Early integration of palliative care facilitates the discontinuation of anticancer treatment in women with advanced breast or gynecologic cancers

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Abstract

Objectives. To evaluate some health indicators in women with advanced breast or gynecological cancers (ABGCs) after discontinuation of active cancer treatment in function of the model of care received.

Methods. This prospective study included patients who were discontinuing anticancer treatment to be followed up only with palliative care (PC). Patients who had been evaluated at least once in PC were categorized as the integrated care model (ICM); those who had not been consulted by the PC team before, as the traditional care model (TCM). Data were analyzed using chi-square, Mann–Whitney, Kaplan–Meier, and Cox regression model.

Results. Among the 87 patients included in the study, 37 (42.5%) had been previously evaluated by the PC team (ICM). Patients who were followed up under an ICM exhibited better QoL (global health, p = 0.02; emotional functioning, p = 0.03; social functioning, p = 0.01; insomnia, p = 0.02) and less depression (p = 0.01). The communication process had no issues in 73% of cases from the ICM group compared with 42% of cases from the TCM group (p = 0.004). Patients who were not previously evaluated in PC received more chemotherapy in the last 6 weeks of life compared to those who had already been evaluated (40% versus 5.9%, p = 0.001). Early evaluation in PC was one of the independent prognostic factors of overall survival.

Conclusion. When followed up concurrently by a PC and clinical oncology team, patients reported better QoL and less depression, received less chemotherapy within the last 6 weeks of life and survived longer than those followed up under a TCM.

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Introduction

Traditionally, palliative care (PC) has been offered only after the exhaustion of active cancer treatment, when tumors are already in very advanced stages. Over the last decade, some studies have shown the benefits of an integrated care model (ICM) with early follow-up by a specialized PC team concomitant with active cancer treatment [1–3]. Among the benefits of the ICM are a better quality of life (QoL) [1–3], higher satisfaction with the care received [2], fewer depressive symptoms [1,3], fewer patients receiving unnecessary invasive measures in the end of life [1] and most likely higher overall survival [1].

However, PC is still offered late, even in comprehensive cancer centers [4]. Among the barriers that hinder the use of the ICM, PC is still stigmatized by patients, and even by health professionals. The PC concept remains strongly associated with death and end of life [5,6], which makes the process of referring patients to this treatment modality and the consequent discontinuation of active treatment an impactful moment, especially in doctor–patient communication. Another significant barrier is the lack of education and awareness of the availability of PC services [7].
Women with advanced breast or gynecologic cancers (ABGCs) tend to receive more palliative chemotherapy at the end of life [8]. A previous study [9] found that 30% of women with gynecologic malignancies received chemotherapy in the last 6 weeks of life. Many invasive and unnecessary treatments were observed in the last 6 months of life, which most likely negatively impacted the QoL of these patients [10].

We aimed to evaluate the QoL, anxiety and depression symptoms of the doctor–patient communication process in women with ABGCs after the discontinuation of active cancer treatment as a function of the care model (integrated versus traditional) adopted. In addition, we evaluated the chemotherapy rates in the final stages of life and the overall survival of patients after discontinuation of anticancer treatment.

Methods

Setting, study design and eligibility criteria

This study was conducted in Barretos Cancer Hospital (BCH; São Paulo, Brazil) which has a unit dedicated only to PC where patients with advanced cancer are treated with either PC exclusively or antineoplastic treatment in conjunction with PC [11]. At the time of study inclusion, data regarding previous follow-ups in PC and also regarding the last receipt of antineoplastic systemic treatment were retrieved from the patients’ medical records. Thereafter, patients included were followed prospectively until death.

Women aged over 18 years with advanced breast or gynecologic (endometrium, ovary, uterine cervix, vulva or vagina) cancers were invited to participate in the study when they were notified that they would not receive anticancer treatment from that moment on and would instead receive only follow-up care with the PC team. Advanced cancer patients were considered those presenting distant metastasis or unresectable locoregional recurrences. Patients with significant neuro-psychiatric problems that interfered with their ability to understand and answer questionnaires were excluded from the study (as per study investigators), as were those with uncomfortable and uncontrollable symptoms at the time of the survey, which could compromise their ability to answer questionnaires (for example, marked dyspnea, uncontrollable vomiting and pain crisis).

Care models

The participants were categorized according to previous follow-ups in PC. Those participants who had been evaluated at least once in PC were categorized as the ICM, and those who had not been consulted by the PC team were classified as the traditional care model (TCM).

