Evidence-based surgery: Dissemination, communication, decision aids

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Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis

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ABSTRACT

Objective: To summarize the evidence available on the effects of decision aids in surgery.

Summary Background Data: When consenting to treatment, few patients adequately understand their treatment options. In order to help patients make deliberate treatment choices, decision aids provide evidence-based information on the disease, treatment options and their associated benefits and harms. Although decision aids are not designed to direct patients towards a particular treatment option, it is possible that their introduction will change the proportion of patients that opt for surgery.

Methods: We searched electronic databases for studies that evaluated a decision aid in patients offered both surgery and alternative treatment options, regarding the effect on the actual treatment choices made. In addition, we documented effects on knowledge, decisional conflict, anxiety, quality of life, patient involvement, satisfaction, mortality, morbidity and costs.

Results: Seventeen studies were included. Overall methodological study quality was good. Patients in the decision aid group less often chose to undergo invasive treatment (RR 0.80; 95% CI 0.67 to 0.95), had more knowledge about treatment options (MD 8.99; 95% CI 3.20 to 14.78), and experienced less decisional conflict (MD -5.04; 95% CI -7.10 to -2.99). Levels of anxiety and quality of life were similar.

Conclusions: Offering a decision aid increases the number of patients who prefer conservative or less invasive treatment options. As decision aids improve patient knowledge and lower decisional conflict without raising anxiety levels, they have a place in surgery to help surgeons and patients achieve well-considered and shared treatment decisions.
INTRODUCTION

Patients’ treatment preferences should guide management decisions, especially where multiple treatment options exist, or if outcomes are uncertain. To involve their preferences in decision making, patients need to be fully informed about the treatment options available and their possible outcomes.\textsuperscript{1-3} However, in daily practice surgeons often only have limited time to discuss this complex matter properly with patients.\textsuperscript{4-8} Information is often concentrated on the proposed treatment option, while alternative treatment options are not always mentioned.\textsuperscript{9,10} As a result, when consenting to treatment only a minority of patients adequately understand their treatment options and the associated risks and benefits.\textsuperscript{9,11}

Decision aids used in addition to regular patient-surgeon communication, may help compensate for these limitations by providing information and involving the patient. Decision aids provide evidence-based information on the disease, treatment options and their associated benefits, harms, and scientific uncertainties. In this way, they can be of help in allowing patients to make careful treatment choices.\textsuperscript{12} A systematic review of 86 studies on decision aids for general medical treatment and screening decisions found that patients who used a decision aid had greater knowledge and less decisional conflict, and were more actively involved in the process of decision making.\textsuperscript{13}

The decision to undergo surgery is different from other decisions about health care in that it can lead to a single, irreversible intervention that can bring immediate and severe harm. This contrasts with the decision to start medication which can usually be reversed at any time. The radical nature of surgical treatment means that the effects of decision aids in surgery may differ from those described in other medical specialties.

Although decision aids are not designed to direct patients towards a particular treatment option, disclosing the range of surgical risks in detail may encourage patients to opt for non-surgical treatment or a less invasive surgical technique. On the other hand, emphasizing long term outcomes can invite patients to focus more on the ultimate benefits when weighing these against the potential harms.

The objective of this systematic review was to summarize the evidence on the effects of decision aids in patients facing a decision about surgical treatment, reflected in actual treatment choices. In addition, we summarized effects on affective, cognitive and clinical patient outcomes, and costs.

METHODS

Literature search

We searched MEDLINE via PubMed, Embase, Cochrane Central Register of Controlled Trials, Psycinfo and Cinahl for studies on decision aids in patients facing general surgical
treatment. Sources were searched up to November 2011. Key words used were: [Surgical procedures, operative (Mesh) OR surgery OR surgical] AND [Patient participation (Mesh) OR decision aid* OR decision support*]. The full search strategy is presented in Appendix 1. To identify additional studies, the references of all eligible studies were evaluated. The International Clinical Trials Registry Platform of the World Health Organization was also searched for ongoing trials involving decision aids.

Inclusion and exclusion criteria
Studies were eligible if they had a controlled comparative study design and evaluated a decision aid for patients facing a choice between surgery and one or more alternative management options. The minimum requirement of the decision aid was to provide information on treatment options and their possible outcomes in relation to the patient’s health status. They also had to contain explicit or implicit methods to help patients clarify their own values regarding treatment options before making a decision. Studies concerning obstetric surgery, ENT surgery, ophthalmologic surgery, and dental surgery were excluded. Studies on patient education programs not geared to a specific treatment decision, and studies considering hypothetical treatment choices were also excluded. There were no language restrictions.

