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Evaluation of a Specialized Oncology Nursing Supportive Care Intervention on Newly Diagnosed Breast and Colorectal Cancer Patients following Surgery: A Cluster Randomized Trial

Authors:

Jonathan Sussman, MD, CCFP, FRCP(C), MSc
Department of Oncology, McMaster University, Ontario, Hamilton, Canada
Juravinski Cancer Centre
699 Concession St. Rm 4-204
Hamilton, ON Canada L8V 5C2
PH: (905) 387-9711 ex. 64509
FAX: (905) 575-6308
Email: sussman@hhsc.ca

Daryl Bainbridge, PhD
Department of Oncology, McMaster University, Ontario, Hamilton, Canada
Juravinski Cancer Centre
699 Concession St. Rm 4-214
Hamilton, ON Canada L8V 5C2
PH: (905) 387-9711 ex. 64515
FAX: (905) 575-6308
Email: bainbridgd@hhsc.ca

Timothy J Whelan, BM, CCFP, FRCP(C), MSc
Department of Oncology, McMaster University, Ontario, Hamilton, Canada
Juravinski Cancer Centre
699 Concession St. Rm 4-204
Hamilton, ON Canada L8V 5C2
PH: (905) 387-9711 ex. 64501
FAX: (905) 575-6308
Email: twhelan@hhsc.ca

Kevin Brazil, PhD
School of Nursing and Midwifery
Queens University Belfast, Ireland
Medical Biology Centre
97 Lisburn Road
Belfast, Ireland NIBT9 7BL
PH: 44 (0)28 9097 5782
Email: k.brazil@qub.ac.uk

Sameer Parpia, PhD
Department of Oncology, McMaster University, Ontario, Hamilton, Canada
Juravinski Hospital and Cancer Centre
711 Concession St. Section G, 1st Floor, Rm. 131
Hamilton, ON Canada L8V 1C3
PH: (905) 525-9140 x42685
Email: parpia@mcmaster.ca

Jennifer Wiernikowski, MN, NP, CON(C)
Department of Oncology, McMaster University, Ontario, Hamilton, Canada

Juravinski Hospital and Cancer Centre
Unit C4, Room C4-59
699 Concession St. Rm 4-204
Hamilton, ON Canada L8V 5C2
PH: (905) 387-9711 ex. 64148
Email: wiernikj@hhsc.ca

Susan Schiff, BScN
Department of Oncology, McMaster University, Ontario, Hamilton, Canada
Juravinski Cancer Centre
699 Concession St. Rm 4-214
Hamilton, ON Canada L8V 5C2
Email: tsely@icloud.com

Gary Rodin MD, FRCPC
Department of Supportive Care, Princess Margaret Cancer Centre,
Department of Psychiatry, University of Toronto, Ontario, Canada
610 University Avenue Rm: Ste. 16-724
Toronto, ON Canada M5G 2M9
PH: (416)-946-4504
Email: gary.rodin@uhn.ca

Myles Sergeant, MD
Department of Family Medicine, McMaster University, Ontario, Hamilton, Canada
St Peter's Hospital
88 Maplewood Avenue
Hamilton, ON Canada L8M 1W9
PH: (905)-777-3837
Email: myles_sergeant@hotmail.com

Doris Howell, RN, PhD, Corresponding and senior author (in print)
Faculty of Nursing, University of Toronto, Toronto, Ontario, Canada
University Health Network
610 University Avenue
Toronto, ON Canada M5G 2M9
PH: (416) 946-4501 x3419
Email: doris.howell@uhn.on.ca

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Conflict of Interest

The authors have no conflicts of interest, financial or otherwise, to disclose.

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Author Contributions: JS, DH, TW, KB, JW, and GR designed the study. DB and SS enrolled the surgeons and patients, and gathered data. SP and DB did the statistical analysis. DB, JS, DH, and TW interpreted the data and drafted the manuscript. All authors reviewed, edited, and approved the manuscript before submission.

Running Head: Randomized Trial of a Specialized Oncology Nursing Supportive Care Intervention

Key Words: cancer care; coordination; nursing; supportive care needs

Evaluation of a Specialized Oncology Nursing Supportive Care Intervention on Newly Diagnosed Breast and Colorectal Cancer Patients following Surgery: A Cluster Randomized Trial

BACKGROUND: Better coordination of supportive services during the early phases of cancer care has been proposed to improve the care experience of patients. We conducted a randomized trial to test a community-based nursing-led coordination of care intervention in cancer patients.