Ethics statement

The study was approved by the institutional Ethics Committee (no. HCBT/2012) and complied with the ethical standards of the Declaration of Helsinki and Brazilian National Health Council resolution no. 196/1996. All participants volunteered to participate in the study and signed an informed consent form.

Data collection

Before approaching the patients, attending physicians were asked whether they had informed the patients about the entire reality of their disease. For this purpose, a Communication Assessment Protocol (CAP) developed for the present study (Supplementary material 1) was used. Next, patients completed the CAP (the specific section for patients), and interviewers administered the European Organization for Research and Treatment of Cancer — Quality of Life Questionnaire — Core 30 (EORTC QLQ-C30) and Hospital Anxiety and Depression Scale (HADS) questionnaires. The patients were followed up until either their death or the last evaluation of the present study. All interviews were conducted by the same professional, who was properly trained to do so. Clinical and socio-demographic characteristics and the following dates were obtained from the medical records: date of diagnosis of the incurable disease, date of referral to PC, date when the patient received the last dose of chemotherapy, date when the patient was notified about the discontinuation of the anticancer treatment and date of death (or last evaluation).

Instruments

Hospital Anxiety and Depression Scale (HADS)

HADS was developed in 1983 by Zigmond and Snaith [12] specifically to assess anxiety and depression in patients in non-psychiatric hospitals. The scale was validated for Brazilian Portuguese by Pais-Ribeiro et al. [13] in 2006 and is composed of 14 items, seven related to depression (HADS-D) and seven related to anxiety (HADS-A). Each item can be scored from 0 to 3 points, so the overall score of each subscale may range from 0 to 21. Scores less than eight indicate the absence of disorders, while scores greater than 10 indicate psychiatric impairment.

European Organization for Research and Treatment of Cancer — Quality of Life Questionnaire — Core 30 (EORTC QLQ-C30)

The EORTC QLQ-C30 is a questionnaire composed of 30 items that incorporates five functioning scales (physical, social, cognitive, role and emotional performance), three symptom scales (pain, fatigue and nausea/vomiting) and six individual items (insomnia, loss of appetite, dyspnea, constipation, diarrhea and financial difficulties). All answers are provided in a four-point Likert scale, except for questions regarding the overall health status, whose answers are provided in a seven-point Likert scale. The scores range from 0 to 100, where 0 is the worst health status and 100 is the best health status. There is an exception regarding the symptom scales because higher scores represent a higher level of symptoms and a worse QoL. [14]. The EORTC QLQ-C30 is considered valid and reliable for use in Brazil [15].

Karnofsky Performance Scale (KPS)

The KPS was developed in 1948 by Karnofsky et al. [16] to measure the functional performance of patients with cancer and may vary between 0% (worst performance) and 100% (best performance).

Communication Assessment Protocol (CAP)

Before approaching the patient, attending physicians were asked about the sites where the tumor was active. In addition, physicians detailed the tumor sites that could be causing symptoms in the patient and reported whether they had informed the patients about the entire reality of their disease. For this purpose, a questionnaire was developed for the present research (CAP — physician section; Supplementary material 1). Subsequently, the patient was similarly evaluated by completing the patient section of the CAP. From the patients’ answers and information provided by attending doctors, “communication without any difficulty” (when the patient correctly understood what the physician said and the physician informed the patient about the entire reality of their disease or most of it) and “communication with difficulties” (when the patient did not understand what the physician said and/or the physician did not inform the patient about the entire reality of their disease) were established.

Statistical analysis

The results were reported as medians (interquartile ranges — IQRs). The scores of the EORTC QLQ-C30 and the anxiety (HADS-A) and...
depression (HADS-D) symptoms were compared using the Mann–Whitney test as functions of the ICM and TCM groups. Spearman’s rank correlation test was performed to correlate the number of previous medical consultations with PC team with QoL, anxiety and depression scores. The care model received by the patients was associated with both the communication process and the anticancer treatment received in the last 2, 4, and 6 weeks of life using the chi-square test. The time received to prevent the study from last treatment until death was calculated. Overall survival Kaplan–Meier curves were constructed and compared using the log-rank test. The variables with p < 0.2 were included in the multivariate Cox regression model, as was age (continuous variable), marital status (married versus unmarried), KPS (continuous variable), number of previous lines of palliative systemic therapy (continuous variable), number of metastatic sites, and cancer primary type (breast versus gynecologic variables). The significance level adopted was 0.05. The statistical software used was SPSS version 19.0 (SPSS; Chicago, IL).

