Impact of providing booklets about chemotherapy to newly presenting patients with cancer: a randomized controlled trial


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Received 26 April 2005; revised 3 August 2005 and 30 September 2005; accepted 4 November 2005

Background: There has been limited research examining the efficacy of providing written information to cancer patients in southern and eastern European countries. This study investigated the impact of a booklet about chemotherapy on patient satisfaction, quality of life (QoL) and emotional distress, and assessed booklet use.

Patients and methods: A total of 145 Greek cancer outpatients prior to commencing chemotherapy completed a questionnaire and were randomized to receive (n = 72) or not receive (n = 73) the booklet. All patients completed the second questionnaire before the following cycle of chemotherapy.

Results: Baseline characteristics were well balanced between the two groups. Experimental group patients reported being significantly more satisfied with the information received and care overall than those in the control group, felt significantly more and better informed, and perceived the information received as being clearer and detailed. The intervention produced no benefits in terms of anxiety, depression or QoL. The booklet was read by almost all patients and to a great extent by significant others. The majority considered the booklet useful to read and helpful in recalling chemotherapy-related information.

Conclusions: The current results provide further evidence on the efficacy of information-giving interventions in societies where disclosure of information to cancer patients still remains controversial.

Key words: anxiety, booklets, chemotherapy, depression, quality of life, satisfaction

introduction

There is now clear evidence to suggest that the need for detailed information is especially elevated among cancer patients and their families [1–4]. However, the general pattern that emerges from the literature is that large numbers of patients with cancer often report poor understanding and recall of what doctors tell them and, in addition, often express dissatisfaction with the quantity and quality of information they receive about aspects of their disease and treatment [4–6]. Poorly informed patients are less likely to comply with treatment and adhere to medical advice, or participate in the medical decision-making process [5, 7–9]. They are also more likely to experience a high degree of uncertainty and anxiety, or seek scientifically unacceptable therapies, for example, from alternative healers [7, 10].

Over the years, various methods for providing information to cancer patients have been developed, including the use of written material, audiotapes, videotapes, telephone helplines, multimedia resources and the Internet [6, 7, 10–13]. Recent reviews of controlled clinical trials of information-giving approaches have demonstrated that in the main, these methods are valued by patients and are effective in enhancing understanding, knowledge and recall, and promoting satisfaction with communication [6, 10]. With regard to anxiety and depression—emotional distress outcomes in general—the evidence is equivocal, because a number of studies have shown positive effects, whereas others have shown no benefit [14–16]. Much less is known about the impact of information-giving approaches on quality of life (QoL) or functional ability [10]. To date, the evidence from the few controlled clinical trials that have been conducted is inconclusive, hence this issue merits further exploration [14].

The provision of verbal information to patients supplemented with written material in the form of booklets, handouts, general cancer literature and specifically designed information packages, has long been the mainstay of information-giving approaches [1, 6, 17]. Research has shown that the majority of patients receiving written information express favorable attitudes towards it [5, 18]. Written material is a relatively simple and cost-effective method to implement. The content can cover all important points, and it is also available to patients and significant others for future reference [5, 19]. A large part of this material has been devoted to preparing patients for cancer
treatment, and booklets have been used extensively [17, 20, 21]. Most commonly, such booklets contain a combination of sensory, procedural and practical information, and are given as an adjunct to information presented orally [5, 21]. It has been shown that in order to be effective, preparatory information should be responsive to patients' needs, be clear and easy to comprehend and be distributed before cancer treatment commences [5, 20, 21].

However, most of our knowledge in this area comes from Anglo-Saxon countries where preparatory information has long been a part of routine cancer care. In contrast, far less is known about the impact of such material on other societies and cultures, and this is among the issues that research on communication needs to pursue [10]. To our knowledge, only two randomized controlled trials have to date been conducted in a southern and eastern European context, one in Spain and one in Italy, and they both produced positive results. In the Spanish study [22], hospitalized breast cancer patients were given information booklets on surgical procedures 2–3 days before surgery and an additional booklet specific to adjuvant chemotherapy 1 month after surgery. Experimental group patients reported better adjustment in their working, domestic and sexual lives as time progressed compared with women who did not receive written information. The study from Italy [19] assessed the impact of oral, written and video information about chemotherapy on cancer patients who were about to start treatment. At follow-up, before the following cycle of chemotherapy, the results demonstrated that significantly more patients in the oral, written and video information group felt their QoL had improved as compared with those in the less intensive information groups. In addition, patients were positively disposed toward the provision of booklets and videotapes and reported high levels of utilization.

