Title[1]: **The impact of individualized evidence-based decision support on aneurysm patients' decision-making, ideals of autonomy, and quality of life**

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Running title: Individualized decision support for aneurysm surgery

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Abstract

Background:A major challenge in surgery is the integration of evidence-based medicine and patient autonomy. We present a randomized trial studying the effect of an individualized evidence-based brochure (IB) on patients' autonomous behavior, patients' ideals of autonomy and quality of life.

Method: Patients with an asymptomatic abdominal aneurysm and their surgeon were randomized to receive a general brochure (GB) or an IB presenting survival information and a ranking of the treatment strategies. Before and after receiving the brochure patients filled out questionnaires on their behavior during the consultation, ideals of patient autonomy, and quality of life. Surgeons answered a short checklist evaluating the consultation.

Results: One hundred patients participated, 49 in the intervention, 51 in the control group. The IB group had a better understanding of important issues in the treatment decision, had prepared more questions, and was less satisfied with the duration of the consultation. Their impression that the surgeon perceived them more as a medical problem than a patient with a problem, increased. They agreed less with the surgeon's advice, and lost some of their belief in 'the doctor knows best'. Beforehand, the IB group had a stronger preference for patient-based decisions, but afterwards they displayed more surgeon-based decisions. No effects were seen on patients' quality of life.

Conclusion: Individualized evidence-based information stimulated patients' active involvement, but in the context of our study led to less patient-based decisions. Patient-made decisions and patient autonomy should, however, not be equated.

Keywords: Decision-Analysis; vascular surgical procedures; patient satisfaction; physician-patient relations; autonomy

Introduction

Western medicine is currently characterized by two important ideals: evidence-based medicine and patient autonomy. The general aim of evidence-based medicine is twofold: to rationalize the process of medical decision-making and to maximize expected outcomes.(1) Patient autonomy generally implies an active involvement of patients in the process of medical decision-making and the implementation of patient preferences in the final treatment decision. Clinicians face a major challenge in integrating both paradigms in clinical practice. Some authors have suggested a new normative framework: 'Evidence-Based Patient Choice' (EBPC) (2-5). EBPC aims at the ideal of patient choice within the boundaries of existing evidence on (cost-) effectiveness.

Not all advocates of patient autonomy automatically aim at the ideal of patient choice. According to the ethics literature, patient autonomy may be realized in various ways.(6) EBPC seems to refer to an autonomous patient who rationally and independently chooses the best treatment according to his own norms and values, taking into account all relevant evidence (7). However, empirical research has shown that many patients do not behave like this (especially not when elderly, when less well-educated, or when seriously ill) nor do they prefer to make the final treatment choice themselves (8-10). We therefore wished to assess the views of elderly patients with life threatening disease on the ideal of patient autonomy and on the desirability of EBPC before and after they received evidence-based information.(11-13)

For this purpose, we conducted a randomized controlled clinical trial of an evidence-based decision-analytic model for treatment of abdominal aneurysm patients.(14;15) The model, based on a meta-analysis of 128 scientific articles (49.880 patients), consists of a Markov decision tree that simulates the natural course of the aneurysm over time, and the effects of diagnostic and therapeutic interventions. This model calculates 'individualized' (i.e. tailored to a specific subgroup) mortality and life expectancy rates for different treatment options on the basis of information of the health condition of the individual patient. In the trial, we assessed the impact of individualized evidence-based decision support on decision-making behavior (e.g. patient choice), quality of life, and autonomy ideals of abdominal aneurysm patients. Specifically, we focused on three research questions:

1. Do patients report more autonomous behavior (e.g. patient choice) due to this individualized evidence-based decision support?

2. Do patients' ideals of patient autonomy change due to this individualized evidence-based decision support?

3. Does the individualized evidence-based decision affect the quality of life of the patients?

PATIENTS AND METHODS

Participants and procedures

Data were collected within the framework of a larger research project on patient autonomy and individualized evidence-based decision support. Patients with an asymptomatic abdominal aneurysm of the aorta (AAAA) who either visited the outpatient clinic for the first time, or were shown to have an expanding aneurysm at follow-up, were recruited from the outpatient clinic of two teaching hospitals in the West of the Netherlands during 1998-2001. Inclusion criteria for patients were: informed consent, literacy in Dutch, no previous aneurysm surgery, and no preference and suitability for endovascular surgery (at the time of the study insufficient evidence existed on the outcomes of this procedure). Patients were informed about the study and were asked for a two-step consent. The first consent was for an attitude study, assessing patients' attitudes towards patient autonomy. Next, during their visit to the outpatient clinic, patients were asked for consent for the randomized trial (figure 1). In case of consent, patients and surgeons completed a risk factor questionnaire, and the responses were used to individualize the risk information. In case of dissimilarities between the patient's and surgeon's responses, we had the patient's general practitioner complete the questionnaire as well (after patient's consent). After the consultation, patients filled out a questionnaire that asked after their decision-making behavior, quality of life, and their ideals of patient autonomy. We report here the results of the randomized trial only.