**Results**

**Participants**

Between February 2012 and March 2013, 109 women with ABGCs had their anticancer treatments discontinued and were subsequently followed up only in the PC Unit of BCH. Of these, 87 were included in the study. Of the 22 patients not included, 5 refused to participate, and 17 had no clinical conditions to participate in the study due to confusion or severe dyspnea (n = 3). Among the 87 patients included in the study, 37 (42.5%) had been previously evaluated by the PC team (ICM).

The median age was 56 years (IQR = 19, range 24–83). The KPS ranged from 30 to 90, with a median of 50 (IQR = 20). The main primary tumor sites were the breast (n = 50, 57.5%), uterine cervix (n = 19, 21.8%) and ovary (n = 14, 16%). Patients were treated with up to eight lines of previous palliative systemic treatments (mean = 1.5, median = 1.0). Table 1 describes the main socio-demographic and clinical characteristics of patients evaluated.

**Quality of life, anxiety and depression**

Women from the ICM group exhibited higher median scores for global health (66.67 versus 50.0, p = 0.022) and in emotional functioning (66.67 vs. 41.67, p = 0.034) and social functioning (83.33 vs. 66.67; p = 0.018) and lower median scores for insomnia (33.33 versus 66.67, p = 0.027) compared with patients from the TCM group. No significant associations were observed for the other variables (Table 2).

**Communication**

The communication process had no issues in 73% (n = 27) of cases from the ICM group compared with 42% (n = 21) of cases from the TCM group (p = 0.004).

**End-of-life chemotherapy**

Of the total number of patients included in the study, 69 of them received palliative chemotherapy as a last treatment. Thus, they were retrospectively categorized as having received chemotherapy in the last 2, 4 and 6 weeks of life. Although no significant differences were identified at 2 and 4 weeks, we observed that the patients from the ICM group received less treatment in the last 6 weeks of life compared with patients from the TCM group (6% versus 40%, p = 0.001). Patients with ABGCs who were in the ICM group received less chemotherapy in the last 6 weeks of life compared with patients in the TCM group (5.9% versus 40%, p = 0.001) (Table 3).

**Survival analysis**

For the overall survival analysis, the dates of the first evaluation in the study and death (or censor) were considered. Patients in the ICM group exhibited a longer, although not significant, median survival when compared with those from the TCM group (HR = 0.692, p = 0.126). However, in the multivariate analysis, the ICM group was associated with higher median survival (HR = 0.480, p = 0.046). The other independent prognostic factors for survival were EORTC/global health (HR = 1.024, p = 0.038), EORTC/loss of appetite (HR = 1.013, p = 0.036), and KPS (HR = 0.959, p = 0.005). The number of metastatic sites was also an independent prognostic marker, with 3, 4 and ≥5
sites associated with hazard ratios of death of 2.7, 4.2 and 6.2, respectively (Table 4). Of note, the number of previous medical consultations with the PC team (as a continuous variable) was not associated with survival times (HR = 0.960, 95% CI: 0.826–0.893).

Discussion

In the present study, we evaluated women with ABGCs at the time the anticancer treatment was discontinued for subsequent follow-up only with the PC team. Among these patients, a group was already in concurrent follow-up with the specialized PC team; this group was categorized as the ICM. We observed that patients under previous PC follow-up were associated with the best QoL indices, lower depression rates, less anticancer treatment in the last 6 weeks of life and higher overall survival.

Traditionally, the benefits of anticancer treatment have been measured in terms of improvement of survival times. Since the eighties, QoL has become an important outcome in clinical trials and is even more relevant in a palliative context. The QoL necessarily involves physical, psychological, social and functional aspects [17,18]. Thus, because QoL is a multidimensional construct, it is best addressed by a multidisciplinary PC team that acts in an interdisciplinary manner. Previous randomized clinical trials have shown the benefits of the early integration between PC and standard anticancer treatment on the QoL scores reported by patients with advanced cancer [1–3]. In our study, we observed significant differences in perceptions of overall health and social and emotional functioning, in addition to lower insomnia scores. Moreover, all of the differences between the median scores of the different care models evaluated ranged from moderate to large clinical magnitudes [18], with minimum values of 16 points.

In addition to being harmful to the communication process, psychosocial disorders are also associated with the worsening of physical symptoms [19]. Depression symptoms usually increase in proximity to the date of death and are associated with the exacerbation of physical symptoms, cognitive impairments, hopelessness, low social support and spiritual suffering [20]. In the present study, there were fewer depression symptoms in the group of patients who have been evaluated in PC, which is consonant with previously published results [1,3]. Considering that patients were interviewed at a psychologically complex moment, these results may at least indicate that the immediate emotional impact of the notification about treatment discontinuation should be lower in patients who are followed up in the context of an ICM. We believe that, among other things, discussions about current tumor status and wishes and expectations regarding treatment must have occurred in PC consultations, which decreased the emotional impact of the notification about the discontinuation of the anticancer treatment.