METHODS: Surgical practices were cluster randomized to a control group involving usual care practices or a standardized nursing intervention consisting of an in-person supportive care assessment with ongoing support to meet identified needs, including linkage to community services. Newly diagnosed breast and colorectal cancer patients within 7 days of cancer surgery were eligible. The primary outcome was the patient-reported outcome (PRO) of continuity of care (CCCQ) measured at 3 weeks. Secondary outcomes included unmet supportive care needs (SCNS), quality of life (EORTC QLQ-C30), health resource utilization, and level of uncertainty with care trajectory (MUIS) at 3 and/or 8 weeks.

RESULTS: A total of 121 breast and 72 colorectal patients were randomized through 28 surgical practices. There was a small improvement in the informational domain of continuity of care (difference 0.29 $p=0.05$) and a trend to less emergency room use (15.8% vs 7.1%) ($p=0.07$). There were no significant differences between groups on unmet need, quality of life, or uncertainty.

CONCLUSION: We did not find substantial gaps in the PROs measured immediately following surgery for breast and colorectal cancer patients. The results of this study support a more targeted approach based on need and inform future research focused on improving navigation during the initial phases of cancer treatment.

Evaluation of a Specialized Oncology Nursing Supportive Care Intervention on Newly Diagnosed Breast and Colorectal Cancer Patients following Surgery: A Cluster Randomized Trial

INTRODUCTION

The transition from an initial diagnosis of cancer through entry into the formal cancer system has been identified as a time of significant emotional distress, physical morbidity, and uncertainty for patients.[1-3] Despite efforts to improve transitions in care and reduce waiting times for cancer diagnosis and treatments, meeting the supportive care needs of patients and families remains a significant challenge.[2,4,5] Newly diagnosed cancer patients report discontinuities in their care due to increasingly complex treatments involving multiple providers at different locations.[2,4,6-8] We and others have found that discontinuities experienced by cancer patients/families can worsen stress and anxiety since they already feel threatened by a difficult disease and uncertain future. [5,6,8,9] Indeed, a recent review found that cancer patients' need for informational support to be prevalent, along with emotional care.[10] Supportive care issues continue to be a priority area for research and policy in the USA, Canada, Australia, and elsewhere, with the aim to lessen the negative burden of care experience.[7,8,11]

Supportive care to meet the psychological, social, physical (symptom control), informational, and practical needs of patients is an essential component of cancer treatment.[12,13]. Active coordination of supportive care is proposed as one method to address care discontinuity and barriers to accessing these resources, [2,4,5] but evaluations of its effectiveness, beyond assessments of patient satisfaction, are lacking.[2,14] In response to the recognized gap in patients' supportive care experience following diagnosis and primary surgical treatment, we evaluated a community based nursing-led coordination of care intervention in newly diagnosed breast and colorectal cancer patients. The study objectives were to determine the effect of the specialized oncology nursing program on continuity of care and unmet needs, as well as, on quality of life, uncertainty, and healthcare use, as compared to usual care. We hypothesised that an improvement in these outcomes would result at two months after surgery among patients receiving support from a specialized oncology nurse, compared to usual care.

ClinicalTrials.gov Identifier: NCT00182234

SONICS - Effectiveness of Specialist Oncology Nursing

METHODS

Trial Design

This was a prospective cluster randomized trial. Participating surgical practices were randomized to usual care (control) or usual care plus a standardized specialized oncology nursing supportive care intervention (experimental) using a permuted block design to ensure groups of equal sizes. The sequence of allocation was computer-generated and each assignment placed in a numbered sealed envelope, which were consecutively opened for each practice recruited. Patient participants were accrued through the individual surgical practices in community hospitals (4) or teaching hospitals (4) in the Greater Toronto Area (GTA) in Ontario, Canada, and assigned to control or experimental arms based on allocation of the practice. This approach was used to minimize contamination between arms and simplify the accrual process for surgical practices.

