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Developing a Novel Model to Improve Research and care for Cancer Survivors: a Feasibility Study

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Abstract Despite a growing number of clinical trials and supportive care programs for cancer survivors, recruitment of patients for these opportunities during the survivorship phase of care is challenging. We piloted a novel process to systematically educate patients about available research studies and supportive care programs as part of a survivorship care visit. Between 3/2015 and 8/2015, patients seen in the Adult Survivorship Program who had not previously received a treatment summary and survivorship care plan (TS/SCP) were provided with one accompanied by a list of survivorship research studies and care programs tailored to their diagnosis. Survivorship providers discussed the opportunities and recorded whether the patient was interested in relevant studies and placed referrals to study staff. Following the visit, we tracked study enrollment and surveyed patients about their experience. Fifty of 56 (89%) pilot participants completed the survey. Almost all (98%) reported that the TS/SCP visit and document helped with knowledge of research opportunities and supportive care interventions. Following receipt of the TS/SCP, 44% were interested in at least one study and in further follow-up with research staff. Of the 30 survivors eligible for at least one study, 6 (20%) have enrolled in at least one study to date. This pilot program demonstrates that the systematic sharing of available clinical studies and supportive care programming as part of a survivorship care plan visit is feasible and well received by cancer survivors and may facilitate and enhance accrual to clinical trials in the survivorship phase of care.

Keywords Cancer survivorship · Survivorship care plan · Clinical trial enrollment

Introduction

Given the increasing number of research studies and clinical programs targeting a wide range of medical and psychosocial issues affecting cancer survivors after completion of active treatment, there is a need to identify effective strategies to reach and disseminate research opportunities and supportive care resources to survivors. The Institute of Medicine (IOM) recommends that all patients receive a treatment summary and survivorship care plan (TS/SCP) at the completion of active therapy [1] and administration to eligible survivors of a TS/SCP has become a standard for institutional accreditation of by the American College of Surgeons Commission on Cancer [2]. While the primary goal of the TS/SCP is to provide patients with information regarding treatments received and recommended follow-up care (e.g., risk-based screening such as bone density tests and echocardiograms), this clinical encounter and document represents an opportunity to counsel patients regarding their needs and to introduce patients to available clinical research studies and supportive care programs that might be of interest to them during the survivorship phase of their care. In an effort to help survivors learn about these opportunities, we sought to pilot a standardized process to identify and recruit survivors for relevant clinical studies at our institution. The primary aim of the pilot study was to

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evaluate this process as part of the TS/SCP survivorship visit, including patient interest in survivorship research and subsequent study enrollment following the visit.

Methods

Study Procedures

Between March 2015 and August 2015, clinic lists were screened to identify patients with a diagnosis of lymphoma, breast, colorectal, testicular, or prostate cancer, who had not previously received a TS/SCP as part of the Adult Survivorship Program at Dana-Farber Cancer Institute (DFCI). Patients presenting for a first TS/SCP visit were offered discussion and materials regarding open research studies and supportive care programs as part of the survivorship visit. If a patient was interested in a particular study introduced during the visit, a clinical research coordinator was notified by the clinician or, if the patient preferred, study contact information was provided to the patient so that he or she could contact the study team. Research staff of the studies offered to patients was contacted twice in follow-up (July 2015 and December 2015) to obtain updated data on patient enrollment.

Survivorship Research Studies and Supportive Care Programs

Research studies were identified prior to the start of the pilot study from investigators affiliated with the Adult Survivorship Program and through institutional investigators. A research coordinator also searched for and reviewed studies targeting survivors that were registered in an institutional clinical trial website. Nine clinical research studies (see Table 1) were offered to patients over the course of the pilot in three disease groups: breast, colorectal, and lymphoma.