Many oncologists choose to continue futile and unnecessary treatments instead of taking the difficult measure of notifying the patients that there are no benefits to maintaining their anticancer treatments [21]. Patients with advanced cancer have unrealistic expectations regarding the treatment and hold to chemotherapy as a great source of hope [21–24]. Furthermore, patients with metastatic cancer who receive early PC most likely have more accurate perceptions of their prognoses, which facilitate the understanding of the real benefits of new types of anticancer treatment [25]. Our results suggest that this type of communication is easier when patients are treated in the context of an ICM. We believe that one of the factors that could explain this easier communication is that during the clinical consultation of a patient who is already being followed up with PC, the physician perceives the patient as more open for frank communication; similarly, because patients are more emotionally prepared, they can pay more attention to the information that the physician provides. It is also likely that much information about the disease and treatment has been previously discussed in consultations with PC physicians.

In the present study, we observed a higher chemotherapy rate in the last 6 weeks of life in the TCM group in comparison with the ICM group, but not in the last 2 and 4 weeks of life. The treatment rates in the last 2 weeks of life in our study were only 2.9% and 8.6% in patients under the integrated and traditional care models, respectively. Both rates were below the 10% considered as a quality criterion of an oncology service [26]. Previous retrospective studies have reported active treatment rates in the last 4 weeks of life ranging from 23% to 55.6% [8,9,27–29]. Some characteristics increase the chances of the patient receiving chemotherapy in the last month of life, such as being a young woman, having a chemo-responsive tumor, and being treated in a small oncology service [28]. Braga et al. [8] evaluated patients who received chemotherapy in the last 3 months of life and observed that patients with breast or gynecologic tumors were more likely to be treated. Even considering only the sample of breast and gynecologic tumors, our active treatment rate of approximately 10% in the last 30 days can be considered low in comparison to the literature, regardless of the care model adopted. Interestingly, we observed that patients who were already followed up in PC had their treatments discontinued earlier. This result does not necessarily point to a better quality of care at the end of life, as we believe that it is acceptable for patients to receive chemotherapy in the last 6 weeks of life. However, the result suggests

### Table 2
Median scores of quality of life, anxiety and depression in function of the model of care.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Models of care</th>
<th>p-Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>EORTC QLQ-C30</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global health</td>
<td>Integrated</td>
<td>Traditional</td>
</tr>
<tr>
<td>n (%)</td>
<td>(50–83.3)</td>
<td>(50–83.3)</td>
</tr>
<tr>
<td>Functional scales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>33.3 (10–53.3)</td>
<td>26.7 (13.3–53.3)</td>
</tr>
<tr>
<td>Role</td>
<td>16.7 (0–66.7)</td>
<td>0 (0–33.3)</td>
</tr>
<tr>
<td>Emotional</td>
<td>66.7 (33.3–83.3)</td>
<td>41.7 (16.7–66.7)</td>
</tr>
<tr>
<td>Cognitive</td>
<td>66.7 (33.3–100)</td>
<td>50 (33.3–83.3)</td>
</tr>
<tr>
<td>Social</td>
<td>83.3 (58.3–100)</td>
<td>66.7 (33.3–100)</td>
</tr>
<tr>
<td>Symptom scales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>77.8 (27.8–100)</td>
<td>88.9 (56.5–100)</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>16.7 (0–66.7)</td>
<td>33.3 (0–54.2)</td>
</tr>
<tr>
<td>Pain</td>
<td>33.3 (0–83.3)</td>
<td>58.3 (28.7–100)</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>33.3 (0–83.3)</td>
<td>33.3 (0–100)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>33.3 (0–66.7)</td>
<td>66.7 (0–100)</td>
</tr>
<tr>
<td>Appetite loss</td>
<td>66.7 (0–100)</td>
<td>100 (33.3–100)</td>
</tr>
<tr>
<td>Constipation</td>
<td>33.3 (0–66.7)</td>
<td>33.3 (0–66.7)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>0 (0–6)</td>
<td>0 (0–0)</td>
</tr>
<tr>
<td>Financial difficulties</td>
<td>0 (0–66.7)</td>
<td>33.3 (0–100)</td>
</tr>
<tr>
<td>HADS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>10 (5–15)</td>
<td>13.5 (7–17.25)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>9 (5–13)</td>
<td>11 (6.7–16)</td>
</tr>
</tbody>
</table>

Abbreviations: *EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire – Core 30. HADS = Hospital Anxiety and Depression Scale.