Participants

The trial included patients with newly diagnosed, histologically confirmed breast or colorectal cancer within the initial stages of surgical intervention (immediately post-surgery). Other inclusion criteria were: no previous or concomitant malignancies (except: non-melanoma skin cancer; carcinoma *in situ* of the cervix), legally able to provide informed consent, 18 years of age or older, and able to speak and read English. Patients had to reside in the intervention program catchment area corresponding to the GTA. Ethical approval to conduct the study was obtained from the hospitals from which surgeons recruited patients.

Intervention

The intervention consisted of usual care plus referral to a standardized specialized oncology nurse service provided by the Interlink Community Cancer Nurses (ICCN) program in Toronto. ICCN was an established program of nurse-led clinical case coordination [15]. This service was structured around four program components: (i) direct oncology nursing practice; (ii) coordinated mobilization and linkage to services; (iii) community-based education and research; and (iv) community resource development [16]. The program was provided by five registered nurses, overseen by a nurse manager. Most of these nurses were Masters prepared; all were

certified in Oncology Nursing (CON(C)) with a minimum of four years specialty cancer experience.

ICCN is modeled after the Macmillan nurse program in the United Kingdom, which provides expert advice and support to patients and families with cancer and health care professionals through home visiting and telephone support [15-18]. The ICCN model was intended to follow a tailored approach to care based on a comprehensive assessment of each patient's needs, care requirements and wishes [15]. The nurses did not provide medical care but information and emotional support, as well as coordinating and navigating access to other needed supportive cancer care services. [15-18] Emotional care by ICCN nurses included supportive care techniques like active listening, clarification, explanation and education, and guidance in coping/managing the effects of cancer [15,17].

ICCN employed a Standardized Nursing Intervention Protocol (SNIP) for the nurses to follow. This protocol included comprehensive assessment, information and emotional support, and care planning specific to breast and colorectal cancers during the initial phases of treatment, with a minimum of two home visits. A training session was held with the Interlink nurses prior to the study commencing to ensure consistency in providing supportive care tailored to this phase of care and in the timing of intervention follow-up. ICCN is previously described in further detail, including a logic model of the intervention.[16,19]

Recruitment and Data Collection

Following randomization, each participating surgical practice received on-site training in patient accrual for their particular arm of the study. All consecutive eligible patients were identified by the surgeons' practices at the pre-surgery consultation. Contact, eligibility, and surgery date information for these patients, with their permission, was immediately faxed to the research office. Trained interviewers, blinded to study allocation, collected patient reported outcomes (PROs) via telephone interviews administered at 3 time points in their care trajectory, specifically, 2 to 7 days post hospital discharge from surgery (T1 [baseline]), 2 to 3 weeks after baseline (T2), and 8 to 10 weeks after baseline (T3).

Patients in the intervention group were referred to the ICCN intervention following baseline completion. Data were collected from ICCN logs on the number and type (e.g., phone, home visit, etc.) of contacts made with each study patient to measure and ensure compliance

with the intervention prior to the second (T2) and third (T3) interviews. The second interview was intended to occur two weeks after the intervention had begun and was not completed until at least one home visit had been made. The names of control group patients were checked with ICCN administration data to ensure that they had not accessed the intervention.

Outcomes

The primary outcome was the mean subdomain scores of the Continuity of Care Questionnaire (CCCQ) at T2.[19,20] Continuity of care and service utilization was not measured at baseline (T1) because community services had not been initiated. Secondary outcomes were the change from baseline to T2 in the domain scores of the Supportive Cancer Need Survey (SCNS-SF34), [21,22] the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Version 3.0 (EORTC QLQ-C30), [23] the Mishel Uncertainty in Illness Scale-Community Form (MUIS-C) score, [24] and a self-reported health care utilization survey. Comparisons were also made between change scores from baseline to T3 to examine change over this period of time (8 to 10 weeks).

The CCCQ measures continuity of care and was adapted specifically for a community-based oncology setting from the Components of Primary Care Index (CPCI) [20] and previously validated in our cohort study of the ICCN program [19]. The instrument asks respondents to rate their experience in four domains of continuity of care: relational, informational, management, and preference for the same health care provider.

The SCNS-SF34 evaluates supportive needs in five domains: Psychological Needs; Health System and Information Needs; Physical and Daily Living Needs; Patient Care and Support Needs; and Sexuality Needs. [21,22] The MUIS-C measures four domains of uncertainty: Ambiguity; Complexity; Inconsistency; and, Unpredictability.[24] This instrument has been used extensively in patients with breast cancer and other malignancies.

