DANISH BREAST CANCER COOPERATIVE GROUP RANDOMIZED TRIAL SHARED DECISION MAKING (DBCG RT SDM)

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Shared Decision Making for Breast Cancer Patients – with a main focus on adjuvant radiotherapy

I) AIM

The aim of this project is to elucidate whether the clinical use of shared decision making (SDM) and a patient decision aid (PtDA) will influence patient engagement in the decision process about adjuvant radiotherapy for patients operated with breast conservation for early node-negative breast cancer or ductal carcinoma in situ (DCIS).

Secondary aims: to elucidate if the clinical use of SDM and a PtDA for the decision process about radiotherapy in early breast cancer patients will influence on patients' fear of recurrence, decisional conflict, decisional regret, sense of collaboration in decision making, or patients' quality of life.

To customize and test a PtDA for the choice of adjuvant radiotherapy in early breast cancer patients.

II) INTRODUCTION

Every year, approximately 4.800 women are diagnosed with breast cancer and 1.200 patients die of breast cancer in Denmark (1–3). The primary treatment of breast cancer is most commonly surgery. Thereafter, the patient is most often offered adjuvant treatment including radiotherapy (RT) or medical treatment involving chemotherapy, endocrine therapy or biologic targeted treatment.

Women with breast cancer find themselves in many decision making situations during their treatment. One of these situations occurs after surgery when the patient is referred to the oncology department for adjuvant treatment. At this point, the tumor has been removed by surgery and the patient is cured for all visible cancer. Some patients will never have recurrence of the breast cancer even without adjuvant treatment; others will have recurrence despite adjuvant treatment. Adjuvant treatment is given to help the third group: those for whom a recurrence is prevented by adjuvant treatment. Distinguishing between these three groups, at the point of time where visible cancer has been removed by surgery, continues to be a challenge (4–8).

Most patients are recommended adjuvant treatment with one or more of the options mentioned above depending on their risk profile and patient characteristics. However, the situation is rather complex, as the patient's individual risk profile, defined by the patient's age, type of cancer, tumor size, nodal status, human epidermal growth factor receptor (HER2) status, and hormone-receptor status, is essential to estimate gain and risk from the adjuvant treatment (4,5,9).

All the adjuvant treatments offered have side effects, some of these side effects are acute and will pass, while others may be long term side effects. Calculations of expected side effects and expected gain are essential in recommendations for adjuvant treatment (9–11).

In recent years de-escalation of RT has been in focus, thus since 2016 partial breast irradiation has been DBCG standard as opposed to whole breast irradiation in selected low risk patients. More recent studies seek to investigate differences in local recurrences between partial breast irradiation versus no irradiation in early breast cancer (11,12). Some patients benefit from RT while others receive overtreatment. Considering the well-known side effects of irradiation (13), involving patients in the decision on whether to receive irradiation seems appropriate.

Shared Decision Making (SDM) is a clinical process in which clinicians and patients work together to make appropriate health decisions based on clinical evidence and the patient's informed preferences (14). SDM may increase patient involvement by making the patient comfortable in taking active part in decision making in situations where there is more than one option and neither is clearly better. Furthermore, SDM may help physicians respect the fact that patients value potential benefits or harms of a certain option differently. One model of how to practice SDM could be, with the help of a Patient Decision Aid (PtDA), to facilitate patient awareness of that she is in a decision making situation and invite the patient and relatives to take part in the decision making. During this process, options and patient values may be clarified to facilitate deliberate decision making (15).

Patient Decision Aids are tools developed to support the process of SDM. A PtDA should present options in a clear, understandable, evidence based order and facilitate the clarification of the patient's values (16). The use of PtDAs improve patients' knowledge of options, make patients more clear about what matters to them, and to decrease their decisional conflict.

Fear of that patients might deselected recommended life-saving treatment may keep physicians from engaging patients in decisions about their treatment. However, the effect of SDM and a PtDA on the decision made varies in different clinical situations. For instance, the use of a PtDA has shown to decrease the number of patients choosing elective surgery but results have been mixed for the choice of colon cancer screening and breast screening. Physicians should be aware that they will still have a high impact on the decision made when using a PtDA (17,18). The aim of this project is not to encourage patients to deselect or select certain treatments. The aim is to engage the patient in the decision process, thus making the patient more comfortable about an important decision in her life.

III) PLAN, METHODS AND TIME SCHEDULE

We are planning a multicenter, national, randomized phase III trial where doctors are randomized to either use or not use SDM and a PtDA when informing the patients about benefits and risks of receiving adjuvant radiotherapy.

The primary endpoint will be patient engagement, which will be evaluated using the validated 9-item SDM Questionnaire (SDM-Q-9)(19). The secondary end points will be measured with the questionnaires FCRI-SF (fear of recurrence)(20), the Decisional Conflict Scale (21), the Decisional Regret Scale (22), the CollaboRATE

scale (23,24) , and the EORCT instrument (25). The doctor's experience of the level of SDM will be measured with SDM-Q-9-doc (26). Furthermore, consultation time, whether the patient and clinician are ready to make a decision and the decision made will also be registered in both arms.

OVERVIEW OF DATA COLLECTION

	Screening	Before the consultation	After the consultation	After 6 months
Informed consent	X			
Patient characteristcs	X			
Demografic data	X			
SDM-Q9			X	
SDM-Q9-doc			X	
SDM Process_4			X	
FCRI-SF			X	X
Decisional Conflict Scale		X	X	
Decision Regret Scale				X
EORCT				X
Collaborate			X	

Setting: The study will be conducted on behalf of the DBCG Radiotherapy Committee and Danish Comprehensive Cancer Center (D CCC). This national trial will take place on the oncology departments in Aalborg, Aarhus, Odense, Herlev, Naestved, and Vejle. At each location study nurses will include the patient, distribute questionnaires and register consultation time and the decision made.