Following the consultation, patients were randomized to receive an individualized brochure (IB) or a general brochure about surgery for abdominal aneurysm (GB). Randomization was stratified by surgeon. The individualized brochure incorporated the output of an aneurysm Markov decision tree (DATA 3.5, Treeage, see Appendix 1). This output consisted of information on three strategies concerning the management of AAA patients (elective surgery, regular follow-up until a threshold, and no surgery/no follow-up), and one reference scenario of an otherwise similar patient (age, sex and risk factor adjusted) without an aneurysm. Expected outcomes for each of these four scenarios were patient-specific risks, yearly occurrence of events, and life expectancies. Decision model outcomes were imported into a pre-programmed spreadsheet (Excel 2000, Microsoft) and converted to understandable clinical information, such as survival curves, median survivals, and 1- and 5-year mortalities. Finally, the three treatment strategies were ranked on the basis of expected Quality Adjusted Life Years (QALYs), with utilities (quality-adjustment factors) based on a systematic review of the literature. This ranking was framed into a transparent, non-obligatory and individualized treatment advice, based on a maximum life expectancy, corrected for quality of life and a time discount. It was explained that based on the patients' own preference for quality of life in certain health states (mostly living with an aneurysm and recovery from surgery), and his time preference, the best strategy could be a different one, and that he should discuss this with his surgeon. The advice was further qualified by stating that other factors than those incorporated in the model might also influence his decision, and that the patient (and the surgeon) could therefore decide not to follow the model's advice. Pre-programmed formulas and macros in the spreadsheet file provided graphs and pictures aimed at clarifying quantitative information (see Figures 2 & 3). Data and figures from the spreadsheet were exported into an individualized brochure (IB) in Word format (Word, 1998, Microsoft), which contained both general risk information and the individualized information from the Markov model. A control brochure consisted of only the general risk information (general brochure (GB, see Appendix 2). Brochures were sent to patients at their home address. Next, patients had a second (i.e. additional) outpatient visit, in which surgeon and patient discussed the brochure and made the final treatment decision. We wished to interfere as little as possible with usual practice, and therefore decided not to standardize the second visit. Following this visit, patients filled out the

second consultation evaluation questionnaire at home, as well as the quality of life questionnaire, and the questionnaire concerning ideals of patient autonomy. Surgeons filled out a short checklist immediately after the consultation.

The study was approved by the Medical Ethics Committees of the hospitals.

Measures

Socio-demographic characteristics. Patients reported their age, gender, and level of education.

Patient perceived autonomous behavior. The first and second consultation evaluation questionnaires were developed specifically for this study (16) in order to assess aspects of patients' decision-making behavior associated with patient autonomy, as well as aspects conditional for autonomy (see Table 1). One aspect concerned understanding, a requirement for autonomy. A second concerned the consultation, and the role of the surgeon therein. A third concerned the participation of the patient, and a final concerned the process of decision-making and surgeon-patient decision-making roles. Most items were to be answered on 5-point Likert scales.

Table 1: Consultation evaluation questionnaire: aspects of patient autonomy, as perceived by the patient

Ideals of patient autonomy. In order to elicit patients' opinions on the ideal of patient autonomy, the Ideal Patient Autonomy Scale (IPAS) had been developed on the basis of different moral ideals of patient autonomy.(6) This instrument informs us about the way respondents think of the desirability of different concepts of patient autonomy. The IPAS consists of 14 normative statements inspired by six different ideals of patient autonomy. Responses to the statements were collected on a 5-point Likert scale ranging from '1' fully disagree to '5' fully agree.

The IPAS consists of four scales (for details see (6)). The 'Doctor Knows Best Scale' (5 items) describes that physicians should make the treatment decision and that patients should submit themselves trustfully to the expertise of the doctor without much risk information. The 'Patient Should Decide Scale' (4 items) states that the patient should choose the treatment and that the physician has to respect patient's choice. The 'Obligatory Risk Information Scale' (2 items) expresses

the norm that patients should receive all risk information. Finally, the 'Right to Non-Participation Scale' (3 items) represents patients' right to disengage from treatment decision-making and risk information. The scale scores consist of summing the responses of the related items, and transforming these sum-scores into a 0-100 point scale, ranging from '0' total disagreement with the content of the scale to '100' total agreement.

Patients' quality of life. Patients filled in the Hospital Anxiety and Depression Scale (HADS)(17) and an item evaluating Quality of Life (7-point scale, ranging from very poor to very good) as well as a 100 mm Visual Analogue Scale (VAS) (anchored by lowest Quality of Life on the left and highest Quality of Life)(18).

Surgeons' perceptions. Surgeons filled in a short checklist developed specifically for this study, asking after the information provided, e.g. whether they presented probabilities, which risks were discussed (e.g. risk of rupture and mortality, risk of amputation of a leg, risk of erection problems). They were asked whether much discussion had taken place, and whether they felt the patient understood the information.

Statistical analyses

Data were analyzed using SPSS 11 for windows. To assess the impact of the intervention, repeated measures analysis of variance was used, with time as a within participants factor and intervention as a between participants factor, for those variables assessed at both T1 (after first consultation) and T2 (after second consultation). If an interaction was seen between time and group, paired t-tests were used for the two groups separately to test the effect of time. For those variables assessed at T1 or T2 only, independent samples t-tests were performed. If baseline measures between IB and GB group were equal, independent samples t-tests were performed at T2. For dichotomous data chi-square analyses were performed, and McNemar tests to check for changes over time. For interaction effects between time and group, a more lenient criterion of 0.30 was used, so as not to miss important effects due to lack of power. Otherwise, p=0.05 was used as criterion.

RESULTS

Study population

Of 136 patients participating in the larger attitude study, 117 (86%) consented to randomization. During the trial, after completing the intake questionnaire and first consultation evaluation form, 17 patients (15%) dropped out (of whom four immediately after the consultation, before randomization): 10 were annoyed by the many evaluation forms, one patient's partner considered the brochure too confronting for him and hided the brochure from him, one patient was not interested in brochure, one was angry about the waiting list, and four dropped out because of moving to another city or not bothering to fill in one or more of the questionnaires. Thus 100 out of the 117 patients supplied sufficient data to evaluate study outcome, 49 in the index arm and 51 in the control arm. Patients in the index and control arm were similar with respect to socio-demographic characteristics and major medical characteristics (see Table 2). Patients were seen by 15 vascular surgeons and residents, all of whom saw both index and control patients.

