Evidence-based surgery: Dissemination, communication, decision aids
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Chapter 7

Design and development of a decision aid to enhance informed decision making by patients with an asymptomatic abdominal aortic aneurysm

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ABSTRACT

Objective: To design, develop, and evaluate an evidence-based decision aid for patients confronted with an asymptomatic abdominal aortic aneurysm to inform them about the pros and cons of the various treatment options and to help them in informed decision making.

Methods: A multidisciplinary team defined criteria for the desired decision aid as to design, medical content and functionality, particularly for elderly users. Development was according to the international standard (IPDAS). A group of 15 patients with an abdominal aortic aneurysm that was either treated or not yet treated evaluated the tool.

Results: A decision aid on CDROM was developed to offer information about the disease, the risks and benefits of surgical treatment and watchful waiting, and the individual possibilities and threats based on the patient’s aneurysm diameter and risk profile. The decision aid was improved and eventually judged favorably by doctors and patients.

Conclusion: This evidence-based decision aid for patients with an abdominal aortic aneurysm, developed according to IPDAS criteria, is likely to offer a simple, and practical tool to uniformly inform patients about the pros and cons of optimal treatment for their aneurysm. It may also be useful to reduce decisional conflict in both patients and doctors.
INTRODUCTION

Patients with a dilatation (aneurysm) of the abdominal aorta may never suffer any symptoms of it during their lifetime or, on the other hand, may die from an unexpected acute rupture of the aneurysm. Approximately 75% of the abdominal aortic aneurysms are asymptomatic and are found coincidentally during physical examination or by ultrasonography or CT scanning. The prevalence is estimated between 1.7% and 6% in the elderly, primarily male, population.

Basically, two treatment options for patients with an abdominal aortic aneurysm exist: elective surgical repair (via an open or endovascular procedure) or watchful observation. Surgical treatments generally intend to heal a disorder or prevent a sequel of it, but can simultaneously inflict harm (i.e. morbidity or even mortality) due to the very procedure. For example, surgery of an abdominal aortic aneurysm should prevent rupture of the aneurysm, but may also induce complications and premature death due to the procedure. Key issues in decision-making are the size of the aneurysm related to risk of aneurysm rupture, and the risk of surgical complications as a result of advanced age or serious (cardiovascular) comorbidity. Hence, patients with small aneurysms (<5.5 cm in diameter) are considered not to require surgery, but are usually managed by means of watchful observation with regular ultrasonography. For larger aneurysms, surgery is commonly advised and applied if the risk of complications is acceptable. However, most patients with a large abdominal aortic aneurysm are at intermediate or high surgical risk due to serious cardiovascular comorbidity. Results of studies have provided insight in the average percentages of benefit (prevention of rupture) and harm (major morbidity and mortality) of elective surgery of an abdominal aortic aneurysm.

As the disorder per se does not necessarily lead to disease, the treating vascular surgeon and the patient face the dilemma of weighing the risk of rupture of the aneurysm during watchful observation against the risk of complications of surgery. Beside the patients’ desire to be informed, health care laws increasingly demand from physicians to inform their patients about any (major) risk of medical interventions. Hence, especially in the case of an abdominal aortic aneurysm, the patient’s preference should be involved in the treatment decision, based on the information supplied by the surgeon. However, surgeons vary in their explicit communication of available evidence. Even if they would convey a substantial amount of information, the patient usually cannot grasp this all at once, particularly when confronted with a possibly life-threatening diagnosis and different, more or less invasive, treatment options. However, accurate understanding is essential for informed consent and empowered participation in decision making. Thus, whenever such preference-sensitive decisions are to be made, decision supportive interventions may be useful to help patients make an informed choice and to uniform the information given.

Such decision aids have been developed over the years for a wide range of (mainly malignant) conditions as an adjunct to physicians’ counseling, to facilitate informed
decision making, and increase patient care quality as its ultimate goal.\textsuperscript{10-13} decision aids comprise visual, graphic, or video-assisted illustrations of the risks and benefits involved. They may better prepare patients to participate actively in preference-sensitive decisions.\textsuperscript{14} In a Cochrane systematic review, in which over 200 decision aids were identified, decision aids performed better in terms of: decreasing decisional conflict related to feeling informed, increasing knowledge and realistic expectations, increasing active participation in decision making, and reducing the proportion of patients who remained undecided post intervention.\textsuperscript{15}

The aim of this project was to design and develop a decision aid for patients with an asymptomatic abdominal aortic aneurysm to supply information as to the pros and cons of the various treatment options, presented in a structured and easily accessible manner, in order to facilitate well-informed and satisfactory decision making. Also, the decision aid should offer surgeons a tool to share this information in an evidence-based, uniform format.