A recent observational study by our group showed that Greek cancer patients reported a high need for factual information and expressed a strong preference for chemotherapy-related written material relevant to their condition and management [3]. It was this that led us to examine, for the first time in Greece, whether the provision of written information might be capable of bringing salutary effects on a number of outcomes. Thus, the first objective of the current study was to test the effectiveness of a booklet about chemotherapy provided in addition to verbal information in promoting satisfaction and QoL, and reducing emotional distress. The second objective was to assess the attitudes of patients towards the intervention.

patients and methods

This prospective, single center, randomized, controlled study was conducted at the Division of Oncology, Department of Medicine of the University of Patras Medical School between December 2003 and January 2005. Male and female chemotherapy-naïve outpatients 18–75 years of age with a confirmed diagnosis of solid malignancy scheduled to commence adjuvant or first-line systemic chemotherapy with an Eastern Cooperative Oncology Group performance status of 0 or 1 were invited by their medical oncologist to take part in the study at the end of the initial treatment consultation and shortly before their initial course of chemotherapy. Non-Greek patients were excluded, as were those with pre-existing major neurologic or psychiatric problems. Also excluded were patients who were illiterate or had vision impairments that could affect their ability to read. Eligible patients who agreed to participate were escorted to an office set up especially for the purpose, in which the study was summarized and written consent was obtained. The conduct of the study was approved by the institutional review board of University of Patras Medical School.

Patients who consented to participate were administered the baseline questionnaire (T1) prior to the first chemotherapy session by a researcher who offered assistance when needed, and checked the answers for omissions. After baseline data had been collected, patients were randomly assigned without stratification to either the intervention or control group in a 1:1 ratio. The allocation sequence was generated by the random placement of shuffled marked cards into sequentially numbered, sealed opaque envelopes by the clinic secretary. Patients in the intervention group participated in the booklet-presentation session delivered by an oncology nurse, during which they were given a booklet about chemotherapy to take home. Patients in the control group received no written material but only the routine verbal information about chemotherapy provided earlier that day in the treatment consultation by their medical oncologist. Patients on both arms were administered the second questionnaire by the same research assistant who had no knowledge of the patients' group assignment before the following cycle of chemotherapy (T2). Sociodemographic data were elicited from patients at T1 and disease-related information was obtained from the treating physicians or from the hospital charts.

the booklet

The booklet, entitled What is Chemotherapy? Information for Patients and their Families, was the updated version of the original booklet used in our earlier study on physician communication training [23]. The findings of our recent investigation on patients' information needs were utilized to improve the content [3]. Also, 10 randomly selected patients and five caregivers gave feedback on content and structure. The booklets were printed by a professional group, and the principles for enhancing readability of written material were applied [5, 21]. There were 20 (20 × 10 cm) pages altogether with no illustrations. Booklets were written to help patients and their families understand more about chemotherapy, and answer most of their common questions, pointing out that booklets cannot substitute the discussion with the doctor. The content was designed to outline both the procedures and the sensations the patient would experience, as well as to present practical information about diet, precautions and self-care. There was also a section outlining positive coping modes such as seeking social support, expressing feelings and engaging in pleasant activities. The sections were headed 'Introduction', 'What is chemotherapy?', 'How is chemotherapy given?', 'How long does the therapy last?', 'What are the possible adverse effects of chemotherapy and how can you control them?', 'What can you do to feel better?', 'Some useful advice concerning your daily life during treatment' and 'Contact information'.

eperimental intervention

After completing the baseline questionnaires, each patient allocated to the experimental group attended the booklet-presentation session given by an oncology nurse with experience caring for cancer patients. The session lasted a little under 30 min and consisted of the presentation of the booklet, section by section, during which the patient was encouraged to ask questions and express concerns. The research protocol prescribed that the nurse would not provide any additional information other than that included in the booklet. Questions that could not be addressed by the nurse were referred back to the treating oncologists. At the end of the session, patients were given the information booklet to take away and read at their leisure, and were immediately started on treatment.

measures

Patients' QoL was obtained at T1 and T2 using the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaire...
quality of information, and patient’s satisfaction, all of which were taken from his or her last value, and were examined using independent sample t-tests for means or Mann–Whitney U-tests for ordinal data and $\chi^2$-tests for categorical data.

**Results**

**Sample**

A total of 150 eligible patients were approached to participate. Of these, five (3.3%) refused to provide written informed consent. The remaining 145 eligible patients were randomized to the experimental group ($n = 72$) or to the control group ($n = 73$). As can be seen in Table 1, one patient from each group declined to complete the assessment at T2.