Two reviewers independently identified potentially eligible studies in the search results from titles and abstracts. Full papers of potentially eligible studies were then obtained. Decisions about eligibility were made by two reviewers who read the complete study reports. If there was disagreement between the reviewers, the judgment of a third reviewer was decisive.

Quality assessment
The methodological quality of the studies included was assessed by means of the Cochrane Collaboration’s Tool for Assessing Risk of Bias, again independently by two investigators.

Data extraction
Data were extracted using a predesigned form. We collected data on first author, year of publication, study design (randomized or controlled trial), types of treatment option available to the participants, decision aid content, timing and mode of delivery, number of participants in each group (decision aid and no decision aid groups), and inclusion and exclusion criteria. Outcome measures recorded were proportion of patients choosing surgery, and any summary statistics on knowledge, decisional conflict, anxiety, quality of life, patient involvement, satisfaction, mortality, morbidity, and costs. Authors were contacted to obtain any information missing from the trial report. A single reviewer extracted all data, while a second reviewer independently checked the completed data extraction forms for accuracy and completeness.
Statistical analysis

Effects on choices for surgery were summarized as risk ratios, comparing the proportion of patients opting for surgery in those who had been allocated to the decision aid with those allocated to care as usual. Mean difference (MD) was used for continuous variables to summarize the effect of the decision aid on the additional outcome measures in an inverse variance model.

Data were processed and analyzed using Review Manager 5.0 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011). Summary estimates of the effects of decision aids were calculated with 95% confidence intervals. A fixed effects approach in an inverse variance model was used if the study interventions and outcomes were judged to be homogeneous. \(^{15}\) Statistical heterogeneity was evaluated by calculating the \(I^2\) statistic. If \(I^2\) exceeded 50%, a random-effects Mantel-Haenszel model was used for the meta-analysis. \(^{16}\) This report was prepared using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. \(^{17}\)

RESULTS

Results of the literature search

A total of 1086 potentially eligible papers were identified in the literature search. After reviewing titles and abstracts, 43 full-text papers were retrieved. After reading the complete study report, 26 papers had to be excluded: 16 for reporting on an intervention not meeting our decision aid criteria, 6 for being a non-controlled study, 2 for not having

![Figure 1. Identification of eligible studies](image-url)
the decision aid as the primary focus of research, one article for not including general surgery, and one article reporting on a hypothetical treatment choice. A total of 17 studies were included for data extraction and meta-analysis (Figure 1).

**Characteristics of studies included**

Fifteen randomized clinical trials, one cluster randomized trial and one of quasi-experimental, longitudinal, pre-test post-test design were included. Decision aids used in lower back problems, abdominal aortic aneurysm, prostate cancer, early stage breast cancer, cystic fibrosis, in BRCA 1/2 mutation carriers, in women with heavy menstruation, and in patients meeting criteria for bariatric surgery were studied. Details of participants’ treatment options are given in Table 1.

Decision aids were offered by means of interactive computer programs, booklets, videos with linear booklets, decision boards and patient interviews. Decision aid utilization was