The Patient Decision Aid: A PtDA template earlier developed and clinically tested in according to the International Patient Decision Aids (IPDAS) criteria will form the basis for a customized patient decision aid for this specific decision on whether to receive adjuvant radiotherapy after breast conserving surgery (27) . The adjustment of the PtDA will also follow the IPDAS guidelines (16). The participating radiotherapy centres, the DBCG radiotherapy committee, patient representatives and the Centre for Shared Decision Making are collaborating to adjust and refine the PtDA to this clinical situation. This cooperation will take place at workshops and by email correspondences.

Participants: We are planning to enroll 748 patients, 374 in each arm.

We will include patients over 18 years of age with histologically verified breast cancer, who are offered adjuvant radiotherapy DBCG type F after breast-conserving surgery for T1-2, N0-Nmi, M0 disease according to national guidelines. All participating patients must give written and oral confirmation of participation.

Time schedule: Enrollment of patients is planned to be initiated in 2019.

DBCG RT SDM is part of a Ph.d. project.

OVERALL PLAN FOR THE Ph.d. PROJECT

Project 1: a systematic review on SDM for breast cancer patients offered adjuvant treatment

Project 2: A prospective cohort study testing SDM and the use of a PtDA for breast cancer patients offered adjuvant treatment. Data has been collected.

Project 3: DBCG RT SDM

	2019				2020				2021				2022				2023			
Ph.D. enrolment				x	x	x	x	x	x	x					x	x	x	x	x	
Ph.D. courses					x	x	x	x	x	x										
Project 1: systematic search for articles						x	x													
Project 1: writing paper								x	x	x										
Project 2: analyzing data and writing articles				x	x	x														
Project 3: planning and initiation				x	x	x														
Absent from PhD project, working at the oncology department											x	x	x	x						
Project 3: enrollment of patients					x	x	x	x	x	x	x	x	x	x						
Project 3: analyzing data and writing articles															x	x	x			
Preparing thesis and defence																	x	x	x	

IV) THE PRACTICAL IMPLEMENTATION OF THE PROJECT

In Denmark approximately 2000 patients are operated annually for local breast cancer and thereafter offered adjuvant radiotherapy. Many of these patients may be eligible to participate in project 3.

The project is organizationally based at the Centre for Shared Decision Making, Vejle Hospital, which will collaborate closely with the DBCG's radiotherapy committee to ensure the completion of the project. The leader of Center for Shared Decision Making, Karina Dahl Steffensen, is main Ph.d. supervisor for this project.

To ensure organizational support, the Centre for Shared Decision Making has a close and direct collaboration with the management of the oncology departments at many Danish Hospitals. Furthermore, the Centre for Shared Decision Making has direct access to ongoing test proto types of PtDAs on breast cancer and other cancer patients.

V) COLLABORATORS

Members of the DBCG's radiotherapy committee will participate as an advisory board during the project. Co PhD supervisor Birgitte Offersen is chairman of the DBCG radiotherapy group and co PhD supervisor Troels Bechmann is a member of the same group. The Centre for Shared Decision Making will provide the skills on shared decision making and project management.

The Centre for Shared Decision Making has established an international advisory board consisting of members with international expert knowledge on research about shared decision making. This advisory board will provide research support during the project.

VI) ETHICAL CONSIDERATIONS

The study has been submitted for approval by The Regional Committee on Health Research Ethics and will be submitted for approval at the Danish Data Protection Agency. The study will support early breast cancer patients in making decisions in accordance to their values and life situation. Potential risk of harm to the patients is considered minimal. Not all patients wish to take part in decision making, which will be fully accepted.

VII) PERSPECTIVES

Politically, a growing interest for SDM is seen internationally (28–31) as well as nationally in Denmark (32–35). Most likely, many clinicians practice elements of SDM when communicating with patients, as they are aware that clear communication is crucial to engage patients in their treatment and improve patient compliance. However, studies show that clinicians do not engage their patients as much as the patients want them to (31,34,36) possibly because patient engagement in a busy hospital environment can be challenging despite every good intention. With its systematic approach, SDM may help clinicians engage their patients, to ensure that the decisions made are based on patient preference as well as evidence-based information.

DBCG RT SDM is part of a Ph.d. project, which is a complete package on shared decision making. A systematic review of PtDAs for breast cancer patients making a decision on adjuvant treatment (Ph.d. project 1) will supplement our local testing of a newly developed PtDA with focus on medical adjuvant treatment (Ph.d.project 2). These two projects will form the foundation for a national randomized study (Ph.d. project 3 = DBCG RT SDM). In all three projects, the main scope is on patients with early breast cancer; however, knowledge gained from this clinical testing of SDM and a PtDA may facilitate the use of SDM and a PtDA in other parts of oncology and beyond.

The aim of this project is to increase patient involvement. When data from this study has been analysed, the DBCG radiotherapy committee may decide whether to implement using SDM and

the PtDA for consultations with patients operated for local breast cancer. Evidence from this study is likely to facilitate further implementation of SDM in oncology and beyond. The collaboration between DBCG radiotherapy group and Center for Shared Decision Making at Vejle Hospital may continue after this study to ensure continuously development and refinement of PtDAs relevant for patients in oncology care as well as training of doctors in practicing SDM. This study may lead to a new, practice changing, national standard for SDM.

VIII) PUBLICATION

Results from the Ph.d. project including DBCG RT SDM will be published at international conferences, at Danish Comprehensive Cancer Center annual meetings and other national conferences and in international peer-reviewed journals. Results will be published no mattes if they are in favor of SDM or not.

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