Treatment decision support for early breast cancer patients
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Summary and general discussion
Introduction

The research described in this thesis was initiated to contribute to a better understanding of the merits of decision support for patients. More particular, the effects of an interactive decision aid for women with early stage breast cancer (stage I/II) were investigated. Many breast cancer patients are given the opportunity to choose between breast conservation therapy and mastectomy. These treatments have been proven to provide equivalent survival. Consequently, the treatment decision may be based upon the preference of the patient. Physicians generally provide information, support and educational materials to help patients with decision making. More recently, so-called 'decision aids' have been developed and introduced in health care. Decision aids are educational interventions to help patients make a deliberate choice among treatment options with different profiles of potential benefits, drawbacks and risks. As decision aids are relatively new interventions, it is important to gain insight into their feasibility, acceptance by patients and physicians, and efficacy.

An interactive Cd-Rom was developed as a decision aid for breast cancer patients (see page 12 of this thesis). The primary aim of the studies in this thesis was to investigate the acceptance of this decision aid by patients, their surgeons, and to establish its effect on the treatment decision, satisfaction and quality of life. Moreover, to gain a better understanding of the decision making process, it was investigated whether the decision aid and socio-demographic, psychological, and decision style factors predicted patients' treatment preferences and the treatment decisions. Additionally, it was investigated how much and which information patients selected from the interactive decision aid. Finally, patients' level of decisional conflict was examined, and the psychometric properties of a measurement instrument to study this concept were addressed.

Summary of the results

Following an introduction in the first chapter, Chapter 2 presented an overview of the literature concerning decision aids in health care. In this review, the following research questions were addressed: a) which types of decision aids have been developed?; b) to what extent were they feasible, and acceptable to patients and health care providers?; and c) did decision aids affect the decision making process and patients' outcomes? Thirty non-controlled (e.g. one-group only designs) and controlled studies (e.g. randomized experimental designs) were identified. Decision aids were found to be feasible and acceptable to patients, to increase patients' knowledge and the agreement between patients' values and decisions. The effects of decision aids on decisions and patients' outcomes including decision uncertainty, satisfaction, and health has rarely been addressed. When studied, the beneficial
effects of decision aids on these outcomes appear to be rather modest.

An overview of both controlled and non-controlled studies, published over the period September 1998 to April 2004, was provided in the Addendum to Chapter 2. Except for the effect on satisfaction, the results of the studies included in this update largely corroborated previous findings. It was concluded that few well-designed studies investigated the effect of decision aids on health outcomes, and that more process studies are needed to explain the efficacy of decision aids.

Chapter 3 described the results of a study in which women with breast cancer were provided with the interactive CD-Rom as a decision aid. The aim of this study was to gain insight into the acceptability of patients, and surgeons regarding this intervention. Immediately after using the decision aid, patients provided reactions to different aspects of the information provided on a written questionnaire. Surgeons were sent a written questionnaire to assess the perceived reactions of patients; the contribution of the decision aid to information giving and decision making and the program’s feasibility.

The decision aid was offered to ninety-two patients. Reactions of 86 (93%) patients were obtained. The program was evaluated as ‘good’ by all patients. Most patients found the program to be interesting, clear, useful, encouraging, and reassuring. A majority (n=76) expressed that the amount of information received was ‘about right’. The interactive, computer-based method was evaluated as ‘agreeable’ by 74 patients. Almost all patients (n=82) recommended the program to other patients. The surgeons (n=14; 100%) believed their patients had positive evaluations of the intervention. Moreover, most surgeons (n=10) said the program contributed considerably to the provision of information. With the exception of one surgeon, they all found that the program can be offered to patients on a standard basis. It was therefore concluded that the decision aid on breast cancer was acceptable to both patients and surgeons.

In Chapter 4 the results of the main investigation were presented. The study was designed to examine the extent to which the decision aid on breast cancer affects the decision between breast conservation therapy and mastectomy, patients’ satisfaction and quality of life. Consecutive patients with stage I/I breast cancer were enrolled. A quasi-experimental, longitudinal, pre- post-intervention design was used. Follow-up was scheduled three and nine months after discharge from the hospital. Control patients (n=88) received standard care (oral information and brochures). The breast cancer decision aid was provided to patients in the experimental condition (n=92) as a supplement to standard procedures. Outcome variables were: treatment decision, satisfaction, and quality of life.
No effect of the breast cancer decision aid on treatment decision was found. Patients who had received the decision aid expressed more general satisfaction with information at three and nine months. These patients were also more satisfied with their treatment decision at three and at nine months. Moreover, at nine months patients who were provided the decision aid were more satisfied with breast cancer specific information, the decision making process and communication with the physician. At three and nine months a positive effect was found on general health. Moreover, at nine months Cd-Rom patients reported better physical functioning, less pain and fewer arm symptoms. It was therefore concluded that the interactive decision aid on breast cancer had no effect on the treatment decision, but improved decision making in patients with early breast cancer, as evaluated in terms of patients’ satisfaction and quality of life.