In addition to the clinical studies, patients who participated were informed about a variety of supportive care programs available through the Adult Survivorship Program and the Leonard P. Zakim Center for Integrative Therapies, also at our institution. These included acupuncture, massage, yoga, reiki, qigong, meditation, expressive arts, sleep, mindfulness, and exercise programs.

Survey

Participants were asked to complete a brief in-person paper survey immediately following their visit. The investigator-developed survey included a series of questions about the TS/SCP visit experience including discussion of and potential interest in survivorship research studies, satisfaction with the timing and length of the visit, and a series of questions about prior research participation.

This project was undertaken as a quality improvement initiative at the Dana-Farber Cancer Institute and as such was exempted from formal oversight by the Institutional Review Board per their policies. Descriptive statistics, including means and frequency distributions, were used to summarize survey data that was collected. Analyses were conducted in SAS 9.4 (SAS Institute, Cary, NC).

Results

Sixty eligible patients presenting for a first TS/SCP visit were offered discussion and materials regarding research and supportive care programs (Fig. 1). Three of them declined to discuss research studies with their provider and studies were not discussed with one patient due to time constraints. Fifty of

Table 1 Clinical research studies offered to pilot participants

Clinical research study	Disease eligibility
DHA vs. placebo in triple-negative breast cancer	Breast
Hereditary and other risk factors for cancer	Breast, lymphoma
Low-dose tamoxifen for radiation-induced breast cancer	Lymphoma
Act for others tissue repository	Breast
Flaxseed lignan as a prevention strategy for pre-menopausal women at high risk for the development of breast cancer	Breast
A randomized pilot study of acupuncture for chemotherapy-induced peripheral neuropathy in breast cancer patients	Breast
Randomized phase II study of exercise and metformin in colorectal and breast cancer survivors	Breast, colorectal
A phase 2 pilot feasibility study of palbociclib in combination with adjuvant endocrine therapy for hormone receptor-positive invasive breast cancer	Breast
A phase Ib biomarker trial of naproxen in patients at risk for DNA mismatch Repair Deficient Colorectal Cancer	Colorectal

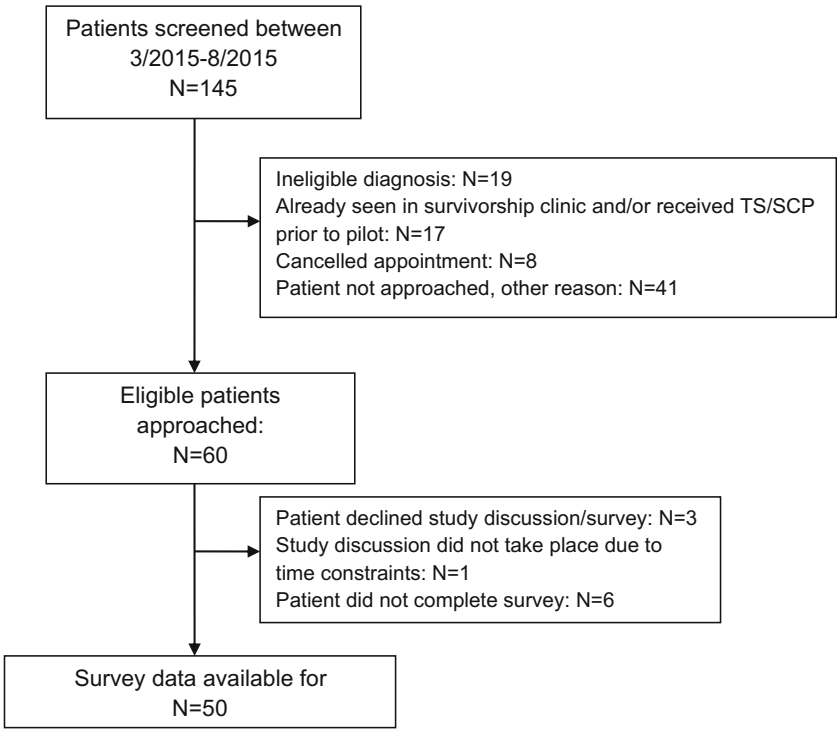

Fig. 1 Pilot study flow diagram

TS/SCP = Treatment summary and survivorship care plan.