METHODS

The decision aid was designed at the Academic Medical Center, Amsterdam, The Netherlands. A multidisciplinary team, consisting of physicians and vascular surgeons, clinical psychologists, information and computer experts, and former and actual abdominal aortic aneurysm patients, contributed to the development and pilot-evaluation of the decision aid. No commercial sponsoring was obtained.

Content and functional requirements

The development was commenced by formulating minimal requirements. The desired decision aid should match the following criteria:

- It should be simple to use, read, and understand by elderly persons
- It should be readily available in a format usable both at home and the (outpatient) clinic
- It should contain essential information about the disorder itself.
- It should explain the surgical (open and endovascular) and watchful waiting treatment options, their possible benefits and risks, and the known as well as unknown aspects as to the prognosis after the different treatment options.
- It should inform patients about their risk level and its consequences, i.e. mortality and (major) morbidity in relation to the anticipated (non-)surgical procedure.
- This information should be presented in an interactive mode to guide the patient primarily along the information and options relevant to his or her particular condition and risk level.
- Its content should be in accordance with legal standards and in agreement with the quality criteria for patient decision support technologies as developed by the International Patient Decision Aids Standards Collaboration (IPDAS).\textsuperscript{16}
- It should provide (references to) the best available, up-to-date evidence from the medical literature to underpin the information given about all treatment options.

**Included evidence**

Data on rupture risk and beneficial or harmful treatment effects were based on evidence from the literature searched from the major medical databases such as PubMed and the Cochrane Library up to March 1, 2008 (i.e. UK and USA small aneurysm trials, DREAM, EVAR I and II trials, GAS studies). Accuracy of data extraction was checked by our group of vascular surgeons. From these data, overall estimates of survival, risks, and complications for the various treatment options were derived to incorporate in the decision aid.\textsuperscript{5-8}

The indication for and prognosis after the various treatment options is known to be influenced by the comorbidity of the patient. A history of renal insufficiency and vascular comorbidity increases the risk of postoperative complications in abdominal aortic aneurysm patients. To quantify this risk, the Glasgow Aneurysm Score (GAS) has been developed, which is a risk score calculated from the patient’s age, kidney function, and history of cerebrovascular disease.\textsuperscript{17,18} This GAS is now a commonly used and validated prediction rule to help decision making in abdominal aortic aneurysm patients.\textsuperscript{19}

**Format and design**

Considering the age and possible ignorance regarding the use of computers of the anticipated elderly patients for whom the decision aid was meant, we contemplated whether the ideal decision aid should be in a written or digital form. We initially aimed at producing a decision aid that would provide information tailored to the patient’s condition and that would also allow us to record the parts of information that would be accessed and appreciated most by the patients. We therefore opted for a digital format for the decision aid, in which these data could be recorded automatically. Moreover, several graphical images could be included to depict the risks and benefits involved in the different treatment options. Although it has been shown that graphical presentation of numerical data helps understanding such risks,\textsuperscript{20} a wide range of graphical presentation forms is available, but it is still unclear which one patients prefer most. Hence, we would record and study this preference at the same time.

The choice for a digital solution entailed designing a very user-friendly, only mouse-driven application, in which the patient would be guided through simple clicks along a preferential information route tailored to the patient’s situation. This situation would be determined by the patient’s GAS and aneurysm diameter, to be entered at the beginning of the decision aid. If desired, however, the patient should be able to access the information regarding any of the other treatment options.
We decided to refrain from adding video clips of interviews of like patients or doctor-patient conversations to prevent any bias due to one-sided information about success stories.

**Project execution and evaluation**

After the initial definition of the functional requirements (DU, AG, SM) and retrieval of the relevant evidence (AMK), the computer programmers would try and realize this project. Subsequently, this prototype version was to be tested by four vascular surgeons mainly for its medical content and four healthy subjects for its usefulness and user-friendliness.