Univariate analyses revealed no significant differences at baseline between groups for any of the demographic and clinical characteristics, that is, sex, age, educational level, primary tumor site, performance status, disease extent or type of chemotherapy (Table 1). Likewise, the data on QLQ-C30, HADS-A and HADS-D at study entry were well balanced between the two arms (Table 2).

**Primary and secondary outcome measures**

As can be seen in Table 3, statistically significant differences emerged between groups at T2 on satisfaction. That is, experimental group patients were found markedly more satisfied with the information received than patients not just at T2, were analyzed by Mann–Whitney U-tests to compare the experimental and control arms. All tests were two-tailed and statistical significance was set at $P < 0.05$.

**Table 1. Baseline demographic and clinical characteristics of experimental and control patients**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Experimental</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>72</td>
<td>73</td>
</tr>
<tr>
<td>Completed study</td>
<td>71</td>
<td>99</td>
</tr>
<tr>
<td>Age, years (mean ± SD)</td>
<td>55 ± 12</td>
<td>56 ± 11</td>
</tr>
<tr>
<td>Educational level, years (mean ± SD)</td>
<td>9 ± 4</td>
<td>8 ± 4</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>28</td>
<td>39</td>
</tr>
<tr>
<td>Female</td>
<td>44</td>
<td>61</td>
</tr>
<tr>
<td>Cancer diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung (SCLC and NSCLC)</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>Breast</td>
<td>30</td>
<td>42</td>
</tr>
<tr>
<td>Colorectal</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>Other gastrointestinal</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>11</td>
</tr>
<tr>
<td>ECOG performance score</td>
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<tr>
<td>0</td>
<td>61</td>
<td>85</td>
</tr>
<tr>
<td>1</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>Disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limited</td>
<td>35</td>
<td>49</td>
</tr>
<tr>
<td>Advanced</td>
<td>37</td>
<td>51</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjuvant</td>
<td>35</td>
<td>49</td>
</tr>
<tr>
<td>First-line</td>
<td>37</td>
<td>51</td>
</tr>
</tbody>
</table>

*None of the differences was statistically significant.

SD, standard deviation; ECOG, Eastern Cooperative Oncology Group; SCLC, small-cell lung carcinoma; NSCLC, non-small-cell lung carcinoma.
provided with the booklet and reported significantly more satisfied with care overall. In addition, they felt significantly better informed compared with patients allocated to the control group and reported having been provided with significantly more information relating to their disease and treatment (Table 3). Likewise, patients provided with the booklet evaluated the information received as being more clear and detailed than their control group counterparts (Table 3).

In contrast, no reliable differences emerged in mean change scores (experimental group change versus control group change) on any of the QoL measures, with the exception of QLQ-C30 emotional functioning (Table 4). In other words, experimental group patients experienced a statistically significant improvement in emotional functioning compared with control group patients ($P = 0.014$). However, the mean difference between groups was <10 points, and hence it was not clinically meaningful.

As for psychological distress, there were no statistically significant differences between groups in the median change scores on anxiety or depression (Table 5). In addition, no marked differences were observed at T2 between the two groups in the proportion of patients classified as borderline or definite cases of anxiety or depression: (HADS-A: booklet group 38% versus control group 44%, $\chi^2 = 0.61, P = 0.44$; HADS-D: booklet group 30% versus control group 36%, $\chi^2 = 0.69, P = 0.41$).

### booklet usage and evaluation

Of the 71 experimental group patients who completed the study all but one (98.5%) read the booklet. Of these, 61 (87%) read the whole booklet and nine (13%) part of it. Patients read the booklet an average of two times (49% read it once, 17% twice, 16% three times and 18% four or more times), and 48 patients (68%) had someone else read the booklet in addition to themselves. The average number of other persons who read the booklet was 1.1.

The vast majority of patients (68/71; 96%) reported that they would recommend the booklet to other patients with cancer. They also rated the booklet as quite a bit useful (14/71; 18%) or very much useful (53/71; 75%), and reported that it helped them quite a bit (13/70; 19%) or very much (52/71; 74%) to recall medical instructions and advice. Finally, patients were satisfied (11/71; 15%) or highly satisfied (57/71; 80%) overall with the booklets.

### discussion

The findings of the current single-center randomized trial corroborate previous evidence that the provision of well-structured and adequate written information about cancer treatment is greatly appreciated by patients and exerts beneficial effects. However, the improvement was not clinically meaningful, and no reliable differences were observed in the mean change scores on anxiety or depression between the two groups. These findings suggest that the provision of written information about cancer treatment can improve patient satisfaction with care and perceived quality of care, but further research is needed to identify the most effective approaches to delivering this information.
effects on a number of outcomes [6, 10]. Patients provided with the information booklet reported significantly higher rates of satisfaction with the information and overall with medical care than those allocated to the control group, felt significantly more and better informed, and perceived the information received as being clearer and detailed.

