Project title: Optimizing Patient Engagement in Reporting Outcomes Among Women With Metastatic Breast Cancer

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Inclusive Dates of Project: July 1, 2016 Ending date:(via no cost extension)-Dec 31, 2019

Acknowledgement of Agency Support: National Comprehensive Cancer Network (NCCN) and Pfizer Independent Grants for Learning & Change (IGLC)

Grant Award Number: NCCN Pfizer patient education grant #2015ON1

Abstract – 250 words

Purpose: Pilot-study a new approach for integrating the collection of patient-reported outcomes (PROs) into clinical care that allows Metastatic Breast Cancer (MBC) patients to record the PROs they consider important to their care and share them using a new tool called “My PROfile”

Scope: An emphasis on patient-centered care has led to a growing interest in collecting PROs in cancer care. Unfortunately, PROs are not routinely captured in clinical care, and are usually absent from medical records. Providers cannot optimally manage MBC without access to quality of life and PROs for patients undergoing treatment. Yet prior efforts to collect PROs have tended to focus on a specific domain – such as symptoms – which are important but may not represent the issues or concerns of greatest importance to individual patients. Our prior work has demonstrated substantial variation in what types of PROs patients deem most important; although physical symptoms are common, a substantial minority of patients report concerns in non-physical symptom (non-PSx) domains.

Methods: We enrolled women who had started a treatment regimen for MBC within the past 6 weeks at Smilow Cancer Hospital of Yale New Haven Hospital or an affiliated care center. Using My PROfile, participants responded to validated surveys and provided PROs (physical and non-PSx domains). Patients were followed prospectively for 6 months and asked to complete My PROfile at least once prior to each visit with their provider. For this analysis, we analyzed the frequency of reporting individual symptoms and domains by patient.

Results: Across the different PRO domains, most patients reported difficulties with physical symptoms (67%) or emotional well-being (56%). Overall, 19% of patients reported physical symptoms only, and 48% of patients reported difficulties with both physical symptoms and non-PSx domains; however, 33% of patients reported difficulties from non-PSx domains only. The location in which patients felt comfortable completing the PRO instruments varied according to the domain assessed.

Key words: Metastatic breast cancer, Patient-reported outcomes, MyPROfile

Purpose

A patient-centered approach to metastatic breast cancer (MBC) requires treatment that is supported by medical evidence and tailored to patients' needs and preferences. Routine collection of patient reported outcomes (PROs) not only facilitates decision-making and treatment evaluation, but also improves quality-adjusted survival and overall survival [1, 2]. Unfortunately, PROs are not routinely captured in clinical care, and are usually absent from medical records. Providers cannot optimally manage MBC without access to quality of life and PROs for patients undergoing treatment. Yet prior efforts to collect PROs have tended to focus on a specific domain – such as symptoms – which are important but may not represent the issues or concerns of greatest importance to individual patients. To address this critical gap, we implemented a study to develop a new approach to integrate the collection of PROs into clinical care that allows patients to select which PRO measures they want to report, culminating into a new tool for displaying the results of these PRO assessments and improving patient engagement, called "My PROfile".

This study focuses on the following aims:

Aim 1: To evaluate the feasibility of My PROfile (i.e. patient willingness to engage with the interface and answer questions regarding their PROs) and its impact on patient participation in PRO assessment.

Aim 2: To assess patients' perceived efficacy of their interaction with their provider.

Aim 3: To assess patient satisfaction with MBC care and MY PROfile.

Scope

Caring for women with MBC requires a tailored approach to address the patient's social, physical and psychological needs. Assessing and incorporating PROs into medical care and treatment decisions embodies patient-centered care. Routine capture and review of PROs is essential for providers to have full knowledge of potential treatment toxicities and for patients to more effectively evaluate treatment effects on their quality of life. While this is applicable to all clinical practice, this is even more important when cure is not the main goal, as is the case with MBC. However, PROs are not captured in a standardized manner among women undergoing MBC treatment. For women with MBC, as more therapeutic options become available, there will be an increasing need to determine how different treatments impact outcomes of importance to patients.

While patient electronic health records (EHRs) provide an invaluable resource for clinical care, the "patient's voice", a very important consideration in the context of incurable disease such as MBC, is most often absent. PROs represent this missing patient voice in EHRs. PROs capture patients' self-reported health-related quality of life, provide short and long-term information about treatment and disease burden, and can only be obtained from patients and/or their families. Quality of life (QOL), including emotional distress, physical and financial burden, and other social support concerns are essential to comprehensively assessing MBC care, but are not routinely captured during a regular medical encounter. Patient health status in physician notes is often ambiguous and non-standardized, such as "patient is doing well".[3] It has also been shown that clinicians miss or underreport on symptomatic adverse events experienced by patients, and that both physical and financial toxicity may go unrecognized by providers.[4, 5] Most often physicians do not inquire about a patient's financial stress as a result of cancer care.[6, 7] In the absence of this information, providers cannot adequately

address the patient's social, physical and psychological needs related to MBC. Yet QOL is not routinely captured in a standardized manner.