After improving this prototype decision aid based on the suggestions made, the pilot version of the decision aid was presented to a group of 15 former and actual abdominal aortic aneurysm patients to more formally evaluate comprehensibility and user-friendliness. These patients were invited via the Dutch Society of Vascular Patients. A representative patient sample was composed regarding age, gender, computer proficiency, education level, place of residence, and previous aneurysm treatment. They received the decision aid via email or were visited personally by the investigator (AMK).

**RESULTS**

Starting April 2007, the prototype was designed as a Powerpoint presentation (Microsoft Office 2003). This version was used to present the main medical contents and to explain our aims and functional requirements to the computer programmers. During a period of three months they subsequently investigated the possibilities of designing an underlying open database structure to record user statistics, numbers of page visits and user preferences for specific information or types of graphical presentations for each patient individually. However, realization of these functional requirements was found to be too time-consuming, while the primary goal was not met to produce an informative tool to help patients with informed decision making.

We therefore decided to further develop the key functionality in Powerpoint, mainly by introducing action buttons to enable the users to thumb through the decision aid and choose for information tailored to their physical condition. Thus, a pilot version of the

| Table 1. Characteristics of 15 patients who tested the pilot version of the decision aid. |
|-----------------------------------------------|------------------|
| Male gender                                   | 12 out of 15 (80%) |
| Age (mean; range)                             | 71.4 (62 – 78)   |
| AAA since (years; range)                      | 5.5 (2 – 13)     |
| AAA diameter (cm; range)                      | 4.8 (3.3 – 7.5)  |
| Surgery (open or endovascular)                | 40% (half of them open) |
| Computer (+ internet) user                    | 73%              |
An 'Aortic Abdominal Aneurysm' (abbreviated as 'AAA') is a disorder characterized by a local widening of the aortic wall. The normal abdominal aorta has a diameter of about 2 cms. An widening of the aorta of more than 3 cms, or more than 1.5 times its original diameter, is called an aneurysm.

**Slowly wider**
The widening of the aorta is a gradual process. The growth rate may vary, but is usually a few millimetres per year.

![Diagram of normal aorta and aorta with a large aneurysm](image)

**Figure 1.** Sample page from the decision aid illustrating the pathologic anatomy of the abdominal aortic aneurysm.

The figure shows the risk of a rupture (tear) of the aneurysm in the next year. You can read your personal risk from the figure.

This risk increases considerably when the aneurysm grows to more than 5 cms in diameter.

If you click the speaker icon, the figure is explained verbally.
(Switch on your computer loudspeaker).

![Risk graph](image)

**Figure 2.** Sample page in the decision aid depicting the risk of rupture in relation to the aneurysm diameter. Additional spoken information is provided by clicking the speaker button.
Figure 3. Various graphical presentations provided of the benefits and harms involved in surgical AAA treatment to suit patient preferences: natural frequency trees, bars, percentages, and visual aids.

Figure 4. Sample page from the decision aid concerning the comparison of surgery versus expectative treatment options and assessment of the patients’ individual opinion about their anxiety and considerations.
Design and development of decision aid for AAA
decision aid could be developed, which took an additional four months. This version was tested by the vascular surgeons, patients and outsiders. A common comment was about getting lost in the program because the end of the program was not clearly indicated. To overcome this, a ‘breadcrumb trail’ was added to indicate the progress of and location in the program. To further comply with the IPDAS criteria, we added the date of last update, a statement the developers of the decision aid do not benefit from whichever choice the patient would make based on the decision aid, and references to the (level of) evidence for the various bits of information given in the decision aid. In addition we elaborated the section in which the patient can consider their own situation as to treatment options, risks and anxiety. The final pilot version of the decision aid complied with 33 out of 40 criteria.

Some of the pages in the decision aid (translated in English) are presented in figures 1-4. They illustrate the information supplied on the disease itself (figure 1), the risk of rupture presented as a figure (the user can choose to get verbal explanation as well; figure 2), the various graphical representations of the benefits and risks of the endovascular therapy (figure 3), and a summarizing comparison of the pros and cons of surgery vs. watchful waiting, including an interactive part where the patient can fill in their personal anxiety or reluctance regarding a certain treatment option (figure 4).