In contrast, the intervention produced no significant benefits in terms of anxiety, depression or QoL. The booklet was read by almost all patients and to a great extent by significant others. The vast majority of patients were highly satisfied overall with the booklet, reported that they would recommend it to other patients, and considered it as being useful in general and helpful in refreshing their memories of chemotherapy-related information.

This controlled trial, the first to have been conducted in Greece and the third in a southern and eastern European context, provides further evidence on the efficacy of information-giving interventions in a region where disclosure of information to cancer patients remains a controversial issue. In Greece and other Mediterranean countries, the attitude of withholding detailed information from the patient is still dominant, although in recent years there has been a tendency towards increased openness, following the trends set in Anglo-Saxon and northern European societies [3, 27, 28].

The fear of causing damage to the patient has been the main argument in favor of withholding information [28]. Contrary to this opinion, our study, together with the two earlier studies from Italy and Spain [19, 22], indicates no harmful effects of providing information to the patient. However, considering the diverse communication preferences among cultures [4, 28], comparable studies in other non-Anglo-Saxon countries are needed to clarify further which findings are of universal significance.

Those were the main findings of our trial, and they led to a number of issues for further research. The first is how to improve the intervention. There are really two issues. The first is that it operates, at present, mainly at a cognitive level and there is almost no emphasis on affect. Perhaps, the provision solely of information without elements of counseling or psychotherapy may not have been sufficiently powerful to improve psychological well-being. Both cognition and affect are known to be important in medical communications, and our next step will be to redress the balance [23]. Strengthening the affective component of the intervention should have positive effects on mood, particularly for patients who are found on screening to experience severe levels of emotional distress [15].

The second issue relates to the short duration of our intervention. The one-time 30-min session during which the booklet was presented and imparted to patients may have also been responsible for the lack of effects on distress and mainly QoL. In fact, a recent meta-analysis of controlled clinical trials suggested that psychosocial interventions, including psycho-education, should be planned for at least 12 weeks if reliable benefits to QoL are to emerge [29]. Thus, the effectiveness of multicomponent and more intensive, yet non-obstructive programs to the practice of oncology clinics needs to be addressed further.

The second question our results pose is how long the effects of the intervention will be sustained. The current study cannot answer this question, because it was designed to examine short-term follow-up. Further trials with repeated measures over longer follow-ups are needed before definitive results will be made available, especially with regard to outcomes such as emotional distress and QoL. Unlike communication satisfaction, it is perhaps unreasonable to expect benefits on emotional distress and QoL over the short-term but rather over the medium and longer terms [14].

However, in drawing overall conclusions, we must take notice of two methodological considerations of this trial. The first relates to the method of randomization. In our study, we used the conventional sequentially numbered, opaque, sealed envelopes method in the randomization process. Approaches that use envelopes may have some potential for allocation to the experimental or control group.
concealment bias [30], although in our study baseline comparisons suggested that the two groups were similar in background characteristics and patient-reported psychosocial data. To eliminate this potential problem, future studies must use, whenever it is feasible, more secure methods such as the central randomization, for example, by telephone or fax to a trials office, or an automated assignment system [30].

The second consideration concerns the study design. That is, patients in the experimental group were not simply given the booklet, but they participated additionally in the booklet-presentation session during which they were encouraged to ask questions and express concerns. Although the oncology nurse was instructed not to provide any additional information other than that included in the booklet, we cannot detect whether it was the information from the booklet, the verbal information given in the booklet-presentation session or the further information provided following expression of concerns that contributed the most to the positive findings.

There is one final point to make about our research, and it concerns the need to incorporate validated written information about various aspects of cancer and its management into the Greek oncology setting. In Greece, although the importance of informational resources for cancer patients is rarely denied, the presence of such material is notably absent. We believe it is no longer tenable for cancer centers not to provide at least a minimum of written information to patients, particularly at the beginning of a stressful and complex process like cancer treatment. Our results clearly demonstrate that this relatively simple method is beneficial, practical, inexpensive (each booklet costs just under €1) and causes minimal disruption in a busy oncology clinic. This is a potentially strong output for a minimal input. In our department, the booklets are now being presented briefly by a nurse and distributed to all newly presenting patients. We therefore strongly suggest the use of thoroughly developed written material and the evaluation of other sources of information in other parts of the country, bearing in mind that openness in communication and the imparting of sufficient and appropriate information to patients and their families constitute a part of comprehensive cancer care.

acknowledgements

Supported by the Greek Ministry of Health (research grant No. 106/98).

references