these 56 patients (89%) responded to the survey following their visit. Reasons for non-response included the following: patient decline ($N = 1$) and patients leaving clinic before having the opportunity to complete the survey ($N = 5$). Two survivorship clinicians (a nurse practitioner and a physician assistant) saw the majority of patients ($N = 44$); a breast cancer-focused nurse practitioner and medical oncologist saw the remainder of patients ($N = 6$) as part of dedicated breast oncology survivorship visits.

Of the 50 respondents, the majority (78%) were female and the median age at the time of survey completion was 51 (range 26–73) years. Median time from diagnosis (most recent diagnosis if a patient had more than one) to survivorship visit for the 46 of 50 respondents for whom this information was available was 72 (range: 5–332) months. Over half of respondents (54%) were survivors of breast cancer, 42% were lymphoma survivors, one patient had been diagnosed with breast cancer and lymphoma, and one patient was a colorectal cancer survivor.

Regarding interest in survivorship research studies in light of their clinic visit, 44% (22/50) of respondents were interested in one or more of the studies that they heard about and said they would follow up about the research opportunities or wanted a research coordinator to follow up with them. Of the 30 survivors determined eligible by clinician assessment for at least one available study, 6 have enrolled on at least one study to date.

Satisfaction with the TS/SCP and visit was high, with 84% (42/50) responding that the timing of the visit was appropriate while 16% said it occurred too long after treatment ended. Similarly, almost all respondents (48/49, 98%) thought that providers spent the right amount of time discussing survivorship research opportunities, with only one participant responding that there was not enough time spent on this discussion. Almost all patients (45/47, 96%) said that the information they received about survivorship research studies was useful to them and almost all said that the visit and TS/SCP document has or will help with knowledge of research opportunities and supportive care interventions (46/47, 98%).

Regarding prior research participation, 47% (23/49) of respondents said their doctor offered them an opportunity to participate in a treatment (related to primary surgery, chemotherapy, or radiation) clinical trial *during* their cancer treatment. Of 20 respondents who were offered a treatment clinical trial, over half (12/20, 60%) did not participate in any trial, 35% (7/20) participated in one trial, and one person reported participation in two or more trials. Regarding non-treatment research studies, approximately half of respondents (24/49) reported being offered this type of research *during or following* treatment for cancer. Participation in non-treatment studies was higher, with 35% (8/23) reporting participation in one study and 30% (7/23) reporting participation in two or more studies.

Discussion

Despite a growing number of clinical trials and supportive care programs available to cancer survivors at our institution

and other cancer centers, recruitment during the survivorship phase of care is challenging and novel strategies are needed to engage survivors and educate them about these opportunities. In this pilot study, we demonstrated that using the survivorship visit and TS/SCP as a tool to facilitate the sharing of studies can enhance trial accrual through the systematic identification of potentially eligible patients, who otherwise would not be aware of these studies. Importantly, survivors who participated in our pilot valued learning about these studies and programs as well as the TS/SCP and survivorship visit in general.

