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Are patient-reported outcomes useful in post-treatment follow-up care for women with early breast cancer? A scoping review

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Background: Patient-reported outcomes (PROs) are frequently used to evaluate treatment effects and quality of life in clinical trials. The application of PROs in breast cancer clinics is evolving but their use to generate real-time information for use in follow-up care is uncommon. This proactive use might help to shift healthcare delivery toward a more patient-centered approach by acting as a screening tool for unmet needs or a dialogue tool to discuss issues proposed by the patient.

Aims: This review aims to determine the effects and feasibility of using PROs proactively during follow-up care in early breast cancer.

Materials and methods: A systematic search was conducted in January 2019 in PubMed, Cochrane Library, Embase, and CINAHL. Studies that exclusively concerned women treated for early breast cancer where PROs were used as a proactive tool during follow-up were included.

Results: The search revealed a total of 653 records and four eligible studies were identified; three of which concerned the use of PROs both as a screening tool and as a dialogue tool, and one study in which PROs were used solely as a screening tool. The studies explored the feasibility of collecting and integrating PROs in the clinic and their ability to detect otherwise unrecognized problems. All of the included studies were prone to bias, but they point to potential benefits in respect of better symptom management in follow-up care.

Conclusion: Our search identified a small number of low to moderate quality studies of the proactive use of PROs during follow-up after treatment for early stage breast cancer. The limited evidence available suggests that PROs may be useful for providing a more complete picture of the patient’s symptoms and problems, possibly leading to improvements in symptom management.

Keywords: proactive, patient-reported outcome, PRO, breast cancer, follow-up

Introduction

Early stage breast cancer patients experience multiple symptoms following diagnosis and treatment.¹,² In policy-making and healthcare research, patient involvement has been valued as a way to assess whether the healthcare system delivers what matters most to patients.³,⁴ Accurate assessment of health status and quality of life is essential for improving well-being and rehabilitation in cancer care.⁴,⁶

Patient-reported outcomes (PROs) measure quality of life, physical and social functioning, symptoms, side effects, and emotional well-being. According to the US Food and Drug Administration, PRO data are “any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.”⁷ These measures are distinct from,
but complementary to, disease-focused outcomes such as survival, mortality, and other clinical outcomes. Self-reported data are collected using questionnaires that can be repeated over time or used as a single evaluation, depending on the purpose. Systematically collected PRO data are being used increasingly in clinical trials of cancer treatments, mainly as a secondary outcome to support a primary clinical outcome.

Breast cancer is the most frequent cancer among women, with an estimated 2.08 million new cases diagnosed worldwide in 2018, constituting 24.2% of all cancers. Advances in breast cancer treatments and improved diagnostics continue to increase the population of breast cancer survivors around the world. Within this population, PRO data have the potential to provide valuable information about long-term side effects and quality of life during survivorship. PROs are mainly used to evaluate treatment effects. Their use in real time, to inform decisions in follow-up care for individual patients, is relatively rare, but may have the potential to shift healthcare delivery toward a more patient-centered approach.

PROs can potentially be used as a screening tool to customize supportive care for breast cancer survivors. If patients are provided with PROs at several fixed time points during follow-up, the measurements can be used to allocate the patients to the intervention needed. Exposure of new problems may give an early indication of recurrence of breast cancer or of the appearance of unacceptable sequelae to prior treatment. Reports of fewer problems may be an indicator of effective supportive care, potentially avoiding further interventions and unnecessary clinical appointments, which could be beneficial to both the patient and the healthcare system.

The potential benefits of using PROs proactively during follow-up care are somewhat different from their use during active treatment. During treatment, symptoms may arise and change rapidly, and patients are usually scheduled for mandatory consultations in order to handle side effects properly and to be prescribed the continued treatment. In this case, PROs are primarily used to illuminate the dialogue about symptom management. In follow-up care, breast cancer patients experience a more varying set of needs, but with fewer opportunities to report problems to the clinician. Here, the potential of a screening tool to detect patients’ individual needs may be helpful to support personalized rehabilitation.