Table 2: Characteristics of the patients in the Intervention (IB) & Control (GB) group

Decisions made in relation to model advice

Before we show the results relating to our research questions, we first present data on the decisions made during the second consultation. Table 3 shows the decisions by group, in relation to the model advice, for the 97 patients for whom the decision had been reported in the medical record. Decisions were similar in the IB- and GB-group: about one quarter was to have surgery, about half would have regular follow-up. No significant differences were seen between IB- and GB-patients ($p=0.73$), although a slight difference seemed to exist in the number of patients without a decision (generally because further investigations were ordered): 25% in the IB-group, 19% in the GB-group. Decisions were not more in accordance with the model in the IB-group, despite the fact that the GB-group did

not see the model advice. When we looked at those for whom a decision was made, however, we noticed a significant difference in relative gain in QALYs (by first preferred option according to the model compared to second option) between IB-group patients for whom the decision was according to the model (n=26) and those for whom it was not (n=11). For those in whom the decision was according to the model, the relative gain was almost twice that of those in whom the decision was not according to the model (0.0501, s.d. 0.0300 vs. 0.0255, s.d. 0.02693, p=0.02). Apparently, the model was followed more often when the relative gain was larger, and the advice therefore stronger. In the GB-group this difference was not seen, the relative gains were similar (0.0487, s.d. 0.0322 vs. 0.0524, s.d. 0.0510, p=0.79). When patients and surgeons received the model advice, decisions were thus more evidence-based.

Table 3 Agreement of post-consultation decisions with model advice, by trial arm (%)

IB and patients' autonomous behavior

Understanding. The only difference that was seen for the items related to understanding was a difference in favor of the IB group in the stated understanding of the issues that were important in the treatment decision: 84% (n=32) of the IB group felt that due to the brochure they had better understanding vs. 62% (n=21) of the GB group (Chi-square test p=0.04).

Consultation with the surgeon. A main difference between the two groups was seen in satisfaction with the duration of the consultation. Whereas 89% of the IB group was (rather) satisfied, all patients (100%) in the GB group were satisfied with the duration of the consultation (Chi-square test p=0.04). For patients' impression whether the surgeon perceived them more as a medical problem than as a person with a problem an interaction effect was observed ($F(1,68) = 4.31$, $p = 0.04$). Further analysis showed that in the IB group from first to second consultation the feeling increased that the surgeon perceived them more as a medical problem than as a person with a problem (mean increased from 1.9, s.d. 1.3, to 2.3, s.d. 1.4), whereas for the GB group this feeling decreased (from 2.0, s.d. 1.3, to 1.7, s.d. 1.2).

Active participation of the patient. At the second visit, more patients had prepared questions at home (58%) than at the first visit (31%) (McNemar p = 0.004). This effect was mostly observed in the IB group (T1: 27%, T2: 62%; McNemar p = 0.001) since at T1 the GB group had already prepared more questions than the IB group (T1: 45%, T2: 56%, p = 0.77). The difference at T1 failed to reach statistical significance, though (p=0.07).

The IB group agreed somewhat less with the surgeon's advice (M = 1.4, s.d. 0.9) than the GB group (M = 1.0, s.d. 0.2), p = 0.01. Disagreement was not related to the decision, nor to the correspondence between the decision and the model advice.

Patients' decisional role. Irrespective of the intervention and time, on average 65% of patients perceived no choice between one or more treatment options at both consultations. There seemed to be a slight tendency in the IB group for the decision to be more surgeon-based (M=2.3, s.d. 1.3) than in the GB group (M=2.9, s.d. 1.3, p=0.08), whereas the IB group had preferred a (non-significant) more active decision-making role beforehand (M 2.9, s.d. 1.3 vs. 2.5, s.d. 0.9, p=0.15). Therefore, we calculated a discrepancy-score (actual role minus preferred role, both on a 1-5 scale, with a higher score indicating a more patient-based decision). Negative scores thus indicate that from T1 to T2 decisions became more physician based. The IB group showed a tendency to experience a stronger decisional role discrepancy (-0.57; s.d. 1.7) as compared to the GB group (0.37; s.d. 1.4) (p=0.06).

Surgeons' perception. No differences were seen between the arms of the trial in the surgeons' reply to the question whether and how they presented probabilities, nor to the questions on the risks that were discussed, the total number of risks that were discussed, the understanding of the information by the patients, nor on the question whether much discussion had taken place during the consultation.

IB and patients' ideals of patient autonomy

All patients favored the 'Obligatory Risk Disclosure Scale' most (means of T1 and T2 for all patients (n=73) M=93, s.d. 12) and the 'Patient Should Decide Scale' the least (M=51, s.d. 25), irrespective of the intervention or time. For both groups, at both visits, the 'Doctor Knows Best Scale' occupied the second place (M=77, s.d. 19) and the 'Right to Non-Participation Scale' occupied the third place (M=67, s.d. 22). For the Doctor Knows Best Scale an interaction was seen between group and time (p=0.08). Paired t-tests showed that over time the IB group lost some of its belief that the Doctor Knows Best (T1: 76, s.d. 21, T2: 68, s.d. 25, p = 0.06), whereas in the GB group this belief remained high (T1: 82, s.d. 20, T2: 83, s.d. 18, p=0.65). As a consequence, an independent samples t-test showed that after receiving the brochure the IB group agreed less with the Doctor Knows Best Scale than the GB group (p=0.05).

IB and patients' quality of life.

Patients' quality of life was stable over time, in both groups. No effects were observed in the repeated measures for the anxiety and depression scales of the HADS, nor on the quality of life scales. A major worry at the onset of the trial had been that IB patients might think the brochure much more confronting than the GB patients. Whether the risk information was threatening was however not affected by the intervention or by time. Note however that 72% of patients found the information to be threatening (69% in the IB-group, 76% in the control group); only 15% fount it not to be threatening (17% in the IB-group, 14% in the GB-group) and 13% were not sure.