In Chapter 5 we investigated the extent to which patients’ treatment preferences and treatment decisions can be predicted by socio-demographic, psychological, and decision making factors, and the breast cancer decision aid. Information about predictor variables was collected at baseline, before decision making and surgery.

A total of 180 patients participated in the study. In all, 72% decided to have breast conservation therapy and 28% chose mastectomy. Multivariate analysis showed that what patients perceived to be their surgeons’ preference and the patients’ concerns regarding breast loss and local tumour recurrence were the strongest predictors of treatment preference. Treatment preferences themselves were highly predictive of the treatment decision. The decision aid did not influence treatment choice. It was concluded that adequate, neutral information and communication are essential to establish that treatment decisions reflect the preferences of the patients.

In Chapter 6, the results of a study addressing the amount and type of information patients select from the breast cancer decision aid were presented. Moreover, associations between patients’ characteristics and information selection were established.

The interactive decision aid was provided to 106 patients after an initial discussion with their surgeon about their diagnosis and treatment options. The information they selected from the program was registered into logfiles. These logfiles were analyzed by socio-demographic background, treatment preference, psychological functioning, decisional conflict, and decision style factors.

Patients (n=97; 92%) used the interactive decision aid intensively. On average, patients spent almost 70 minutes searching for information and selected 21
information topics. Overall, treatment related information was more frequently selected than more general information. The interactive format was found to facilitate differences in information selection between subgroups. Age, education, and decision style factors were associated with information selection. No such relation was found for decisional conflict, treatment preference and psychological functioning. It was concluded that the interactive decision aid was intensively used, provided insight into patients' information needs, and appeared to facilitate more personalized information seeking.

Chapter 7 presented a study on the validity and reliability of the Decisional Conflict Scale (DCS). The DCS was translated and provided to two Dutch samples of cancer patients. In patients with breast cancer, facing a choice between breast conservation therapy and mastectomy, the DCS appeared to be able to distinguish between women who experienced decisional conflict, and those who did not.

However, in the sample of patients with metastatic cancer, no decisional conflict could be assessed. This finding was in accordance with the perceptions those patients were having, namely; that they had nothing to decide. Watchful waiting was not seen as a realistic treatment option. For such decision contexts, the DCS appears to be less useful.

**General discussion**

Women with stage I/II breast cancer are frequently asked to choose between breast conservation therapy and mastectomy. In this thesis, different results related to patients' decision making were reported. In view of overall results presented in this thesis, it may be concluded that the investigated breast cancer decision aid, is feasible, acceptable (Chapter 3) and effective (Chapter 4) in increasing patients' satisfaction and quality of life. The decision aid did not influence patients' treatment preferences or decisions (Chapter 5). Moreover, the decision aid was used intensively by patients (Chapter 6). It appears to be a valuable tool to address patients' needs and expectations regarding the provision of information and participation in treatment decision making.

**Methodological issues**

A few limitations in the studies reported above (Chapter 2 through 6) need to be addressed. First, it is important to bear in mind that a standard randomisation design was considered inappropriate for ethical and practical reasons, and a quasi-experimental was used. In order to prevent contamination of the standard care condition, patients were accrued sequentially in distinct time-periods. When the
effectiveness of the decision aid was assessed, significant effects, whichever found, of hospital and time-period on the study’s outcomes, and baseline differences between study groups were entered in the analyses as covariates (main study Chapter 4). Still, unknown factors, not controlled for, may have influenced the results.

Second, it is important to acknowledge that in all studies in this thesis, the decision aid was provided to patients in the presence of a specialised breast cancer nurse. Patients in the control condition received standard consultations, supplemented with brochures. A placebo intervention to avoid the potential of an attention effect was not provided to patients in the control condition. Although the nurses in our study did not educate the patients, the results of this study should be assigned to a nurse—decision aid combination.