* Mann-Whitney test.

### Table 3
Chemotherapy rates in the last 2, 4 and 6 weeks of life in function of the model of care (n = 69).

<table>
<thead>
<tr>
<th>Chemotherapy in end-of-life</th>
<th>Model of care</th>
<th>p-Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Integrated (n)</td>
<td>Traditional (n)</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>In the last 2 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (2.9%)</td>
<td>3 (8.6%)</td>
</tr>
<tr>
<td>No</td>
<td>3 (97.1%)</td>
<td>31 (91.4%)</td>
</tr>
<tr>
<td>In the last 4 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (5.9%)</td>
<td>5 (14.3%)</td>
</tr>
<tr>
<td>No</td>
<td>32 (94.1%)</td>
<td>30 (85.7%)</td>
</tr>
<tr>
<td>In the last 6 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (5.9%)</td>
<td>14 (40%)</td>
</tr>
<tr>
<td>No</td>
<td>32 (94.1%)</td>
<td>21 (60%)</td>
</tr>
</tbody>
</table>

Statistically significant results are shown in bold type.
that patients receiving follow-up in PC may be more aware of their disease, more involved in therapeutic decisions and more accepting of their incurable condition than patients not yet in a PC follow-up program.

A previous retrospective study [30] showed that patients with advanced gynecologic malignancies followed up by PC teams, especially when follow-up occurred for more than two weeks before death, received less chemotherapy, sought emergency care less often and had lower rates of hospital and Intensive Care Unit stay for more than 14 days compared with patients not receiving PC. In a multivariate analysis involving age, staging, tumor type and race, receiving PC in a timely manner was the only significant predictor of fewer invasive measures at the end of life. Besides, those who were consulted by palliative care staff ≥ 30 days before death received less invasive measures at the end of life and were associated with lower direct hospital costs [31].

We believe that active treatment needs to be started at the right time but that it should also be discontinued at the ideal moment. The recognized lack of optimum prognostic tools and the acknowledged optimism of oncologists favor the occurrence of unnecessary “super-treatments” [29,32]. When receiving chemotherapy, patients with tumors with low chances of responding to treatment and/or with borderline or inadequate functional performances will most likely experience iatrogenic decreases in their life expectancies. This occurrence can be inferred in the study by Temel et al. [1], wherein patients randomly chosen for early PC underwent fewer invasive measures at the end of life but exhibited 2.7 more months of median overall survival. Our results indicate the same finding, as patients treated in an ICM received less active treatment in the last 6 weeks of life and still exhibited better prognoses after multivariate analysis.

This study has some limitations. The referral to PC occurred according to the care practice; no specific protocol has been established for this purpose. Patients who were referred to PC early were more likely in better clinical conditions and therefore exhibited better QoL when compared to patients receiving follow-up in PC and health outcomes. Further studies, with larger sample sizes, will probably better investigate the relationship between duration of follow-up in PC and health outcomes.

**Future perspectives**

The findings from the present study encourage early PC referral of ABGC patients in our hospital. Nevertheless, the stigma of PC perceived to be the only signiﬁcantly involving age, staging, tumor type and race, receiving PC in a timely manner was the only signiﬁcant predictor of fewer invasive measures at the end of life. Besides, those who were consulted by palliative care staff ≥ 30 days before death received less invasive measures at the end of life and were associated with lower direct hospital costs [31].
by our patients hinders referral in a timely manner [5]. Thus, our research group is starting a randomized phase II clinical trial that will evaluate the impact of early PC in association with a brief psychosocial and educational program in advanced cancer patients starting first line palliative chemotherapy. The psychosocial and educational intervention will be conducted immediately before the first PC consult, as a psychological preparation to early PC (PREPARE trial, clinical trials identifier NCT02133274). Although we did not measure costs of care, the significant difference in the rate of chemotherapy use in the last 6 weeks of life between the two models of care suggests a reduction in the health care costs when patients are treated in an ICM. Chemotherapy is generally expensive and is associated with indirect costs, like more emergency visits and hospital admissions. Future studies are warranted to investigate the impact on cost savings of early PC in the Brazilian public health care system.

Conclusions

Women with advanced breast and gynecologic cancers, when followed up concurrently by clinical oncology and PC teams, reported better QoL, exhibited fewer depression symptoms, received less chemotherapy in the last 6 weeks of life, and were more likely to live longer after the discontinuation of active cancer treatments. Moreover, the communication process is facilitated when patients are treated in the context of an ICM.

Conflict of interest statement

The authors declare that they have no conflicts of interest.

Acknowledgments

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Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ygyno.2014.08.030.

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