Discussion

In this randomized controlled trial, patients with a life-threatening disease who received an individualized brochure felt they had a better understanding of the issues that were important in the treatment decision. These patients had prepared more questions at home, and agreed less with the surgeon's advice, than those who received a generalized brochure. They lost some of their belief in

'the doctor knows best',' were less satisfied with the duration of the visit, and were more likely to feel that the surgeon perceived them more as a medical problem than a patient with a problem. No effects were seen on patients' quality of life. To our knowledge, this is the first randomized trial to assess the impact of providing detailed individualized risk information to elderly patients with a life threatening disease.

This study had several limitations. First, the findings may have been due in part to the larger amount of information presented in the IB group, not just to the tailoring per se. Had we provided the GB patients with similar survival graphs, and overall QALYs, they may have reacted similarly. While providing an equal amount of information to both groups would have improved the validity of the study, one may question whether it is ethical to provide such highly specific and threatening information to patients when it is not based on their own situation, and may very well not apply to them.

Second, we did not include an arm with no brochure, which would have represented usual care at the time the study was conducted. Compared with usual care, both the individualized evidence-based brochure and the general brochure functioned as a decision-support intervention in the decision-making process. This could explain some of the similarities in results between the intervention and GB groups. Third, in order not to intervene too much in the patient-surgeon decision-making process, the decision support only consisted of presentation of the brochure and an extra visit. A more intense intervention might have encouraged active patient participation and choice to a greater degree than simply delivering evidence and allowing her or him to make his or her individual choice.(19)

Fourth, we could have used individualized utilities in the Markov model, too, but we preferred to use data from the literature, for two reasons. Firstly, utility assessment is a cognitively demanding task, which we deemed not feasible in the context of our consultations. Secondly, utility assessment methods such as the Time TradeOff or Standard Gamble have until now not been found to be

sufficiently reliable (reliabilities never exceeding 0.90) to be used for individual patient decision-making.

Fifth, we ended up with fewer patients than originally planned because 15% of subjects dropped out during the study period. Possible explanations are the high age and low education of the typical AAA patient, the amount and complexity of the questionnaires, and the complexity of the decision-making process. Only two patients said the reason they dropped out was the brochure; the others felt the outcome measures of our study too burdensome. Despite the unanticipated dropouts, however, for the major issues in our study the sample size appeared to be adequate: some significant effects were seen, and other results were similar in both groups, i.e., no clinically significant differences were seen that may have failed to reach statistical significance.

Sixth, six patients in the GB group had congestive heart failure, vs. none in the IB group. Congestive heart failure increases the surgical mortality by a factor of 2-2.5, a fact that the model takes into account, but that not many surgeons will take into account in their decision. As may therefore be expected, for three of these patients the model recommended a less aggressive approach (follow-up or do nothing) than was decided upon (surgery). The impact of the imbalance in CHF on our results is not expected to be large, since the patients were all in the control group, and did not receive the recommendation from the model. Had they been in the intervention group, who received the model results, the impact on decision-making might have been higher, since the model would then have been more conservative than usual practice.

Finally, our data were clustered within surgeons, but due to the imbalance in the design, with one doctor seeing as many as 26 patients, others as few as only one, we could not do a multilevel analysis. We did some additional analyses to assess the impact of the surgeon (assessing e.g. the interaction between surgeon and group, and redoing analyses for those surgeons with large patient numbers), and these analyses gave us confidence that we have not presented artificially inflated p-values. We also redid the analysis leaving out the surgical residents (who had seen only nine of the 100 patients), and

results remained the same. The fact that we did not randomize surgeons may also have led to some of the similarities between the arms of the trial, since one runs a risk of contamination if a surgeon sees both intervention and control patients. But it is highly unlikely that surgeons could have reproduced the individualized information without access to the model.

With respect to patients' autonomous behavior it seems reasonable to conclude that the individualized evidence based decision-support did not lead to an increased rate of evidence-based patient choice. On the contrary, IB group patients less often reported that they had made the treatment choice themselves (in absolute numbers the proportion of patients making the treatment choice themselves was low). At the same time, IB patients beforehand had preferred more strongly to decide for themselves, and therefore a larger decisional control discrepancy was seen in this group. Patients' better understanding of the disease and its risks, including the risks of treatment, and their more active involvement may be seen as benefits for both doctor and patient. However, the findings that some patients felt that they could trust the doctor less and that the doctor perceived them to be more of a medical problem than a patient with a problem, are clearly drawbacks of delivering this information. The complexity of the information provided may have made subjects less inclined to take the responsibility for making a decision themselves, but less comfortable with the surgeon's decision-making. In qualitative interviews after the study, surgeons indeed indicated that the information probably was too complex for this particular patient group. In particular, the survival curves were seen as too difficult for patients to understand.

Some of our findings may have been due to time constraints, since active involvement calls for more time for the consultations, and specifically the patients in the intervention group were less satisfied with the duration of the visit. It is questionable however, whether more time can be spent in a busy surgical practice and whether the benefits will outweigh the costs. If not more time can be spent, the information may have more negative than positive effects. In that case, the information could still be provided to surgeons only, since it was shown to lead to more evidence-based decision-making.

With respect to patient autonomy in general, many clinicians and researchers seem to focus primarily on the final choice. The emphasis on patient choice as a synonym for patient autonomy unjustly neglects the existence of various conceptualizations of patient autonomy.(6;20) As discussed in the ethics literature,(21-23) patient autonomy also should consist of process elements of decision-making. An actively involved patient who understands the complexity of the medical problem and who experiences the opportunity to deliberate openly with the surgeon, can be rightfully described as autonomous, even if he does not make the final treatment choice. In this respect, the individualized evidence-based decision support has been convincingly successful.