The present study reviews the literature on the proactive and real-time use of PROs in post-treatment follow-up care for early stage breast cancer patients. We seek to evaluate the feasibility and potential effects of PROs used proactively as screening tools to help clarify the patients’ individual needs and as discussion prompts to enhance the quality, depth, and breadth of dialogue in the clinical consultation.

Materials and methods
Scoping reviews are systematic literature reviews in a broad topic area that provide relevant and quantified results about the knowledge available on a particular topic and aim to rapidly map and synthesize the evidence to emphasize what is known. Scoping reviews are used to identify knowledge gaps, set research agendas, and identify implications for decision-making.

Search strategy
A systematic search was conducted in November 2017 and updated through January 9, 2019 in PubMed, using the key words “breast cancer” and the MeSH term “breast neoplasms” combined with the key words “patient reported outcome” and the MeSH terms “patient outcome assessment” and “patient reported outcome measures.” No restrictions on language, year, or type of study design were applied and relevant references were examined for additional studies. A similar search strategy was applied to the Cochrane Library, Embase, and CINAHL databases. Please refer to Supplementary materials for the entire search string.

Selection criteria
Studies that met the following criteria were included: 1) the study population exclusively concerned women treated for early stage breast cancer; and 2) PROs were used proactively as a screening or a dialogue tool during follow-up care. In the first selection stage, all relevant citations were screened based on the title and abstract for the use of PROs in a breast cancer population during follow-up. Secondly, full-text articles of potentially eligible studies were obtained and assessed for eligibility. Both procedures were performed by one reviewer (CLR), but any doubt of eligibility was resolved by achieving consensus among three reviewers (CLR, TB, KDS). We excluded studies if the population consisted of mixed cancer types or if some patients had metastatic disease, and we excluded studies if PROs were collected as an outcome measure but not used proactively. Hence, only studies concerned with the proactive use of PROs were included, by which we
mean data reported by a patient and used to inform care for the same patient during follow-up.

Information was extracted in a standardized format according to a prespecified Data Extraction Sheet to summarize the studies under the following headings: patients, study methods, aims and outcome, assessments, description of the PROs, how they were used, principal findings, and comments. Extracted data are presented in Table 1.

A PRO used as a screening tool was defined as a tool for allocating breast cancer patients to the most optimal supportive care based on symptomatology. A PRO used as a dialogue tool was defined as a tool, which revealed the patient’s physical and psychological symptoms or concerns ahead of a clinical visit and contributed to the discussion of those at the clinical visit. Follow-up care was defined as the post-treatment rehabilitation assignment, which follows and complements the primary surgery and adjuvant treatment with chemotherapy and/or radiotherapy. Defining the initiation of follow-up care may be difficult, since some patients receive only surgery while others have several kinds of adjuvant treatments, including up to 10 years of endocrine therapy. In the current review, the management of acute side effects from chemotherapy and radiotherapy is not considered to be part of follow-up care. Consequently, follow-up initiates at the end of these treatments. Adjuvant endocrine treatment is recommended for 5–10 years and is thereby included as one of the challenges follow-up care needs to provide for.

Assessment of risk of bias
Risk of bias at the individual study level was assessed using the Risk of Bias in Non-randomized Studies – of Interventions (ROBINS-I) tool. The ROBINS-I tool is based on the Cochrane Risk of Bias tool for randomized controlled trials (RCTs) and was developed for intervention studies that did not use randomization, so in a review with heterogeneous study designs this tool was found to provide the best comparison. Risk of bias is assessed within specified bias domains, and review authors are asked to document the information on which judgements are based. Seven domains were assessed: confounding, selection, classification, departures from intended interventions, missing data, outcome measurement, and selective reporting. An assessment of bias was reported for each of these domains and summed to an overall judgement presented in Table 2. Two review authors (CLR, TB) used the ROBINS-I tool and independently assessed the risk of bias across the seven domains for each included study. Any disagreements were discussed and resolved by consensus.

Results
As shown in the PRISMA (Figure 1), a total of 653 records were identified and screened for eligibility. Ninety-six articles concerned women treated for early stage breast cancer with PROs used as a primary or secondary outcome measure in a follow-up setting. These were further scrutinized and those articles not concerned with the proactive use of PROs in follow-up care were discarded, leaving four studies that met the eligibility criteria.

