of reducing decisional conflict or improving satisfaction are, at best, very limited.

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