The reservation against too much emphasis on patient choice fits well with the ideals of the aneurysm patients themselves. All patients scored lowest on the Patient Should Decide Scale. And even though patients agreed less with the Doctors Knows Best Scale after they had received the IB, patients still scored quite high on that scale. The fact that neither patients' behavior nor patients' ideals displayed patient choice is in accordance with other empirical studies in which patient behavior and patient preferences have been assessed.(24)

Finally, it is important to stress that we found no effect of the IB on patients' quality of life. At the beginning of the study, many surgeons had worried that the IB would induce anxiety, or would be felt to be threatening, but neither turned out to be the case. Linked with this are patients' high scores on the Obligatory Risk Disclosure Scale after they had received the brochures: 'patients have to be informed of all the risks involved'. For that matter, to some extent even an increase in anxiety due to risk disclosure would not automatically lead to a moral rejection of this disclosure. Experiencing anxiety when facing a life threatening disease can be seen as normal, and much of the anxiety can be dealt with if patients receive the right emotional support.

This study showed that an individualized decision support system for patients with abdominal aortic aneurysm is both technically and clinically feasible. Its information improves understanding, does not lead to more anxiety, and endorses choices that are more evidence-based. If sufficient time is available to discuss the information, individualized evidence-based decision support can stimulate patient's active involvement rather than suppress it. In this way, we can make a first step towards a successful integration of evidence-based medicine and patient autonomy within the clinical context.

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Appendix 1: The Decision Model

The Markov model

The Markov decision tree concerning the value of surgery and follow-up for patients with abdominal aortic aneurysm was implemented as a Markov model in DATA (Decision Analysis by TreeAge, version 3.5, TreeAge Software Inc).[2] In order to fit on a particular patient, ten characteristics of aneurysm and patient are entered into the model. These characteristics are: aneurysm diameter; patient age and sex; diastolic blood pressure (>100 or below, with or without medication); renal function (Creatinin >150 or below); ischemic heart disease (present/absent); myocardial infarction (ever/never); COPD (present/absent); congestive heart failure (present/absent); and excess mortality risk due to serious co morbidity (e.g. cancer). Clinical information on these risk factors was obtained from a minimum of two and a maximum of four sources (the patient himself, the referring specialist, the patient's general practitioner, and the vascular surgeon concerned). When discrepancies existed between the information obtained from these sources, the doctors concerned were contacted until agreement about the correct information was obtained.

Four scenarios are represented in the Markov tree. Three of these are clinically realistic choice strategies of elective surgery, regular follow-up, and a wait & see policy doing nothing?. The fourth is the reference scenario of the same patient without aneurysm (i.e. as if the patient were cured by a hypothetical risk-free intervention). Output of the Markov tree consisted of information on three strategies concerning the management of AAA patients (elective surgery, regular follow-up until a threshold, and follow-up without intervention), and one reference scenario of an otherwise similar patient (age, sex and risk factor adjusted) without an aneurysm. Expected outcomes for each of these four scenarios were patient-specific risks, yearly occurrence of events, and life expectancies, as well as Quality Adjusted Life Years (QALYs), in which life expectancy was corrected for quality of life (utilities were based on a systematic review of the literature) and a time discount (3%,). The various events and outcomes that may occur over time are shown in figure Appendix, and are listed in the description that follows below. Information on the evidence base of the model can be obtained from the last author (j.kievit@lumc.nl).

[2] An "elementary" decision tree provides a singular graphical representation of various events and outcomes, which are depicted in a logical and chronologically correct order. Such a tree is unsuitable to model events that may occur and/or recur at different moments in time. A Markov decision tree models events and outcomes that may occur over a predefined time period, spanning from the moment of choice until a future time horizon considered clinically relevant. This period is subdivided into time intervals of equal length, in our model intervals of 1 year. Patients may experience a predefined number of mutually exclusive relevant health states, ranging from health to death. The chance of changing from one health state into another is defined by various risks that are relevant for that specific patient state and time cycle. A Markov model thus resembles a series of successive "elementary" decision trees, representing one time cycle each, which trees are identically structured but may differ with respect to their relevant chances and other variables.

Disease course over time

The initial health state with which the model starts is that of a patient with an abdominal aortic aneurysm ("Patient with AAA" in figure]. Over time this patient gets older, and may die from non-AAA related causes (1 in figure) at a death rate that is determined by sex, age and the above mentioned health characteristics. The aneurysm may undergo two changes over time; its diameter may increase (2 in figure), and/or it may rupture (3), at a rate that depends on its diameter, and on the presence of hypertension and/or COPD (COPD increasing rupture risk).

In case of rupture, a patient may die before reaching the hospital (4), or reach the hospital and undergo acute surgery for abdominal aortic aneurysm rupture (5). Acute or non-elective Surgical treatment may result in death (6), or in the successful insertion of an? aortic vascular prosthesis (7)