The extracted four articles were of recent date, published from 2012 until 2017. A summary of the abstracted information is presented in Table 1. Sample sizes ranged from 102 to 172 patients. Three out of four articles used electronic surveys and multiple assessments over time to achieve a longitudinal perception of the patient’s condition during follow-up. In the fourth study, printed PRO questionnaires were provided to patients with a prepaid envelope for completion at a single time-point as a cross-sectional survey analysis.

Characteristics of PRO tools
Three studies used generic, validated PRO tools to capture the patient’s perspective of health, quality of life, anxiety, depression, or other related issues. In one study, the content of the questionnaires included both validated surveys such as the 36-Item Short-Form Health Survey and the 8-item Patient Health Questionnaire depression scale (PHQ-8) as well as a non-validated symptom questionnaire modified from the Memorial Symptom Assessment Scale. The questionnaire also included a free text area for patients to pose questions or report concerns to their provider. The PHQ-8 is validated as a diagnostic and severity measure for depressive disorders in large clinical trials. The Hospital Anxiety and Depression Scale (HADS) is another widely used and validated tool to measure anxiety and depression. The HADS was used together with the European Organization for Research and Treatment of Cancer quality of life questionnaire in a pilot study. This study also used the validated distress thermometer, a numerical scale from 0 (no distress) to 10 (extreme distress), to allocate patients into the study by a cutoff point of >7. This score has been shown to identify breast cancer patients suffering from moderate to severe distress. The fourth study used a non-specified web-based health questionnaire with no further documentation about the origin or validation.

Design, feasibility, and principal findings
The use of PROs both as a screening tool and as a dialogue tool was investigated in three studies. In a Danish RCT
study,32 PROs were used as a screening tool to detect those patients who were in need of a nurse navigator intervention to relieve distress, anxiety, and depression. From a cohort of 116 newly diagnosed breast cancer patients, 50 patients reported scores that indicated a high level of distress. These 50 patients were randomized 1:1 to the intervention group or the control group. The remaining 66 patients were observed and completed PROs at baseline, 6 months, and 12 months.

The nurse navigator aimed to improve rehabilitation and supportive care by empathetic listening and actively engaging in dialogue. Using PROs for assessment of the patients’ needs provided topics for psychoeducation, goal-setting, and debriefing. The dialogue was conducted face-to-face or by telephone and could be assisted by referrals to existing rehabilitation offers. At 12 months, the intervention group reported lower levels of distress, anxiety, and depression

### Table 1 Summary of studies reviewed

<table>
<thead>
<tr>
<th>Study (author, year, country, reference)</th>
<th>Patients (number, mean age, breast cancer stage)</th>
<th>Study methods and setting</th>
<th>Aims and outcome</th>
<th>Assessments</th>
</tr>
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<tbody>
<tr>
<td>Mertz et al, 2017, Denmark32</td>
<td>N=116, 54.8 years. Women with newly diagnosed early breast cancer</td>
<td>RCT-observational, 50 women in an RCT and 66 in an observational group. Patients were recruited at the surgical department</td>
<td>To determine the feasibility and effectiveness of an individual, nurse navigator intervention for relieving distress, anxiety, depression, and health-related quality of life</td>
<td>All patients (control, intervention, and observation groups) were asked to fill in questionnaires at baseline and after 6 and 12 months. Patients in the intervention group filled in three additional short screenings at 1, 9, and 18 weeks</td>
</tr>
<tr>
<td>Wheelock et al, 2015, USA33</td>
<td>N=102, 52.85 years. Stage I–III, during follow-up</td>
<td>RCT comparing SIS.NET with standard follow-up care</td>
<td>To quantify the time between symptom reporting and remote evaluation of symptoms. The secondary endpoint was to compare use of healthcare resources (breast cancer-related visits, total medical appointments, and laboratory and imaging studies) over an 18-month period</td>
<td>Participants in the SIS.NET arm received email invitations to complete an online health questionnaire every third month and could by email request an interim questionnaire</td>
</tr>
<tr>
<td>Thompson et al, 2013, UK33</td>
<td>N=172, 63.7 years. Stage I–III, attending routine follow-up</td>
<td>Prospective study, patients were approached in outpatient clinics</td>
<td>To examine levels of psychological distress for patients approaching discharge from hospital follow-up care to community-based care</td>
<td>Only one assessment at least 2 years past diagnosis. Patients were provided with paper questionnaires and a prepaid envelope so measures could be self-completed and returned to the study team</td>
</tr>
<tr>
<td>Bock et al, 2012, USA34</td>
<td>N=106, 56.9 years. Stage I–III, during follow-up</td>
<td>Retrospective analysis of symptoms reported in a questionnaire, clinic notes, or both, excluding chronic symptoms addressed previously</td>
<td>To investigate the impact of a web-based health questionnaire on symptom reporting, physician documentation of symptoms, and symptom management</td>
<td>A comprehensive questionnaire for completion before each new patient appointment and a shorter survey before follow-up appointments</td>
</tr>
</tbody>
</table>

