Review

Routine administration of standardized questionnaires that assess aspects of patients’ quality of life in medical oncology clinics: A systematic review

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Received 28 December 2012; accepted 12 March 2013
Available online 10 April 2013

KEYWORDS
Quality of life;
Methodology;
Cancer daily practice;
Standardized questionnaires

Abstract Purpose: Increasing interest in the Quality of Life outcomes in cancer patients led to increase implementation of their use in routine clinical practice. The aim of this systemic review is to review the scientific evidence behind recommending the use of quality of life (QoL) scales routinely in outpatient evaluation.

Methods: Systematic review for all published randomized controlled trials in English language between January 1, 1990 till December 31, 2012. Out of 487 articles (476 identified by electronic search + 11 articles identified by manual search), six trials satisfied the eligibility criteria: (1) the study was a randomized controlled trial (RCT) with randomization of patients or health care providers; (2) the findings of the administered questionnaire or scale (the intervention) were given to health care provider, and compared to standard care with no questionnaire administered (the control); (3) study was conducted in outpatient oncology clinics; and (4) an outcome was measured that related to (i) QoL improvement, (ii) reduction in morbidity, (iii) reduction in stress for the patients, (iv) improvement in communication between patients and health care provider, or (v) improved patient satisfaction. Assessment for the quality of the study was done using the GRADE methodology.

Results: Serious methodological issues were affecting most of the trials. Overall the evaluation of the quality of the evidence from these identified trials suggests that there is a weak recommendation to use QoL scales in routine oncology practice to improve communication between physicians and patients.

Conclusion: The routine use of such tools in the outpatient settings at improving the patient outcome or satisfaction cannot be recommended based on the available evidence. The potential harm with the
Introduction

Interest in Quality of Life (QoL) measurement has been increasing in cancer research. This is evident by the number of scales being developed, and increasing incorporation of QoL measurement as the primary endpoint in randomized controlled trials of therapeutic interventions [1]. Publications in the cancer-related QoL field have tripled in the past decade compared to the preceding 25 years [2].

There are reasons which might explain the increasing interest in QoL in cancer research. Chemotherapy and radiation therapy are associated with significant toxicities which affect QoL [3] and, in many cases, palliation of symptoms and improvement in QoL are the primary goals of treatment rather than prolongation of life [4]. Many cancer-related therapeutic interventions are costly with minimal improvement in overall survival and, therefore, need to be justified based on cost-effectiveness [5] which often requires measurement of QoL and utilities (e.g. quality adjusted life year). Improvement in treatment of cancers in the pediatric and young adult population has resulted in greatly improved survivorship; monitoring of functional and emotional disability [6], which are key aspects of QoL, is important in the care of these patients.

The important and valuable results obtained from the clinical trials that included QoL evaluation has led to a logic increase interest in using QoL scales in routine clinical practice. Many major academic cancer centers do this including Memorial Sloan-Kettering Cancer Center, Johns Hopkins, and the M.D. Anderson Cancer Center [7]. A decision aid has been made available on-line and for use with personal handheld devices to facilitate the use of standardized symptom scales for patient management by Cancer Care Ontario (CCO) [8].

The goals behind collecting QoL data in routine practice include: identifying and managing symptoms, monitoring disease progression and improving communication between patients and health care providers [9]. Although all of these goals are valuable, it is uncertain if they are achieved by routine collection of QoL data at each clinic visit.

The goals of this paper is: (1) to review the evidence that the use of such scales influences patient management for randomized controlled trials (RCTS); (2) to evaluate the evidence that the use of such scales resulted in better patient care (i.e. improved outcomes) and; (3) to review the methodology of these trials and suggesting future directions in research.

Literature review

To address the first goal of this paper, a literature review was performed with the aim of identifying all randomized controlled trials that have evaluated the routine use of QoL measurement in oncology clinics. A supplementary literature search, using a less restrictive strategy, was performed to retrieved articles, reviews, and book chapters that addressed the other three goals of this paper.

Data sources

Using the electronic Ovid search engine; Medline, Embase and Psychinfo were searched using the following search keywords (“patient reported outcome” or “health status” or “functional status” or “quality of life” or “QoL”) and (“cancer” or “oncology” or “neoplasm”). All keywords were expanded to include related terms using the ‘explode’ function whenever
possible. The term “clinical trial” filter was applied to the results. The search results were further screened by examining the title or abstract for the following terms: “clinical practice”, “consultation”, “longitudinal data”, “individual”, “intra-individual”, “intraindividual”, “diary”, “daily” or “recurrent”.