A small number of large academic care centers in the U.S. have introduced PROs into their Oncology clinical practice. Some of these electronic PRO systems include patient viewpoint, patient care monitor (PCM) and TELL US™. [8] There have also been prior efforts to share PRO data with patients at the point of care. A Swedish Rheumatology Registry provided patients with a "summary overview" that could be given to patients immediately after supplying PRO data. [9] American models such as the Self-Assessment and Management system piloted at Memorial Sloan Kettering Cancer Center and UCSF also provided patients with reported data after completion. [10] However, to our knowledge, these reports were not created in partnership with patients, rarely provide information to the patient nor were they empirically tested to determine their effects.

The Breast Center at Smilow Cancer Hospital within the Yale-New Haven Hospital (YNHH), together with the affiliated Smilow Care Centers, constitute the largest network of breast cancer providers in Connecticut. Each center offers a comprehensive range of services to patients ranging from diagnosis and treatment to recovery and survivorship for women diagnosed with breast cancer. However, the current practice does not routinely collect health-related quality of life measures. To address this gap in MBC care, we aim to increase patients' engagement in their care using patient-focused tools and strategies that help support shared decision-making. Our project aimed on building a platform to facilitate the integration of PRO information into clinical care in the Yale New Haven Health System. Patients received summary report after entering their PRO details into My Profile, a document which could enable patients to improve communication with their provider and ultimately enhance the quality and patient-centeredness of MBC care.

With the emphasis on patient-centeredness in cancer care, there has been increasing interest to collect and include PROs in EHRs and hospital patient portals, as well as longitudinal patient registries. [11] PROs in clinical practice can improve symptom identification and patient satisfaction, make clinic visits more efficient, improve accuracy of symptom assessment, and, if appropriately addressed in a timely fashion, also improve outcomes. [1, 2, 12, 13] Our approach seeks to engage patients to address important gaps in MBC care at Yale New Haven Health System

Methods

The study design was a single group pre- and post-comparison study. Patients consenting to participate in the study completed a baseline survey that assessed their perspectives about provider communication (Perceived efficacy in patient-physician interactions Survey, PEPPI survey, approximately 3 minutes to complete), and satisfaction with MBC care (Patient Reported Outcomes Domain survey, PROD survey, approximately 5 minutes to complete). Participants also completed the My PROfile surveys prior to receiving their scheduled MBC treatment. After enrollment, patients received follow-up for 6 months, during which they responded to My PROfile surveys before each clinic visit (approximately every 3-4 weeks). Patients received a report each time they completed the series of My PROfile surveys, which could be shared electronically with their providers via a secured email link. For this pilot study, however, we required the report to be shared electronically with the provider and printed out for the provider to review at the patient's appointment. During follow up, participants completed the PEPPI and PROD surveys again at 3-months.

At the end of the 6 months follow up period, participants completed the PEPPI and PROD surveys once again to assess their communication with their providers and satisfaction with MBC care. We determined the proportion of women who completed all required PRO instruments, assess their satisfaction with My PROfile (My PROfile Satisfaction Survey, approximately 3 minutes to complete), and asked them to fill out the PEPPI survey and PROD survey. We also assessed the satisfaction of the providers with My PROfile. Our research team members designed the My PROfile surveys and Archetyp Mobility converted these questionnaires into a web-based version. This web-based version was accessible by computer, smartphone, and tablet, to collect patient PROs. My PROfile PRO collection tool relied on the NCCN distress thermometer to serve as its basic structure, and it uses additional validated instruments that provide detail information to problems or concerns selected in the NCCN distress thermometer. My PROfile includes questions that addressed a broad range of problems that patients may encounter during their cancer treatment (i.e. physical symptoms, practical problems, emotional well-being, social well-being, etc.), and depending on the problems indicated, the patient received additional standardized instruments.

The time to complete the survey can vary from 5 minutes to 30 minutes depending on what modules the patient selects. Upon completion, patients were directed to the MyDashboard section of My PROfile. The dashboard provided a summary report of the completed survey, time trend of overall distress and other measures such as physical symptoms. This summary and detailed reports could be printed onto a single sheet of paper for ease of discussion with the provider.

Yale IT department assessed the final web-based version of My PROfile for HIPAA compliance before actual implementation of the intervention, to ensure that national and hospital patient privacy and security standards were met. Data was stored on a Yale server meeting HIPAA compliance as deemed appropriate by the Yale IT department. Our intervention did not impair or affect patients' planned treatment for MBC. Patients could complete the survey anytime at their preferred location (at home, at waiting room, at infusion center, etc.) using their preferred device (personal computer/laptop, smartphone, tablet, etc.). However, to ensure standardization of this intervention, the research team set some default features. We asked that patients: 1) fill out the survey within 3 days before their physician visits, 2) agree to share the report with the provider electronically and have the paper report printed out for the providers to review at the appointment.

Baseline Assessment

Patient provided their email address and phone number after consent. The research coordinator assigned a study ID to the patient, with which the patient registered on the My PROfile platform and received training regarding the use of My PROfile. The patient completed My PROfile with the research coordinator by their side, to determine if they have any questions. The training was the baseline My PROfile survey and patients' response.