<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>Participants</th>
<th>Invasive</th>
<th>Conservative/Less invasive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street^24</td>
<td>1995</td>
<td>stage I or II breast cancer</td>
<td>mastectomy</td>
<td>lumpectomy plus radiotherapy</td>
</tr>
<tr>
<td>Deyo^19</td>
<td>2000</td>
<td>lower back problems</td>
<td>lumbar spine surgery</td>
<td>no surgery</td>
</tr>
<tr>
<td>Goel^32</td>
<td>2001</td>
<td>stage I or II breast cancer</td>
<td>mastectomy</td>
<td>breast conserving therapy</td>
</tr>
<tr>
<td>Molenaar^28</td>
<td>2001</td>
<td>stage I or II breast cancer</td>
<td>mastectomy</td>
<td>breast conserving therapy</td>
</tr>
<tr>
<td>Phelan^20</td>
<td>2001</td>
<td>lower back problems</td>
<td>lumbar spine surgery</td>
<td>no surgery</td>
</tr>
<tr>
<td>Kennedy^18</td>
<td>2002</td>
<td>uncomplicated menorrhagia</td>
<td>hysterectomy</td>
<td>reassurance, drugs</td>
</tr>
<tr>
<td>Auvinen^27</td>
<td>2004</td>
<td>prostate cancer</td>
<td>prostatectomy</td>
<td>watchful waiting, drugs, radiotherapy</td>
</tr>
<tr>
<td>van Roosmalen^23</td>
<td>2004</td>
<td>deleterious BRCA1/2 mutation</td>
<td>prophylactic mastectomy</td>
<td>intensive screening</td>
</tr>
<tr>
<td>Vuorma^31</td>
<td>2004</td>
<td>heavy menstruation</td>
<td>hysterectomy</td>
<td>active observation, drugs</td>
</tr>
<tr>
<td>Whelan^25</td>
<td>2004</td>
<td>stage I or II breast cancer</td>
<td>mastectomy</td>
<td>lumpectomy plus radiation</td>
</tr>
<tr>
<td>Heller^33</td>
<td>2008</td>
<td>candidates for breast reconstruction</td>
<td>breast reconstruction</td>
<td>no breast reconstruction</td>
</tr>
<tr>
<td>Stiggelbout^22</td>
<td>2008</td>
<td>asymptomatic abdominal aneurysm</td>
<td>elective aneurysm repair</td>
<td>no follow-up, regular follow-up</td>
</tr>
<tr>
<td>Schwartz^29</td>
<td>2009</td>
<td>positive BRCA1/2 gene test result</td>
<td>mastectomy</td>
<td>enhanced surveillance</td>
</tr>
<tr>
<td>Vandemheen^24</td>
<td>2009</td>
<td>cystic fibrosis</td>
<td>lung transplantation</td>
<td>usual care</td>
</tr>
<tr>
<td>Vodernaier^20</td>
<td>2009</td>
<td>early stage breast cancer</td>
<td>mastectomy</td>
<td>breast conserving therapy + radiation</td>
</tr>
<tr>
<td>Jibaja-Weiss^21</td>
<td>2010</td>
<td>early stage breast cancer in low health literate patients</td>
<td>mastectomy</td>
<td>breast conserving therapy</td>
</tr>
<tr>
<td>Arterburn^26</td>
<td>2011</td>
<td>meeting criteria for bariatric surgery</td>
<td>bariatric surgery</td>
<td>drug treatment, diet/exercise program</td>
</tr>
</tbody>
</table>
generally secured by providing the decision aids under supervision. In six studies, decision aids were sent to patients by mail.\textsuperscript{18,22,29,31-33} Patients in the control groups had received either care as usual or general patient education materials.

One trial compared three interventions,\textsuperscript{18} two of which were decision aids that met our criteria. For the purpose of this analysis, data were extracted from both intervention groups and each group was compared with half the sample size of the control group. One group of patients with low back problems was included in two studies.\textsuperscript{19,20} However, as each study focused on different outcome measures, data were extracted from both studies.

Outcomes included in the meta-analysis were treatment chosen, knowledge of disease and treatment options, patient decisional conflict, anxiety, and quality of life.

**Risk of bias in included studies**

In general, the overall methodological study quality was good (Figure 2). Most studies had applied randomization and concealed allocation. Patients were not blinded, as this is inherent to the intervention evaluated. Blinding of the care providers was impossible in some studies,\textsuperscript{18,21-25} as they were involved in providing the decision aid. It was unclear if outcome assessors were blinded to the intervention.

**Effects of decision aids**

Meta-analysis was carried out on the effects of decision aids on the treatment choices made, patient knowledge, decisional conflict, anxiety and quality of life. As $I^2$ exceeded 50% in the meta-analyses of final treatment choice and patient knowledge, random effect models were used. Fixed effects models were used to analyze decisional conflict, anxiety and quality of life.
All treatment options were categorized as invasive versus less-invasive or conservative treatment, for example mastectomy versus breast-conserving therapy. Twelve studies reported on the treatment options chosen by patients and their surgeons. A total of 473 out of 1451 patients (33%) who had used a decision aid chose to undergo the invasive treatment option, while 539 of 1223 patients (44%) in the control groups made the same decision, resulting in an absolute difference of 11%, and a risk ratio of 0.80 (95% CI 0.67 to 0.95) (Figure 3).

Patients who used a decision aid scored 9 points better on the 100-points scale knowledge assessments than those who did not (MD 8.99; 95% CI 3.20 to 14.78) (Figure 4). Two studies that could not be included in the meta-analysis also reported significant differences in patient knowledge in favor of the decision aid group (p-values given: <0.001). In another two studies, the knowledge test scores of patients who had been provided with a decision aid showed greater improvement over time.

Schwartz et al. reported a significant effect over time on patient decisional conflict of providing a decision aid (p-value given: 0.03). Stiggelbout et al. reported insignificant differences in anxiety (p values given: >0.05). Anxiety levels were similar in patients with or without the decision aid. The summary estimate of the difference in State Trait Anxiety Inventory scores was -0.62 points (95% CI -2.45 to 1.20). Heller et al. found a similar decline of anxiety levels over time in both randomization arms.