The titles and abstracts of the retrieved articles were then reviewed to see if they addressed any of the three goals, in which case the full text was reviewed.

The search terms were partially selected based on previous systematic reviews [10,11] and by using key words that were used in landmark articles in this field.

It has been noted, computerized literature searching of this type of topic is more difficult and less reliable than searches that focus on traditional medical interventions [12]. Therefore, I supplemented the search by manual search of relevant database and expert advice. The search was restricted to adults and articles published in English.

Selection of studies

RCTs were included in this review if: (1) the study was a randomized controlled trial (RCT) with randomization of patients or health care providers; (2) the findings of the administered questionnaire or scale (the intervention) were given to health care provider, and compared to standard care with no questionnaire administered (the control) or to administration of a questionnaire with the findings not given to health care providers (“attention control”); (3) study was conducted in outpatient oncology clinics; and (4) an outcome was measured that related to (i) QoL improvement, (ii) reduction in morbidity, (iii) reduction in stress for the patients, (iv) improvement in communication between patients and health care provider, or (v) improved patient satisfaction.

This review excluded studies conducted exclusively in pure palliative care settings or inpatients, as this was not the focus of this review. It also excluded studies with fewer than 50 patients because of the high risk of publication bias associated with very small studies [13]. The search included publications between January 1, 1990 till December 31, 2012.

Results

Six studies were identified [14–19] that fulfilled the eligibility criteria, and summarized in (Table 1). The flow for studies selection is shown in Fig. 1. Five of these studies used the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, (EORTC QLQ-C30). The studies will be discussed with overall assessment of the findings according to the selected outcomes of this review either positive, negative or equivocal.

Analysis of the six studies

Trowbridge [14] randomized oncologists to receive the findings of completed questionnaires or not to receive the findings; all the patients completed the questionnaires. A total of 510 consecutive patients with metastatic or recurrent cancer completed a questionnaire about self-rated pain at baseline and then 4 weeks later. Changes in Cleeland’s pain management index [20] and analgesics use were measured. Using McNemar’s test there was an improvement in the pain rating ($p = 0.05$) and an increase in analgesic use ($p = 0.016$). The study showed that the using of the QoL scale helped in improving patient care (Positive study).

Taenzer [15] randomized 57 patients with lung cancer to complete the EORTC QLQ-C30 before clinic visits with the results provided to the physicians vs. Control arm to completion of the questionnaire after the visits with result not provided to their physicians. Both groups completed The Patient Satisfaction Questionnaire (PDIS) [21] and underwent chart audits. Differences in the scores of the EORTC QLQ-C30 and PDIS were reported and the charts were reviewed to identify the different categories of QoL discussed with patients. There was a better score of physical functioning ($p < 0.05$) and less dyspnea ($p < 0.05$) on the control arm. There was no difference in patients’ satisfaction between the two groups (Negative study).

McLachlan [16] study, randomized 450 patients to complete the EORTC QLQ-C30, the Beck Depression Inventory (BDI) short form and the Cancer Need Questionnaire (CNQ), with the result provided to the treating physician plus an individualized psychiatric intervention for patients at risk of depression vs. standard management where the questionnaires were administered but the result were not provided to their physicians. The result showed that there was no difference in the CNQ assessment for psychological need or information needs at 2 months (the primary endpoint). There was also no difference between the 2 groups on the BDI or EORTC QLQ-C30 at 2 or 6 months (a secondary outcome). There was no impact on the consultation time (Negative study).

Detmar [17] randomized, in cross-over trial, 10 physicians with a total of 214 patients with advanced cancer on chemotherapy. Initially, Researchers randomized half of the physicians to receive result of the completed EORTC QLQ-C30 scale while the other half continued with the conventional way without administration of the questionnaire. After a washout period of 2 months, physicians crossed over to the other arm. There was a better score on checklist for patient-physician communication as assessed by blinded rater for tape-recorded clinic visits. There was a better physician’s awareness of patient’s QoL issues as assessed by agreement between physicians and patients rating of symptoms on the Dartmouth Primary Care Cooperative Information Functional Health Assessment (COOP) and the World Organisation Project of National Colleges and Academics (WONCA) charts [22]. There was no effect on length of visit time (Positive result).