Fifteen patients evaluated the pilot version of the decision aid. Patient characteristics are shown in table 1. They examined the decision aid for a mean of 80 minutes (range 20-300 min.). On a scale from zero to 100, ‘user-friendliness’ scored a median of 75 (interquartile range [IQR] 53-86), ‘clarity’ 86 (IQR 80-90), and ‘feeling better informed’ 68 (IQR 50-90). The vast majority stated the decision aid offered additional value in their decision making, and all but one patient found the figures on possible risks clarifying rather than frightening. Every type of graphical representation was valued most by at least some of the patients. No clear differences were observed between patients who had and those who had not yet undergone surgical treatment for their aneurysm.

Finally, a linguistic check was performed (SM) to ensure the use of plain language and easy interpretation of the decision aid. The program, now available on CDROM, was also equipped with the possibility to print concise information in the form of a brochure the patient can take home. The decision aid has been registered in the Cochrane Decision Aid Library Inventory (DALI) of the Ottawa Health Decision Centre. (https://decisionaid.ohri.ca/DALI)

DISCUSSION

This paper describes the development of the first decision aid regarding treatment options for patients with an asymptomatic abdominal aortic aneurysm. This decision aid is evidence-based and developed following the IPDAS criteria. Even in an elderly population such a computer-based decision aid appeared to be appreciated.
The development of this decision aid was similar to those in other medical realms, e.g., cancer of the breast, prostate, or lungs, in which patients are affected by the disease by the time a decision about treatment needs to be made.\textsuperscript{10,21-23} However, this decision aid focused on the decisional conflict regarding an asymptomatic disorder that will remain without consequences until either rupture or surgical treatment occurs. Decisional conflict levels in this patient category are still unknown.

In only one RCT the benefits of a comprehensive, highly individualized, evidence-based brochure for asymptomatic abdominal aortic aneurysm patients based on information by way of Markov analysis have been studied. The highly individualized information was found to be dissatisfying and impractical.\textsuperscript{24} Therefore, the information offered in this decision aid was mainly on headlines rather than focusing only on the precise situation of the patient.\textsuperscript{23} However, as risk of rupture strongly correlates to the size of the aneurysm, and surgical risk considerably increases with the presence of comorbidity, it was thought to be necessary to tailor information in the decision aid to these two factors. In addition, the IPDAS criteria also describe ‘the possibility to view probabilities based on the patient’s own situation’ as one of the quality criteria.

This decision aid was made in accordance with the vast majority of IPDAS criteria, which is not yet very common, but should improve the value of decision aids to let patients better perceive their own situation, reduce decisional conflict, and help them to make an informed choice.\textsuperscript{25} Although decision aids are being produced for various conditions, further evidence is needed to evaluate its role in reducing decisional conflict and reducing any inter-doctor variation regarding the information supplied. The debate is ongoing about the value of decision aids to improve clinical decision making.\textsuperscript{26} Decision aids did not appear to outperform comparative strategies in affecting patient satisfaction with decision making, anxiety, and health outcomes.\textsuperscript{15} Furthermore, decision aids can only be developed if evidence is available in sufficient amounts to underpin the information supplied for the various treatment alternatives.

The initial version of this decision support had limitations as to the complexity of the individual risk information, which was dissatisfying for the patient. After adjustments, appraisal by abdominal aortic aneurysm patients showed that this decision aid was considered user-friendly, of additional value, and improved understanding. As intended, the decision aid was found to be not simply an informative ‘digital brochure’ containing basic information about treatment options, but rather a useful tool to actually help patients decide on their optimum treatment choice. We do not yet know whether the decision aid really offers more (useful) information than what the vascular surgeons already explain to the patient and whether it is also capable of increasing patients’ knowledge and subsequently reducing patients’ decisional conflict regarding their treatment choice. Ultimately, it would also improve satisfaction, quality of life, and prevent a relevant increase in anxiety of asymptomatic abdominal aortic aneurysm patients. It might possibly reduce
the number of abdominal aortic aneurysm interventions eventually performed. This will be studied in a trial on the usefulness of this decision aid in a randomized setting.

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