Service utilization was captured using an instrument developed for the study containing an inventory list of available community services and a review of other similar instruments.[25] Participants were asked which of these services they used in the given time, frequency of use, and whether these services were accessed on a scheduled or an urgent basis.

Sample Size

Previous work using the CCCQ with cancer patients identified a mean score of 3.65 for each domain and a standard deviation (SD) of 0.85 (scale from 1 to 5). We assumed that a difference of 0.6 in SD (i.e., a delta of 0.5 or a half point on the scale) between treatment groups at T2 would be important to detect [18]. Accounting for the cluster design, we estimated that the correlation between patients within surgical practices was 0.15 and that each surgeon would see an average of 6 eligible patients. Given a two-sided alpha of 0.05, a power of 80%, and a drop-out rate of 10%, 182 patients from 28 surgical practices was required.

Statistical Methods

Instrument scores for the CCCQ, SCNS, MUIS, and EORTC QOL-30 were calculated and analyzed based on scoring guidelines for these validated instruments (see Table 2 for scale ranges). A two-sample t-test adjusting for the increased variance due to clustering was used to compare the means of primary and secondary outcomes between intervention and control groups [26]. Confidence intervals (CI) for the difference of means were adjusted for data clustering. Multilevel mixed models with two levels, cluster and repeated measures were used to investigate the effect of intervention over time on the CCCQ, SCNS, MUIS, and EORTC QOL-30.

Service utilization data from the two time points (T2 and T3) were combined to create a time span of up to 10 weeks from baseline. Usage of individual types of services was summarized using frequencies and means. Mixed models adjusting for clustering were used to compare the number of patients who reported using each service. Data were analyzed using SAS 9.2 (SAS Institute Inc., Cary, NC).

RESULTS

Surgical practice recruitment and patient flow are presented in Figure 1. Of 35 practices randomized, 28 recruited patients during the study period: 13 of these practices were allocated to the intervention arm and 15 practices to the control arm. The intervention and control arm allocated practices had similar characteristics (e.g., surgeon sex, years of practice, solo vs group). Practices were open to patient accrual for up to three years or until 14 patients were accrued from the practice. Each practice accrued an average of 10 patients to the study.

Of the 244 patients who met the study eligibility criteria, 193 (79%) consented to participate in the study, 104 in the control group and 89 in the intervention group. Of these

patients, 186 (96%) completed a T2 survey and 180 (93%) completed a T3 survey. Patient groups were similar with respect to baseline characteristics such as age, sex, disease site, marital status, and income (Table 1). Patients in the intervention had a median of 6 ICCN nursing contacts (telephone or visit) up to T3 and mean of 2.2 home visits (median = 2, range = 1 to 6, SD = 1.1). The most common activities reported delivered to patients by the ICCN nurses were comprehensive health assessment (94% of patients), health teaching and coaching (88%), ongoing re-assessments (55%), emotional support (52%), and symptom management (27%).

Outcome scores are presented in Table 2. Borderline significant improvement was seen in informational continuity (CCCQ) in the intervention group compared to the control group at T2 (difference=0.29; 95% CI: 0.00 to 0.48; p=0.05) but little difference was found in the other continuity subdomains. Sensitivity analysis using multiple imputation to account for patients lost to follow-up showed similar results. At baseline, 20.2% of the study cohort reported high (mean ≥ 4) unmet need in at least one SCNS subdomain, with intervention group patients reporting slightly higher needs at this time point. Level of need decreased in both groups over time, slightly more in the intervention group for all factors except “Patient care & support”, but did not reach significance.

The uncertainty of illness (MUIS) mean change scores did not differ significantly between groups (difference=-1.19; 95% CI: -5.16 to 2.78; p=0.56), as neither did the quality of life (EORTC QOL-30) mean change scores. No additional effects were found at T3 for any of the outcomes (all intervention by time interaction p-values > 0.05). Health service utilization, including hospitalization, and visits to primary care physicians, specialists, allied health professionals, and other community services did not differ between groups (Table 3). Twice as many patients in the control group visited emergency departments in the 10 week study time compared to those receiving the intervention (15.8% vs 7.1%), however this trend did not reach significance (p=0.07).