Survey reminders and alerts to clinical staff

During the study, patients received either a text message or email three days prior to each appointment with their Yale oncology provider. The message asked if they want to complete My PROfile surveys, "Do you want to complete your My PROfile survey today?". If a patient has not filled out the survey before the appointment day, or missed more than one required survey, an "alert" was triggered and the patient was contacted by the study coordinator using the phone number they provided at baseline.

Upon completion of each survey, data collected was immediately available to our research coordinator. Although the goal of implementing this new tool is to improve patient provider communication, we reminded patients during the consent process that My PROfile is not a substitute for prompt communication between them and their providers (e.g. a telephone call to the clinic). The concerns and problems they indicated in the survey may not be immediately conveyed to their doctors/nurses; therefore, patients should call their provider with any concerns that require immediate medical attention.

A limitation of this pilot project was the small sample size of participating MBC patients, which would impact the clinical and sociodemographic representativeness of this study group. However, this study's focus was to assess the feasibility of collecting and presenting PROs using a novel tool to improve patient-provider interactions. Although we currently piloted MyPROfile in an English-speaking population, future investigations may consider exploring the feasibility of such PRO tools in other languages to support the needs of a diverse patient population served at large cancer care facilities.

Results

A total of 32 patients consented to participate and 27 filled out the My PROfile tool at least 1 time corresponding to an 84% access rate (27/ 32). Across the different PRO domains, most patients reported difficulties with physical symptoms (67%) or emotional well-being (56%). Overall, 19% of patients reported physical symptoms only, and 48% of patients reported difficulties with both physical symptoms and non-PSx domains; however, 33% of patients reported difficulties from non-PSx domains only. Approximately 37% of patients reported practical problems problems (including 15% who noted concerns with appetite and 22% who had concerns about monitoring diet and activity in general). Difficulties with daily activities were reported in 30% of patients (with 19% reporting housework and walking specifically). 19% of patients reported difficulties in social well-being including 15% who specifically reported concerns with family health. Within our sample patients did not report difficulties using the toilet or brushing teeth, difficulties with drug use, or difficulties in the ability to have children. The three most common individual symptoms reported were fatigue (56% of patients), pain (52% of patients), and worry (33% of patients). Nearly 60% of our respondents (16 out of 27) used My PROfile at

least twice during follow-up. Among these patients, all but 3 patient reported difficulties with physical symptoms at least twice. Additionally, 44% of these patients reported emotional concerns and 23% of these patients reported daily activity concerns more than once during the follow-up period. Of the 19 survey respondents, almost everyone did not report having issues (practical, emotional, social well-being, religious, alcohol/drug use, problems with daily activities). However, 60% had physical symptoms where most of these patients discussed these issues with their provider. Most participants reported a high confidence in their ability to ask questions and voice their concerns with their doctor. Over 50% of respondents in the follow-up survey indicated the tool helped and was easy to use.

Conclusion

Although physical and mental health symptoms are commonly reported among patients undergoing systemic treatment for metastatic breast cancer, physical symptoms were the top concern for only half of the interviewed patients in this study. There was large variation in how patients prioritized each PRO domain. Participants preferred reporting PROs while in the waiting room for most domains; however, patients preferred reporting emotional well-being in their homes. Also, patients were willing to spend double the time reporting PROs at home. Because the specific concerns of interest vary substantially across patients, tools to collect PROs should include additional domains that can significantly affect quality of life in women with MBC.

Opportunity for improvement

Although over 50% of follow-up survey participants indicated the My PROfile tool helped (53%) and was easy to use (58%), this satisfaction did not reflect the percentage of participants who thought the tool helped them better communicate with their doctor (42%) or would recommend it to others (47%). Further, not all participants who indicated issues related to their cancer or cancer treatment discussed these concerns with their doctor. Future work should further investigate the barriers preventing patients from sharing their concerns with their providers.

Publications

- Mougalian SS, Aminawung JA, Presley CJ, et al. Prioritization of Patient-Reported Outcomes by Women with Metastatic Breast Cancer. JCO Clinical Cancer Informatics. 2019(3):1-3.

Abstracts and poster presentations

- Sarah Mougalian, Maureen Canavan, Renee Capasso, Jenerius Aminawung, Carolyn J. Presley and Cary P Gross. My PROfile: A web-based tool to assess patient reported outcomes in women with metastatic breast cancer (MBC) [Poster presentation at San Antonio Breast Cancer Symposium 2019, San Antonio, Texas December 2019]
- Mougalian SS, Aminawung JA, Presley C, et al. Abstract P5-14-06: Prioritization of patient reported outcomes by women with metastatic breast cancer. AACR; 2019.
- Sarah S. Mougalian, Jenerius A. Aminawung, Carolyn J. Presley Maureen E. Canavan, Margaret L. Holland, Xin Hu, Cary P. Gross. Prioritization of patient reported outcomes (PROs) by women with metastatic breast cancer (MBC) [Poster presentation at San Antonio Breast Cancer Symposium 2018, San Antonio, Texas December 2018]

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