**Figure 3.** Effect of decision aids compared with general patient information on actual treatment choices

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Decision aid Events Total</th>
<th>Control Events Total</th>
<th>Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deyo 2000</td>
<td>44</td>
<td>171</td>
<td>8.8%</td>
<td>0.78 [0.56, 1.09]</td>
<td>2000</td>
</tr>
<tr>
<td>Molenaar 2001</td>
<td>23</td>
<td>92</td>
<td>6.6%</td>
<td>0.79 [0.49, 1.25]</td>
<td>2001</td>
</tr>
<tr>
<td>Kennedy (interview) 2002</td>
<td>40</td>
<td>253</td>
<td>7.8%</td>
<td>0.52 [0.35, 0.77]</td>
<td>2002</td>
</tr>
<tr>
<td>Kennedy 2002</td>
<td>40</td>
<td>232</td>
<td>7.8%</td>
<td>0.58 [0.39, 0.87]</td>
<td>2002</td>
</tr>
<tr>
<td>Auvivinen 2004</td>
<td>60</td>
<td>104</td>
<td>11.6%</td>
<td>0.67 [0.56, 0.81]</td>
<td>2004</td>
</tr>
<tr>
<td>Vuorma 2004</td>
<td>98</td>
<td>184</td>
<td>11.2%</td>
<td>1.08 [0.89, 1.32]</td>
<td>2004</td>
</tr>
<tr>
<td>Whelan 2004</td>
<td>6</td>
<td>94</td>
<td>3.1%</td>
<td>0.26 [0.11, 0.61]</td>
<td>2004</td>
</tr>
<tr>
<td>van Roosmalen 2004</td>
<td>17</td>
<td>44</td>
<td>5.5%</td>
<td>1.11 [0.64, 1.92]</td>
<td>2004</td>
</tr>
<tr>
<td>Stiggelbout 2008</td>
<td>25</td>
<td>49</td>
<td>7.3%</td>
<td>1.17 [0.76, 1.78]</td>
<td>2008</td>
</tr>
<tr>
<td>VanDermheen 2009</td>
<td>60</td>
<td>70</td>
<td>12.5%</td>
<td>0.94 [0.84, 1.06]</td>
<td>2009</td>
</tr>
<tr>
<td>Vordermaier 2009</td>
<td>2</td>
<td>39</td>
<td>1.1%</td>
<td>0.42 [0.09, 2.04]</td>
<td>2009</td>
</tr>
<tr>
<td>Jibaja-Weiss 2010</td>
<td>26</td>
<td>44</td>
<td>7.6%</td>
<td>1.21 [0.81, 1.82]</td>
<td>2010</td>
</tr>
<tr>
<td>Arterburn 2011</td>
<td>32</td>
<td>75</td>
<td>9.0%</td>
<td>0.73 [0.53, 1.01]</td>
<td>2011</td>
</tr>
</tbody>
</table>

Total (95% CI) 1451 1223 100.0% 0.80 [0.67, 0.95]

Heterogeneity: Tau² = 0.06; Chi² = 42.63, df = 12 (P < 0.0001); I² = 72%

Test for overall effect: Z = 2.56 (P = 0.01)
levels measured on the Hospital Anxiety and Depression Scale (MD -0.7; 95% CI -2.64 to 1.24).  

Four studies reported on quality of life by asking patients about their general health on a 100-point scale.  

There was no significant overall difference between patients who did and who did not use a decision aid (MD -0.82; 95% -3.80 to 2.15). Kennedy et al. reported no statistically significant differences in quality of life at any of the follow-up points.  

It was not possible to evaluate patient involvement as different measurement instruments had been applied, e.g. the Perceived Involvement in Care Scale and the Perceived Decision Control Scale. Other methods included asking patients if they had prepared questions at home or just asking them who had decided what treatment option to select. In all four studies patient involvement levels were similar in all patients.  

Nine of the 16 studies reported on patient satisfaction.  

Some, but not all, studies showed evidence of increased patient satisfaction with using the decision aid, but the nature of the satisfaction measure varied substantially between studies: satisfaction with information, with the decision made, with the decision-making process, with the surgeon or personnel, with involvement in decision making, with the outcome of treatment and general patient satisfaction were reported. In addition, different measurement instruments were used.

Data on the mortality and morbidity of the interventions were not reported in any of the studies. In two studies, the total cost of menorrhagia and its treatment were reported to be lower in patients who used a decision aid than in patients who did not.  