**Abbreviations:** CORE, Clinical Outcomes for Routine Evaluation; HADS, Hospital Anxiety and Depression Scale; PRO, patient-reported outcome; RCT, randomized controlled trial; SIS.NET, System for Individualized Survivorship Care, based on patient self-reported data, with review by Nurse practitioners, targeted Education, and Triage.
<table>
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<tr>
<th>Description of PRO tools</th>
<th>How PROs were used</th>
<th>Principal findings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td># Distress thermometer, a numerical scale from 0 (no distress) to 10 (extreme distress)</td>
<td>Dialogue and screening: baseline scores were used to allocate patients to observation or RCT study</td>
<td>Women in the intervention group reported significantly greater satisfaction with treatment and rehabilitation, and lower levels of distress (mean 2.7 vs 5.1, P&lt;0.01), anxiety (mean 5.1 vs 7.8, P=0.02), and depression (mean 2.2 vs 4.4, P=0.04) after 12 months compared to the control group</td>
<td>No significant effects on health-related quality of life. It was a strength to this study that the intervention was restricted to patients with moderate-to-severe distress at the time of randomization, thus focusing on the patients who might gain most from professional support</td>
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<tr>
<td># HADS</td>
<td>Symptom screening assessment at baseline, 9 weeks, 18 weeks, 6 months, and 12 months provided the basis for dialogue between the patients in the intervention group and the nurse navigator</td>
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<tr>
<td># European Organization for Research and Treatment of Cancer quality of life questionnaire Core 30</td>
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<tr>
<td># Short-Form Health Survey # Patient Health Questionnaire Depression Scale # Unspecified symptom questionnaire</td>
<td>Dialogue and screening: completion of the online questionnaire by the patient generated a clinician report summarizing the patient’s symptoms and identifying those symptoms that met a prespecified threshold for clinical concern and generated automated referrals</td>
<td>74% of new or changed self-reported symptoms were reviewed within &lt;3 days. SIS.NET patients reported more new or changed symptoms compared to standard care patients. No statistically significant difference between the SIS.NET and standard care arms with regard to oncology-related appointments, total number of physician visits, or number of medical tests was found</td>
<td>A relatively low questionnaire completion rate of 50% in the SIS.NET arm compared with the 62.5% completion rate of preclinical questionnaires among the patients in the standard care arm indicated some feasibility and compliance issues</td>
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<tr>
<td># HADS</td>
<td>Screening tool: if a patient reported scores indicative of distress, the individual was contacted by the principal investigator to assess their need for additional support and facilitate access to services</td>
<td>Patients reported low levels of distress in hospital-based follow-up, which were comparable or better than general population norms, although there was a significant minority of patients reporting high scores (n=27, 15.7%) on HADS or CORE</td>
<td></td>
</tr>
<tr>
<td># CORE</td>
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<tr>
<td># Measure Yourself Medical Outcomes Profile</td>
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<tr>
<td># A non-specified web-based health questionnaire</td>
<td>Dialogue and screening tool: the clinician summary report was placed within the chart before the clinic visit containing the patient’s self-reported data</td>
<td>Patients reported significantly more symptoms using the online questionnaire (mean=3.8, range 0–13) than were documented by the provider in clinic notes (mean=1.8, range 0–7; P&lt;0.001 for the difference)</td>
<td>This study is of sparse clinical interest, since the findings were not compared to standard procedure. It is reasonable to expect that the clinician performed a prioritized reporting of relevant symptoms and thereby failed to report as many symptoms as reported by the patient</td>
</tr>
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</table>