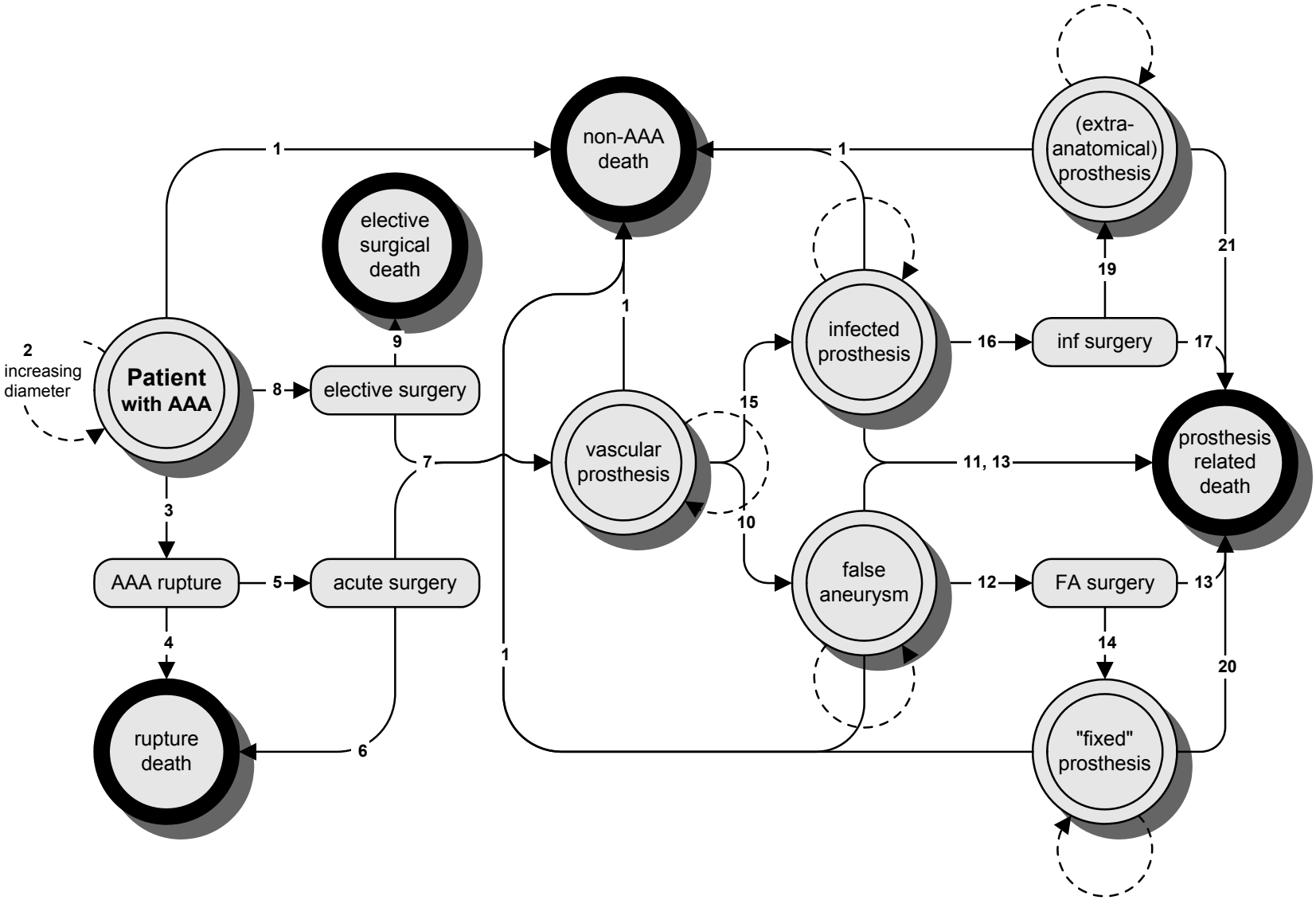
Elective aneurysm surgery

To prevent the above complications from happening, a patient may undergo elective aneurysm surgery (8). Like in case of acute surgery, elective surgery may result in preoperative death (9), or successful exclusion of the aneurysm by an aortic vascular prosthesis (7). A thus operated patient will undergo follow-up over time, as complications may occur because of the vascular prosthesis. Apart from natural mortality (1), a patient with a vascular prosthesis is at risk for two prosthesis-related complications. First he may experience a false aneurysm (10), which runs the risk of prosthesis related death (11) through rupture, or can be treated by surgical correction (12) of the false aneurysm, resulting either in death (13), or in a successful reconstruction of the vascular prosthesis (14). Second the prosthesis may become infected (15), in which death from sepsis is likely (13), or the infection may be surgically treated (16) by replacement of the infected prosthesis, which may result in perioperative death (17) or in treatment with a new vascular prosthesis (19). After revision of the vascular prosthesis for either reason, a patient may live until death from other causes (1), or there may be a certain excess long-term mortality from false aneurysm (20) or infection (21) related complications.

Follow-up

If an aneurysm is not large enough to justify early elective surgery, a patient may also undergo follow-up. In that case, the diameter of the aneurysm is checked at regular intervals (2), and the patient is operated electively (8) if the aneurysm diameter increases with 1 cm or more or exceeds a predefined diameter threshold. In principle the same risk categories apply as to the initial elective aneurysm surgery, however, as the patient is older, risks will be higher.

Figure Appendix: Events over time for an abdominal aortic aneurysm patient, as represented in the Markov model


non-AAA death
(extra-anatomical) prosthesis
elective surgical death
infected prosthesis
inf surgery
Patient with AAA
elective surgery
vascular prosthesis
prosthesis related death
false aneurysm
FA surgery
AAA rupture
acute surgery
rupture death
"fixed" prosthesis
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increasing diameter
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Appendix 2 Information in the general brochure

The general information starts with an explanation of what an aneurysm is, including a drawing, of its silent nature, and with a qualitative description of the risks involved (death, and arterial thrombo-embolism). This is followed by a description of the three strategies available (early elective surgery, regular follow up until the aneurysm has expanded more than 1 cm, and no follow-up or surgery). Choices and procedures are briefly explained, with their pros and cons.

Main advantages of surgery are explained to be the reduction of long term mortality - providing increased life expectancy after successful operation – and the psychological benefit of eliminating worries. Possible complications are explained, the most important being operative mortality (being cited as 7 out of 100 on the basis of a Dutch population based study).