DISCUSSION

Prior literature has reported that cancer patients across the trajectory of care experience inadequate pain management, psychological burden, and other unmet supportive care needs partially due to poor continuity and access to community resources.[2,11,27] We used a rigorous, clustered RCT design, that incorporated validated instruments appropriate to the measurement of

patient navigation interventions, [28] to assess the impact of the ICCN program on PROs for newly diagnosed breast or colorectal cancer patients at the post-surgical period. We found a small improvement in information continuity at two weeks (T2) in the intervention group. Overall, the level of unmet supportive care needs, quality of life, and uncertainty of illness improved over time (0 to 10 weeks) in both study groups. This effect appeared greater in the intervention group for many of these PROs, but no difference was detected in change scores between study groups. Although no significant differences were found in self-reported utilization, we did observe a trend to less emergency room use in the experimental group.

While there have been several trials assessing oncology nurse-led supportive care, [14,29-33] this study is the first trial to specifically examine care coordination and unmet need in the period immediately following cancer surgery. Two recent reviews on the effects of distress screening/triage interventions for psychosocial unmet needs on cancer PROs had mixed findings, with many trials showing no positive effect likely due to being underpowered and possible contamination between study arms [34,35]. Similar to our study, many trials reported improvement in PROs overtime regardless of study arm [27,33,36] and some found post-surgery cancer patients had low levels of unmet need at baseline.[31,36]

This study was conducted in Canada with a universally funded healthcare system that has, as its backbone, a strong primary care structure. Over 90% of the participants in the study had an identified primary care provider. It is likely that the baseline level of care coordination was higher than in populations previously reported in the literature that did not have consistent access to primary care.[11,32] This propensity is reflected in our findings of both groups (76%) reporting contacting their primary care provider over the study period. The self-reported health service utilization patterns did suggest a tendency toward the use of more supportive care services in the intervention group, although these differences did not reach significance. The baseline scores in both the experimental and control groups on unmet need were lower than previously reported in the literature [21,37] and continuity of care at 4 weeks was higher, limiting the range of change that could be captured over time. It would be valuable to test supportive care interventions in health systems that do not provide comprehensive universal primary care.

Some have argued for screening to identify higher need individuals to target supportive care interventions towards those who may derive the most benefit.[22,38] Trials of targeted

oncology nurse-led interventions including patient education, skills training, and counselling specifically for patients with poorly controlled pain found reductions in patient-related barriers to self-management of cancer pain and pain intensity, compared to usual care.[29,30] Our study included only a small number of respondents in the highest quartile of unmet need and therefore lacked the power for a subgroup analysis of these high need patients. Further study of targeted nursing interventions in high need populations is warranted.

A number of other study limitations need to be considered. While we used the most rigorously tested continuity of care scale available at the time, [39] this instrument may lack sensitivity over relatively short periods of time during care transitions. We chose continuity of care as the primary outcome given our previous work of ICCN program [16,19]. However, it may not have been a sensitive outcome and less relevant during this pre-treatment phase, particularly since 80% of the cohort did not report a high supportive care need at baseline. The cluster design of our trial was important to support recruitment and reduce contamination, but reduced the power of our study to detect small effects. It could be argued that a small change observed using a less conservative design may still not be clinically relevant, considering the resources required to deliver this type of intervention. Finally, it is also important to note that patient navigation was not a planned component of the nursing intervention that we studied, in that navigation programs typically follow patients from the onset of cancer-related care, i.e., abnormal screening result. As such, we cannot draw inferences from our data as to the efficacy of cancer patient navigation on the diagnostic care experience, optimizing cancer care trajectories, or reducing unnecessary waits for transition to oncology care, demonstrated in other studies.[40]

Distress screening at the time of initial oncology assessment is essential to address patient needs [35,41]. Our findings suggest that interventions such as the ICCN program to supplement usual care around the time of initial surgical treatment may provide supportive care benefits. Our results are generalizable within health care systems that provide universal access for breast and colorectal cancer patients, who make up a significant proportion of newly diagnosed patients. Furthermore, our finding of low levels of unmet need supports the use of systematic screening to identify populations most likely to benefit from targeted supportive care interventions. The trend observed towards less acute care utilization calls for ongoing research into the role of system navigation, particularly during care transitions. Future research of system navigation should

include PROs, such as those used in this study, to better understand impact on different aspects of patient experience including health system utilization.

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