compared to the control group. No significant effects were seen on health-related quality of life. The intervention was found to be feasible and useful for patients with high distress scores at the time of diagnosis.32

In an RCT from the USA, a web-based system for symptom management after treatment of breast cancer was evaluated against standard care.33 The online questionnaire included a free text area for patients to pose questions or report concerns to their provider. The information was used in the triage of patients for additional follow-up appointments and aimed at facilitating patient–clinician dialogue, when present. The authors hypothesized that PROs would reduce time to symptom management and decrease the number of breast cancer-related hospital appointments, but no reduction in the use of healthcare resources was demonstrated.33 Participants in the intervention group reported a significant higher mean of 7.36 new or changed symptoms during the 18-month study period compared to the standard care arm with a mean
of 3.2 new or changed symptoms. The authors concluded that the online questionnaires facilitated better reporting and more timely assessment of symptoms, particularly for those symptoms not deemed by the patient to be urgent and in need of immediate attention. There was a comparatively low questionnaire completion rate of 50%, which the authors suggested could be caused by the electronic interface, which might have inhibited its use by some patients.

In a retrospective analysis of 106 breast cancer patients, the impact of using a web-based health questionnaire on symptom reporting, physician documentation of symptoms, and symptom management was investigated for its potential of screening for otherwise undetected symptoms and as a dialogue tool in the management of those. The study sample was randomly selected from a population of patients who had filled in a follow-up questionnaire before their appointment and had given consent for data to be used in clinical research. The sample was argued to be representative for the whole breast cancer population. A summary of the information reported by the patients was available for clinician review before the patient’s visit. The questionnaire completion rate was nearly 80% for first appointments and about 40% for follow-up visits in the population from which the sample was extracted. The primary finding was a significantly higher incidence of symptoms reported by the patient than documented by the clinician.

In the fourth study, a prospective study of 172 participants, PRO measures were used solely as a screening tool to identify levels of distress in breast cancer survivors approaching discharge from hospital-based follow-up care to community-based care at least 2 years past diagnosis. This study met the inclusion criterion of proactive use by the fact that patients who reported scores that indicated significant distress were contacted and referred to supportive services. Only a minority of patients reported high anxiety and depression scores on the generic PRO instruments used in this study, but the authors concluded that screening with PROs for psychological/emotional distress should be a vital part of follow-up care. The response rate was 75%.

### Biases in the studies

The assessment of risk of bias by the ROBINS-I tool is presented in Table 1. Only the pilot study achieved moderate bias assessment as a consequence of the RCT design and high response rates. The remaining three studies were assessed as having a high risk of selection bias, confounding, and missing data. The scores according to the ROBINS-I tool across seven domains are reported in Table 2.
Discussion

The majority of the publications on the use of PROs within breast cancer patients deal with the patient's evaluation of a treatment. Using PRO data in clinical trials examining side effects of adjuvant endocrine therapy has revealed a higher frequency of both physical and psychosocial symptom burden than based on clinicians' assessment. Thus, one of the potential benefits with the application of systemically obtained PRO data, used proactively in survivorship, may be to provide a more comprehensive evaluation that includes...
the patient’s perception of problems experienced during follow-up care.11,42–46

PROs collected ahead of a clinical visit and actively used as part of informed care for individual patients seem far more challenging than including PROs as an outcome measure in a clinical trial to assess treatment effects.47,48 Implementation of the proactive use of PROs in everyday care involves changing the clinical culture and workflow, requiring extra training and support for those unfamiliar with these tools. Introducing changes in clinical procedures in the face of busy work schedules can lead to a disturbed work pattern, delays, and resistance from clinical staff. Clarification of the appropriate use and interpretation of PROs and their impact on the healthcare system still needs further investigation.49–52

The present review identified four studies exploring the potential of using PROs as a dialogue tool and a screening tool during follow-up in breast cancer patients. The studies differ concerning design, the selected PRO tools, and how they evaluated the potential of applying PROs proactively during follow-up care. The range of study designs, from a randomized clinical trial to an observational study, complicates comparison of the principal findings but still gives a perspective on the potential for using PRO data proactively.