Third, it is not clear to what extent the results found in our studies are generalizable to other settings. A selection bias may have occurred regarding the participating physicians. The physicians in our study, who participated on a voluntary basis, may be considered early adopters of a shared decision making approach. In addition, they may have been quite confident in their skills regarding shared decision making with patients. It is unclear what the effect would be of introducing the breast cancer decision aid in other settings, with physicians less familiar with the concept of shared decision making, or decision support tools. On the one hand, one may suggest that introducing a decision aid under these circumstances might produce smaller, no or even negative effects, as it may not be sufficiently embedded to reach its full potential. On the other hand, introducing the decision aid in practices less familiar with shared decision making might still be effective to some extent, as it may add quality to the communication skills of physicians.

Fourth, a selection bias may have also occurred regarding patient sampling also. However, to maximise external validity, patients from three hospitals, located in different parts of the country, were asked to participate in the study, in different time periods. One of the hospitals was a specialised cancer hospital with an outstanding reputation regarding cancer treatment. The second hospital was a large, semi-academic teaching hospital in an urban area in the east part of the Netherlands. The third hospital was smaller in size, and located in a town in the south of the country. Within each hospital, all patients eligible for a choice between breast conservation therapy and mastectomy were asked to participate, regardless of age, education, quality of life, baseline treatment preference or other characteristics. Despite our efforts to compose a comprehensive and representative sample of patients, most patients in our studies were being treated in the two larger hospitals, located in urban areas. Patients being treated in those clinics may have higher information
needs, and may be more critical compared to patients in the general population of breast cancer patients.

Fifth, all patients were aware that they were participating in a study. All patients were informed by the research coordinator, provided informed consent, and the patients in the decision aid condition were aware that they were given a new technology. Thus, reactive effects including the Hawthorne, social desirability and novelty effect may have occurred. Moreover, prior to using the decision aid, patients provided baseline data. This may have made them more susceptible for the content of the decision aid. Given these effects, the decision aid’s effectiveness may be different when implemented under usual conditions.

Effects of the decision aid on treatment decision, satisfaction and quality of life
The breast cancer decision aid did not affect the treatment decision (Chapter 4 and 5). Most patients selected breast conservation treatment. Keeping in mind the study presented in Chapter 5, patients’ treatment preferences may have already been fixed at baseline, after initial deliberations with their physicians. Moreover, the study in Chapter 6 demonstrates that patients appeared to select the type of information that concurred with their initial preference. This suggests in fact, that the decision aid functioned as an information device rather than as decision support tool, which is in agreement with what surgeons thought was the aid’s most important purpose (Chapter 3).

The decision aid was developed in cooperation with, amongst others, patients, physicians from different disciplines, psychologists, and health educators. A protocol was developed to guide its implementation. Thanks to the careful development and implementation process, one may have expected patients to become more satisfied. However, we were not expecting improved quality of life after being provided with a decision aid. As it is generally believed that the benefits of information tools, if any, are largely psychological, it is the more surprising that improvements in physical aspects of quality of life were found.

Three potential explanations for improvement in quality of life deserve attention. First, we cannot exclude the possibility that the results are due to chance (type 1 error). A second explanation might be that women’s quality of life may be improved as a result of a better decision making process. Indeed, patients who were given the decision aid were found to be more satisfied with the decision making process and the decision made (Chapter 4). This does not imply that patients made different decisions, as was demonstrated in Chapter 5. However, following the provision of the decision aid, patients may have gone through a more thorough decision making
process. This may have enhanced their conviction that they chose for the best option, which may have resulted in more appropriate health behaviors.

Third, the information in the decision aid may also have contributed to a better coping response in patients. Edelmann cites Janis who argued that patients, on receiving information about treatments, will mentally rehearse what might happen and mobilize appropriate coping resources ('work of worry'). Additionally, Leventhal and Johnson argued that information provision may help in the facilitation of coping strategies. Their self-regulation theory suggests that patients are better able to care for themselves when they understand their situation and when expectations and actual experiences are congruent. This in return is likely to result in increased feelings of control regarding health problems. Lazarus et al.'s, cognitive appraisal model, and Bandura's theory of self-efficacy suggest that patients' perceptions of control are essential in the adjustment to disease. Linking these theoretical assumptions, we hypothesize that the breast cancer decision aid may have improved patients' perceptions of self-efficacy and control. Subsequently, improved self-care activities may have occurred, for example regarding the prevention or treatment of arm and shoulder symptoms. However, this explanation is speculative rather than evidence-based, as our follow-up of patients did not incorporate knowledge, perceived-control, self-efficacy or behavioral measures.

Practice implications

Our decision aid proved to be feasible, acceptable (Chapter 3) and effective in terms of satisfaction and quality of life (Chapter 4), and should therefore be implemented in practice to benefit patients eligible for a choice between breast conservation therapy and mastectomy. Ideally, the decision aid would be implemented within hospitals and provided to patients in the presence of a nurse. However, a few obstacles have to be cleared first.