The mean difference in cost could not be evaluated in our meta-analysis as the individual items
of which costs were measured varied considerably between studies. However, differences of -$344 (95% CI -$370 to -$298) over one year up to -$1184 (95% CI -$2110 to -$684) over two years were reported.

DISCUSSION

In this systematic review we found that patients who used decision aids while considering surgical treatment were more knowledgeable about treatment options. They experienced less decisional conflict and their anxiety levels were similar to those of patients who received general patient information. Patients using decision aids more often chose conservative or less-invasive treatment options.

Several potential limitations need to be addressed regarding this meta-analysis. We were not able to examine decision aids and information provided in the control arm. While decision aid content is bound by several quality requirements, general patient educational materials may well differ between medical centers, which could lead to additional variability in effect sizes when incorporating decision aids into outpatient care.

Six of the 17 studies included in this meta-analysis concerned early stage breast cancer patients, which is one of the most appealing situations in which patient involvement is required and widely accepted. Although it concerns life-threatening disease, there is also time to think about the different options, and the disease as such does not affect patients’ cognitive abilities. In a sensitivity analysis we did not find any striking differences between the effects of decision aids on breast cancer surgery and those of other surgical disorders. More refined sensitivity analyses concerning other medical conditions could not be performed due to the small number of studies.

The use of decision aids in addition to regular surgeon-patient communication seems to engage patients in decision-making, as it affects the final choice of treatment. Although actual patient involvement was not measured in our review, Stacey et al found patients using decision aids were more actively involved in the process of decision making. As nowadays a large number of patients prefer to share decisions rather than leaving this up to their doctors, especially where invasive procedures are an option, this is clearly a desirable effect. However, so far, factors such as the hospital patients attended or treating surgeons appear to prevail in decisions to undergo elective surgery. With the help of decision aids every patient, irrespective of hospital or surgeon, can be provided with complete information on his or her disease and the treatment options available. In this way, decision aids may help to achieve the desired balance between the input of both surgeon and patient in the treatment decision-making process.

The preference for less invasive or conservative treatment options is in line with studies of decision aids for non-surgical treatment, despite the more radical nature of the treatment under consideration. Uptake of anti-thrombotic warfarin therapy was seen to be reduced after patients with atrial fibrillation used a decision aid. In another study fewer
postmenopausal women decided to start hormone replacement therapy after using the decision aid. The effects we found on patient knowledge, decisional conflict and anxiety are consistent with those of decision aids in non-surgical studies.

Less uptake of surgical treatment is advantageous only if it reflects a patient’s willingness to undergo surgery weighed against his or her willingness to take the surgical risk. This means that the reasons why patients opt for conservative treatment are either the realization that their symptoms do not greatly restrict them, or because they are worried at the prospect of postoperative complications. Another context in which less uptake of surgical treatment may be beneficial, is if patients with a high risk of developing postoperative complications decline surgery after viewing a decision aid. This might actually lead to better surgical outcomes in the long run. Unfortunately, none of the studies found in this review provided useful data on these aspects.

In daily practice, decision aids are used for specific decisions in surgery. In situations such as acute appendicitis, it probably suffices to inform patients about their state of health, the appendectomy procedure and its inherent consequences, risks and benefits, and to ask for their informed consent. There is usually little doubt about the effects of appendectomy but in situations where the outcomes of management options are less clear, decision aids could support the decision making process by informing and involving the patient. Elective surgical repair of asymptomatic abdominal aortic aneurysms is an example of this. It is up to the surgeon to identify such situations of clinical uncertainty and to make sure that patient preferences are explored and incorporated in management decisions.

The implementation of decision aids in surgery poses some challenges. First, there are the costs of development and dissemination of decision aids. Second, despite physicians’ stated intentions to adopt them, actual use of decision aids might not come off as they have been expected to prolong physician patient communication. Yet one could argue that when patients are informed about their condition and treatment options beforehand, consultation time might actually be reduced. Future research should aim at these aspects of cost effectiveness. Third, when considering to provide a decision aid, the surgeon has to evaluate if the patient understands the information provided in it; as some patients do not understand enough about their health to be able to make objective decisions, and such patients may be hard to identify.

This systematic review shows that using decision aids improves patient knowledge and lowers decisional conflict without raising anxiety. Using decision aids may increase the number of patients who prefer conservative or less invasive treatment options. Decision aids can help surgeons and patients to achieve well-considered and shared treatment decisions.

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REFERENCES


41. McCaffery K, Irwig L, Bossuyt P. Patient decision aids to support clinical decision making: evaluating the decision or the outcomes of the decision. Med Decis Making 2007;27:619-625.