Regular follow-up is explained to provide careful monitoring of aneurysm diameter, thereby preventing unobserved expansion and increased rupture risk. It largely avoids early surgery and its associated mortality. Disadvantages are the need for regular visits, continuing worries (albeit reduced), and the probably less favorable health condition in later years, which may compromise elective surgery when it is needed then.

The main advantage of "no surgery or follow-up" is the non-occurrence of mortality associated with early elective surgery, especially in high-risk patients. Disadvantages are the continued exposure to the risks described in the introduction.

502 Table 1: Patient decision-making items within consultation evaluation questionnaire

ITEMS OF PATIENT DECISION-MAKING			
'understanding'	**'consultation with the surgeon'**	**'active participation of the patient'**	**'decisional role of the patient'**
- clarity of information - difficulty to think along with treatment decision - insight into medical problem - clarity of presentation of risk information - threatening nature of risk information - understanding of issues important for the treatment decision	- ease of consultation with surgeon due to brochure - satisfaction with duration of consultation - weighing of patient's opinion by the surgeon - surgeon's understanding of implications of having an aneurysm for patients' daily life - surgeon's perception of patient as a medical problem rather than as a person with a problem	- preparation of questions at home - asking of questions - contribution to course of communication - contribution to communication - involvement in consultation - satisfaction with own involvement - extent of having a clear treatment preference - expression of treatment preference - agreement with surgeon's advice - doubts about surgeon's recommendation	- perceived choice - perceived opportunity to choose oneself - making actual choice oneself - perceiving final choice as one's own - actual decisional roles of patient and surgeon (physician-based, shared or patient-based) - preferences for this decisional role - discrepancy between preferred and actual decisional role

503 Table 2 Characteristics of the patients in the experimental and control arm of the trial

504

Characteristics		Index arm (49)	Control arm (51)	p-value
Age (years)		71.4 ± 8.0	72.6 ± 8.0	0.79
Males (%)		44 (90)	49 (96)	0.26
Education	lower	22 (51)	15 (36)	
	middle	12 (28)	16 (38)	0.35
	higher	9 (21)	11 (26)	
Aneurysm size (cm)		5.0 ± 1.0	4.7 ± 0.8	0.15
Risk factors (%)				
At least one risk factor present		30 (61)	29 (57)	0.69
- Hypertension		4 (8)	5 (10)	0.59
- Congestive heart failure		0 (0)	6 (12)	**0.04**
- COPD		9 (18)	9 (18)	0.99
- Myocardial infarction		14 (29)	11 (22)	0.49
- Myocardial ischemia		14 (29)	19 (37)	0.42
- Decreased renal function		6 (12)	2 (4)	0.12

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507 Table 3 Agreement of post-consultation decisions with model advice, by trial arm (%)

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	Model advice			
	Surgery	Follow-up	Do nothing	Total
IB-group decision:				
Surgery	6 (46%)	7 (20%)	0 (0%)	13 (27%)
Follow-up	3 (23%)	20 (57%)	1 (100%)	24 (49%)
Other	4 (31%)	8 (23%)	0 (0%)	12 (25%)
Total	13	35	1	49
GB-group decision:				
Surgery	5 (50%)	6 (17%)	1 (33%)	12 (25%)
Follow-up	0 (0%)	25 (71%)	2 (67%)	27 (56%)
Other	5 (50%)	4 (11%)	0 (0%)	9 (19%)
Total	10	35	3	48

Figure 1: Outpatient process and study events per patient. Patients from a larger study on patient autonomy were asked for informed consent (IC) for the trial before their outpatient consultation. At their first outpatient consultation on the study, patient and surgeon discussed the aneurysm and its possible treatment options, the patient and surgeon filled in a risk sheet, and the patient filled in Questionnaire I. After the consultation the individualized risks were calculated, and patients were randomised to either receive these (IB) or not (GB). Brochures were sent by mail to patients and their surgeons. At the second consultation (T2) treatment options and brochure information were discussed. Patients filled in Questionnaire II, surgeons a short checklist.