Other studies that have tested TS/SCPs in different survivor populations have similarly found that patients are generally satisfied with TS/SCPs and value the information they receive as part of their care plan [3–8]. While the primary recommended purpose of TS/SCPs is to provide a summary of treatments received and post-treatment guidelines to help patients transition back to their primary care provider, results from our pilot suggest that incorporating an informational research component into the TS/SCP is feasible and acceptable to patients. Almost all participants in our study felt that adequate time was spent discussing research and that the information they received about survivorship research was helpful to them. Forty-four percent of participants expressed initial interest in the studies that were shared with them, and at last available follow-up, 6 of 30 eligible participants (20%) had enrolled on a study. This relatively high rate of enrollment is encouraging, giving that it is approximated that fewer than 5% of adult cancer patients participate in clinical trials [9]. However, challenges exist when considering ways to improve upon accrual to trials in this setting: when patients are no longer in active treatment and visit frequency and intensity at the cancer center decreases, engaging survivors requires greater effort. Recruitment outside of the clinic generally results in a lower response rate compared to in-person recruitment for trials. In a recent sexual health intervention trial designed for rectal and anal cancer survivors, those informed about the study during a clinic visit (vs. a recruitment letter sent to them at home) were more likely to participate [10]. Similarly, in an exercise intervention trial designed for young adult cancer survivors, in-clinic recruitment had the highest recruitment rate compared to other methods utilized which included contact by phone or mail, though the total number of individuals approached was very small [11]. The interest in research conveyed by participants in our pilot, together with the fact that many respondents reported prior participation in either a treatment or non-treatment study, suggests that this population is receptive to clinical trial enrollment. Thus, targeting this population for recruitment for survivorship research may be particularly fruitful when considering the challenges of accrual in this setting [12].

Leveraging the TS/SCP survivorship visit as a means to facilitate clinical research is dependent on the integration of care plans into oncologic follow-up care. While the IOM instituted its recommendations regarding provision of TS/SCPs over a decade ago, implementation and dissemination of care plans has been inconsistent across practice settings and providers. Birken et al. surveyed 36 oncology programs across the United States (US) and found most centers reported using survivorship care plans in less than 50% of survivors who visited their center [13]. Among over 1100 oncologists who were surveyed in a study conducted by Blanch-Hartigan et al., fewer than 10% of respondents said they "always" or "almost always" give patients a survivorship care plan [14]. Salz et al. surveyed 245 oncology clinicians affiliated with NCI Community Cancer Centers Programs and found that less than half of respondents reported ever giving their patients treatment or diagnosis summaries, or guidelines regarding continuing care, including what would be offered by their oncology provider [15]. Collectively, these findings point to a need to promote increased standardization of survivorship care plans in clinical care, especially given that the Commission on Cancer now requires provision of a TS/SCP as a condition of accreditation [2].

Limitations of this work include the single-institution, convenience sample of survivors visiting an academic medical center for their survivorship care. While it is encouraging, this model was highly acceptable to patients, nearly half of whom had been approached about trials during their active treatment; it is not clear that this is broadly reflective of the general US cancer population and generalizability may be limited. However, given an increasing number of survivorship programs with expansion of TS/SCPs dissemination, our model may be used and adapted in many of these settings. Further, only one participant in our pilot had been diagnosed with a malignancy other than breast cancer or lymphoma and approximately half of the research studies offered were exclusively for breast cancer survivors, underscoring a need for additional studies targeting survivors of other malignancies. Finally, while supportive care programs were offered systematically, we did not track uptake of these services.

Nevertheless, refinement of this model could potentially support other research initiatives including collection of patient-reported outcomes among groups of survivors to study long-term, late effects of therapy, as well as opportunities for additional support, care, and quality improvement initiatives in survivorship care. Expansion of this novel program, together with an increased focus on re-engaging survivors who express an initial interest in research, should help to enhance clinical trial accrual for cancer survivors and awareness and use of available supportive care interventions. Based on the promising results of this pilot study, we plan to continue this program with expansion to a growing number of survivors in the future.

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Compliance with Ethical Standards

Conflict of Interest Dr. Garber reports the following:

Company	Self/spouse	Interaction
Myriad Genetics	Self	Funded research
Sequenom	Self	Consulting
Astra-Zeneca	Self	Leading a clinical trial
Ambry	Self	Research collaboration
Pfizer	Self/spouse	Consulting
Novartis Oncology	Spouse	Consulting funded research
SV Life	Spouse	Consulting
GTx Pharmaceuticals	Spouse	Consulting

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