To begin with, concerns regarding physicians' skills related to shared decision making have been raised, and key figures in the field of shared decision making have called for training programs for professionals.

Second, a possible threat to successful implementation of decision aids is related to the factor of time. Studies examining the adoption of decision aids have reported physicians' reluctance to use the aids due to their concerns that these may add additional tasks for which they do not have time. Indeed, speedier systems of care are being set up, and physicians are not given enough time for information giving, education and communication with patients. When decisions have to be made in a rush, it is not likely that meaningful patient involvement in care will occur.
Third, one must realize that a decision aid is only as effective as the information it contains, and therefore requires regular updating. Parts of the information in our decision aid are indeed out-dated. For example, information regarding the sentinel node procedure, which is now a standard procedure, is not included. As a result, the current version of the decision aid has not been disseminated yet. When an updated decision aid is available, the need for hardware and software, and a room for patients to use the decision aid may be cost prohibitive. Moreover, personnel is needed to ensure optimal use of the equipment and to support patients whenever necessary. Keeping in mind that specialized breast cancer nurses are withdrawn from some outpatient clinics in the Netherlands, it may be questioned whether hospitals are willing to spend budgets to purchase the decision aid and implement it as suggested.

A reasonable solution to the practical problems regarding the implementation of the decision aid, might be the development of an alternative version of it for publication on the Internet. An important advantage of providing the decision aid on the Internet is that most patients would be able to view the information in their own homes, in their own time, without additional visits to the hospital, and with minimal costs for hospitals. Moreover, decision making processes are likely not restricted to patients and physicians, but may include patients' partners, children, and friends. It is important that all persons involved have the same information, of the same quality. On-line availability of the decision aid may not only address the information needs of patients, but also satisfy those of others involved also.

However, providing the breast cancer decision aid on the Internet may have disadvantages as well. Patients may not have access to the Internet, and when they do they may not use it. Moreover, providing the decision aid through the Internet may not integrate with or parallel the physicians' communication, and consequently may be perceived by patients as an intervention on its own, which exists along many other Internet sites and educational materials. The breast cancer decision aid may then loose a great deal of its effectiveness. However, this latter problem may be dealt with by the development of a protocol, ensuring the integration of the Internet-based decision support with the communication of the caregivers involved. Then, launching the updated breast cancer decision aid on the Internet may be a reasonable option.

Future research
The studies in thesis suggest several additional questions for future research. First, it is unclear whether the results found will hold in other settings. Replication of the study in other places may be warranted.

Second, few studies have investigated the effect of a decision aid on quality of
life. Our study indicated that decision aids have the potential to improve quality of life. Future studies should foremost address whether decision aids affect health outcomes.

Third, future studies should be designed to explain why decision aids are effective. To improve our understanding of the underlying processes of observed effects, studies may explore the communication between patients and physicians. For example, it would be interesting to videotape the consultation and investigate how treatment options are presented to patients. Moreover, to improve our understanding of intrapersonal cognitive or emotional processes in patients, thinking aloud protocols may be helpful to clarify beliefs, perceptions of control, and self-efficacy. Future studies should, moreover, link indicators of processes with the outcomes of interest.

Fourth, positive effects of the breast cancer decision aid were found on an aggregate level. Whether decision aids are more or less effective in certain subgroups remains to be seen. Decision aids may not necessarily be beneficial to each individual patient. For example, interaction effects between the decision aid and socio-demographic characteristics, coping style, disease or treatment-related factors, decisional conflict or the strength of patients' treatment preferences may exist. Future studies should investigate for which patient groups a decision aid works best.

Fifth, the study in chapter 5 revealed that patients were primarily interested in treatment-related information. It would therefore be interesting to investigate whether a shorter version of the decision aid including only treatment information is equally effective.

Finally, the merits of internet-based decision aids are not clear. The processes and outcomes of providing the breast cancer decision aid over the Internet should thus be examined.

To conclude, breast cancer patients will increasingly be asked to participate in treatment decision making regarding primary or adjuvant therapy or in palliative care. Patients need time to adjust to their situation, search for information, compare treatment options, discuss these options with their relatives, and to weigh the pros and cons to reach a final decision. Adequate information and communication are a prerequisite for patients to participate in decision making. Physicians and nurses may increasingly turn to the use of decision aids as adjunct to the consultations. Decision aids are acceptable, support decision making, result in positive outcomes, and are thus important contributions to the quality of care.
References