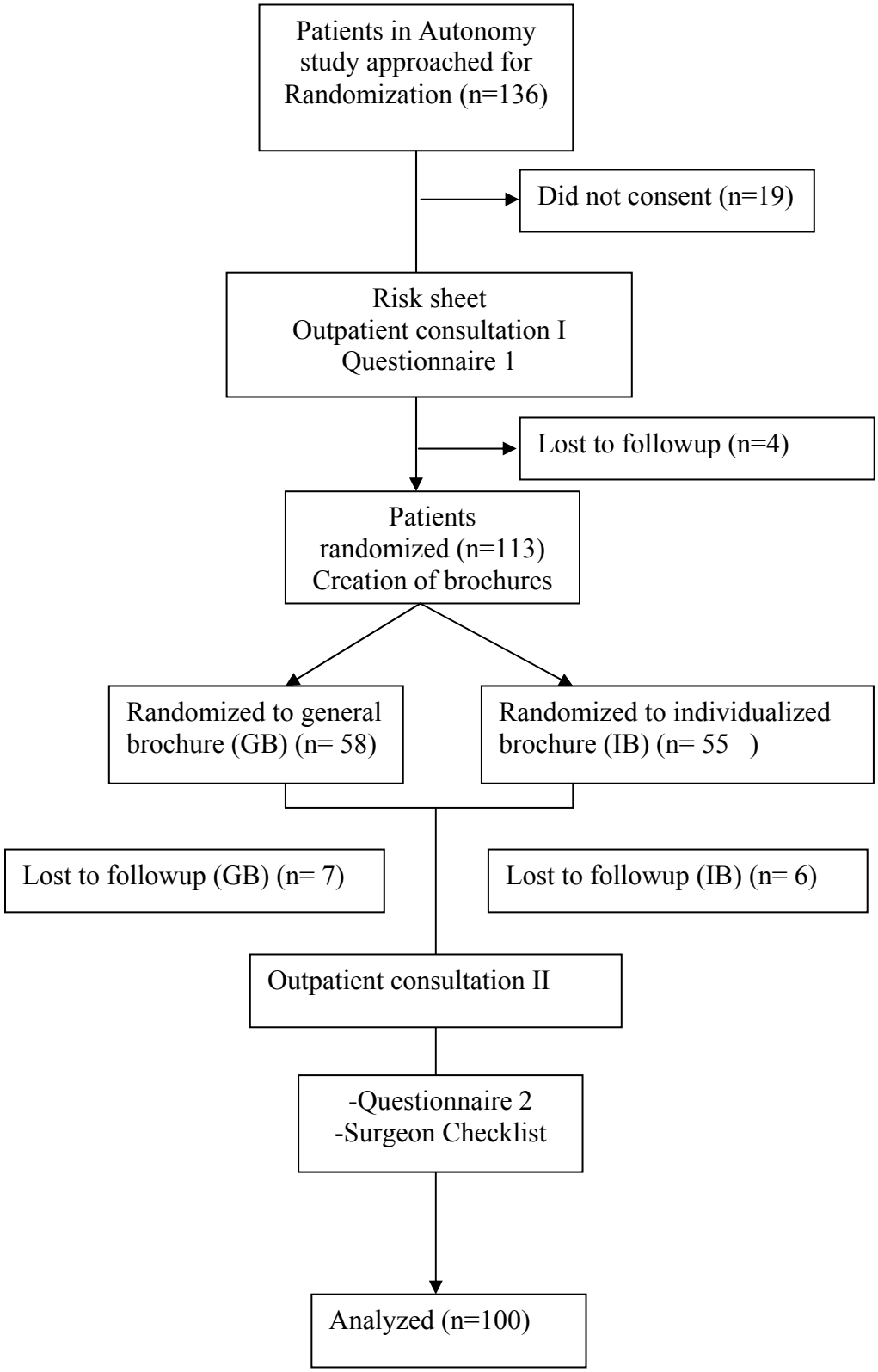

Patients in Autonomy study approached for Randomization (n=136)
Did not consent (n=19)
Risk sheet
Outpatient consultation I
Questionnaire 1
Lost to followup (n=4)
Patients randomized (n=113)
Creation of brochures
Randomized to general brochure (GB) (n= 58)
Randomized to individualized brochure (IB) (n= 55)
Lost to followup (GB) (n= 7)
Lost to followup (IB) (n= 6)
Outpatient consultation II
-Questionnaire 2
-Surgeon Checklist
Analyzed (n=100)

Figure 2: Example of Three survival curves for the three treatment strategies as presented in the IB

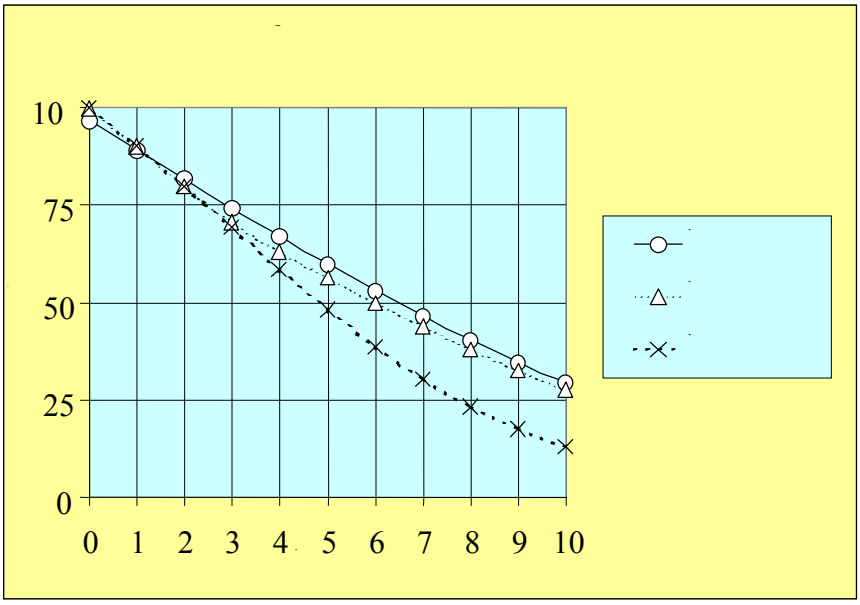
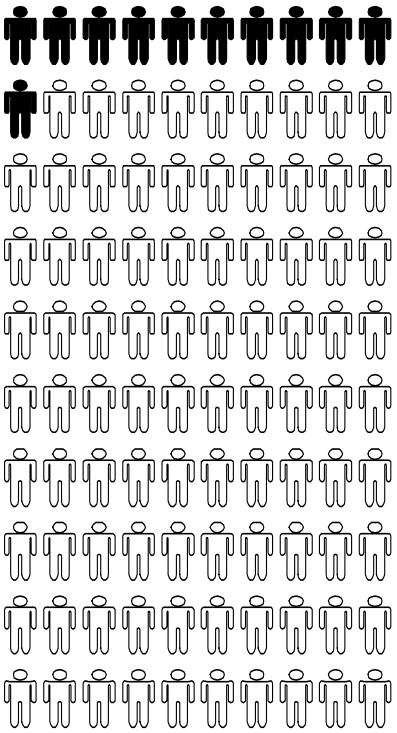

10
75
50
25
0
0 1 2 3 4 5 6 7 8 9 10

Figure 3: Example of Graphic representation of one-year mortality rate of 11% for the treatment strategy 'surgery' as presented in the IB



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