A Decision Aid Regarding Treatment Options for Patients with an Asymptomatic Abdominal Aortic Aneurysm: A Randomised Clinical Trial

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WHAT THIS PAPER ADDS

Patients with an asymptomatic abdominal aortic aneurysm tend to be informed inconsistently and incompletely about their disorder and the treatment options open to them. A patient decision aid helps to share treatment decisions with these patients by increasing their knowledge about the disorder and treatment options open to them, without raising anxiety levels or deteriorating health outcomes. However, it does not reduce patient decisional conflict, nor does it improve satisfaction.

Objective: Abdominal aortic aneurysm patients tend to be informed inconsistently and incompletely about their disorder and the treatment options open to them. 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.

Design: A six-centre, randomised clinical trial comparing a decision aid plus regular information versus regular information from the surgeon.

Methods: Included patients had recently been diagnosed with an asymptomatic abdominal aortic aneurysm at least 4 cm in diameter. The decision aid consisted of a one-time viewing of an interactive CD-ROM elaborating on elective surgery versus watchful waiting. Generally, the decision aid advised patients with aneurysms less than 5.5 cm to agree to watchful waiting, for larger aneurysms the decision aid provided insight into the balance of benefit and harm of surgical and conservative approaches, taking into account age, co-morbidity and size of the aneurysm. The primary outcome was patient decisional conflict measured at 1 month follow-up (Decisional Conflict Scale). Secondary outcomes were patient knowledge, anxiety and satisfaction.

Results: In 178 aneurysm patients, decisional conflict scores did not differ significantly between the decision aid and the regular information groups (22 vs. 24 on the 0–100 Decisional Conflict Scale; $p = .33$). Patients in the decision aid group had significantly better knowledge (10.0 vs. 9.4 out of 13 points; $p = .04$), whereas anxiety levels (4.4 and 5.0 on a 0–21 scale; $p = .73$) and satisfaction scores (74 and 73 on a 0–100 scale; $p = .81$) 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.

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INTRODUCTION

Abdominal aortic aneurysm rupture carries a high mortality rate,[1] 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. Surgeons have an ethical obligation to share these important decisions with their patients, in addition to the legal imperative to inform patients about their health.[2] This has been formulated in a recent statement on the role patients should play in healthcare decisions.[3]

In daily practice, however, aneurysm patients tend to be informed inconsistently about their disorder and the available treatment options, and the amount of information given is often less than is legally required.[4] Moreover, aneurysm patients reported being unaware of their options when making the treatment decision.[5]

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.[6] Decision aids typically contain information on treatment options and outcomes related to the patient's health status and explore patient preferences and values.[7]

The authors had previously developed a decision aid considering elective surgery and watchful waiting for patients with an asymptomatic abdominal aortic aneurysm.[8] 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, it was determined whether patients who used the decision aid were better informed about the disorder, less likely to be anxious, and be more satisfied in terms of their communication with the surgeon. Final treatment choice and health outcomes were also documented.

METHODS

Trial design

A six-centre, randomised clinical trial was conducted 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.[9]

"Intervention": decision aid in addition to regular information

The decision aid comprises an interactive computer program provided on a CD-ROM. It presents up-to-date, evidence-based information about abdominal aortic aneurysms and their treatment options; elective aneurysm surgery and watchful waiting, and the pros and cons of those treatment options, as is required by European law.[2] The decision aid patients with aneurysms of less than 5.5 cm were advised to agree with watchful waiting, in keeping with available evidence at that time.[10] For patients with aneurysms of at least 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 about rupture if you do not get surgical treatment?". In the decision aid no advice towards a certain treatment option was given to patients with aneurysms of at least 5.5 cm. Finally, the 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.[7]

Participants

Eligible patients were identified between November 2008 and June 2011 at the outpatient clinic. Inclusion criteria were patients of at least 18 years of age, who were visiting the outpatient clinic for the first time with an asymptomatic abdominal aortic aneurysm diameter of at least 4.0 cm as confirmed by ultrasonography or CT scanning. Patients also had to understand Dutch well enough to be able to participate in the study. Exclusion criteria were any kind of end-stage disease resulting in estimation of life expectancy of less than a year, or lack of necessary mental capacity to provide informed consent.

Eligibility

During their first contact, the consulting surgeon briefly informed the patients and asked for their verbal consent to participate in the study. Patients received a brochure about the study to take home. If they agreed to participate, they provided written informed consent and returned the baseline questionnaire to the research centre in a pre-paid envelope.

Randomisation

Subsequently, computer-generated randomisation (ALEA v. 2.2, NKI-AVL, the Netherlands) was performed by the investigators after the informed consent form was received. 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 generally not considered to be beneficial according to available evidence.[10–12] The Glasgow Aneurysm Score classifies patients into low versus high risk of postoperative complications based on the patient's age, preoperative renal function, cerebrovascular and cardiac