Three out of four studies used electronic surveys. Apps for phones and tablets focusing on easily accessible electronic surveys are of great importance for the rapid progress of PRO data research.53,54 It is crucial for the collection of real-time data that patients are able to assess their PROs where ever they are.22,55 Electronic collections of PROs also provide the possibility of immediate feedback to the patient and could be combined with some kind of web-based self-management application to support patient education, activation, and empowerment.56 However, electronic questionnaires may not be feasible for all patients due to language or skill barriers, particularly older people who lack computer experience or those with multiple morbidities.57 The technical feasibility of integrating PRO data into the electronic medical record has been provided in some settings and makes the collection of PRO measurements more cost-effective.49,58 Success with the task elsewhere is evolving settings and makes the collection of PRO measurements more cost-effective.49,58

In the study by Thompson et al,35 patients completed paper questionnaires. The researchers obtained a high compliance in completed items for the returned PROs, which may be attributable to the simple design of the study with a single evaluation. Of the 227 patients who voluntarily agreed to participate and who were provided with questionnaires, from a cohort of 323 eligible candidates, only 172 actually completed and returned them. The sample was thus highly selected, with only 53.2% of the cohort represented, calling into question its representativeness, and there was no discussion in the paper to inform judgment about the extent of bias this might have introduced. In research it is acceptable to allocate resources to the management of paper questionnaires, but in routine care it is necessary to minimize workloads and resource use. Infrastructure for data collection and storage, data analysis, and data presentation that is readily understood by patients and clinicians are further challenging factors for the implementation of PROs.16,52–54,57,58 In the RCT by Wheelock et al,33 low response rates were suggested to be caused by lack of skills toward the management of an electronic survey. The development of user-friendly, easy-access electronic PRO instruments, and timing – what to measure, when, and why – is crucial for standardized implementation, integration, and feasibility.51–66

Collection of PRO data has been recommended in the evaluation of lifestyle interventions in breast cancer survivorship and to provide complementary information to more traditional clinical indicators.28 Multiple studies have demonstrated that PROs more accurately capture patients’ experience of symptoms and other problems than physicians’ assessments.46,67–69 The studies we reviewed on use of PROs during follow-up care are suggestive of more complete symptom reporting, but they were too biased to be conclusive.33,34

Conclusion

The potential use of PROs in early stage breast cancer as a symptom screening and dialogue tool during follow-up is promising. However, our review reveals limited knowledge of its potential. Of the four studies we found, three were prone to bias and the fourth has limitations general for pilot studies, with low reproducibility and generalizability, since there was only one nurse navigator and a small sample size. We believe PROs could be useful to provide more complete and accurate information in patient–clinician communication, enhancing the quality of dialogue and revealing otherwise undetected symptoms or needs, but this assumption requires testing in more robust studies. If proven, this could lead to better follow-up care and improvements in health-related quality of life. The challenges, which must be overcome to provide more reliable evidence on this matter, include resistance from clinicians and the need to develop user-friendly, easily accessible technology, available for all involved parties. Further investigations in larger-scale studies are needed to understand every aspect of using PROs proactively in follow-up after treatment for breast cancer.
Disclosure
The authors report no conflicts of interest in this work.

References
Supplementary material

Supplementary S1 search string: (((“Patient Reported Outcome Measures”[Mesh]) OR “Patient Outcome Assessment”[Mesh]) OR “patient reported outcome*”[Title/Abstract])) AND ((“breast cancer”[Title/Abstract]) OR “Breast Neoplasms”[Mesh]).