Velikova [18], randomized 286 patients who were receiving chemotherapy to one of three groups: completion of the EORTC QLQ-C30 and Hospital Anxiety and Depression Scale (HADS) with feedback to the physicians; completion of the questionnaires with no feedback to physicians (attention-control); and a pure control group with no questionnaire completed. The primary outcomes were (i) patients QoL measured using the Functional Assessment of Cancer Therapy-General questionnaire (FACT-G); and (ii) physician–patient communication as measured by blinded content analysis of tape-recorded encounters. Patient QoL sores were better in the intervention and attention-control groups with overall better QoL compared to pure control group ($p = 0.01$), especially for emotional well-being. There was no difference between the intervention and attention-control groups and no difference in patient management between the three groups. There was also no effect on clinic visit time (Negative study).
Table 1  Summary for the included studies.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Design</th>
<th>Unit of randomization</th>
<th>Patients randomized</th>
<th>Rate of completion* (%)</th>
<th>Formal training to health care provider</th>
<th>Scale</th>
<th>Outcome</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trowbridge et al.</td>
<td>Cluster randomization</td>
<td>Physicians (n = 22)</td>
<td>510</td>
<td>62</td>
<td>No</td>
<td>Pain self-rated (?scale 0–3)</td>
<td>Improvement of pain management index, &amp; Prescription pattern use</td>
<td>Very low</td>
</tr>
<tr>
<td>(1997) [14]</td>
<td>2 groups 1:1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taenzer et al.</td>
<td>Sequence randomization</td>
<td>Patients</td>
<td>57</td>
<td>92</td>
<td>No</td>
<td>EORTC QLQ-C30, Patient Satisfaction Questionnaire (PDIS) CNQ, EORTC QLQ-C30, and BDI Short Form</td>
<td>No impact by using QLQ- Very low</td>
<td></td>
</tr>
<tr>
<td>McLachlan et al.</td>
<td>Parallel 2 groups</td>
<td>Patients</td>
<td>450</td>
<td>72</td>
<td>No Study nurse provide individualize planning.</td>
<td>CNQ, EORTC QLQ-C30, and BDI Short Form</td>
<td>No impact on patient satisfaction</td>
<td>Low</td>
</tr>
<tr>
<td>(2001) [16]</td>
<td>2:1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detmar et al.</td>
<td>Crossover</td>
<td>Physicians (n = 10)</td>
<td>214</td>
<td>79</td>
<td>Yes</td>
<td>EORTC QLQ-C30</td>
<td>Equivocal results</td>
<td>Moderate</td>
</tr>
<tr>
<td>(2002) [17]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Velikova et al.</td>
<td>Parallel 3 group</td>
<td>Patients</td>
<td>286</td>
<td>57</td>
<td>Yes</td>
<td>EORTC QLQ-C30, HADS</td>
<td>No impact</td>
<td>Moderate</td>
</tr>
<tr>
<td>Mills et al.</td>
<td>Parallel 1:1</td>
<td>Patients</td>
<td>115</td>
<td>49</td>
<td>No</td>
<td>EORTC-C30/LC13</td>
<td>No impact</td>
<td>Low</td>
</tr>
<tr>
<td>(2009) [19]</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

COOP = Dartmouth Primary Care Cooperative Information Functional Health Assessment.
WONCA = World Organisation Project of National Colleges and Academics.
EORTC QLQ = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire.
CNQ = Cancer Need Questionnaire.
HADS = Hospital Anxiety and Depression Scale.
BDI = Beck Depression Inventory.

* Rate of completion calculated as follow: percentage of all the patients analyzed at the end of study in all arms to patients randomized initially.
Routine administration of standardized questionnaires that assess aspects

Mills [19] randomized patients with inoperable lung cancer were randomized to complete a weekly EORTC QLQ-C30 and lung cancer module (LC13) [23] for 16 weeks with result provided to the physicians vs. no completion of a questionnaire. The outcome was assessed by the Functional Assessment of Cancer Therapy–Lung (FACT-L) scale and patient satisfaction on six-question questionnaire. At four months there was worse QoL score in the intervention arm \( (p = 0.05) \) with no difference in satisfaction (Negative study).

In summary the studies had different methods to address the question about the benefits of the QoL data in clinical practice. Despite EORTC QLQ-C30 being used in 5 of the trials, other scales have been utilized with no clear explanation for their selection. There was diversity of outcome measures which used qualitative measures; including satisfaction, communication or improving care.

Methodological assessment of reviewed trials

There are many methodological issues with the above mentioned trials, including that the randomization process was not described in three studies [14,16,19] or that valid randomization did not occur in a fourth study [15]; as the patients were enrolled in sequence to the control and intervention arms. Lack of valid random allocation has the potential to introduce bias due to systematic differences in prognostic factors at baseline. In addition, even if there had been valid randomization, it is uncertain if measures were taken to assure allocation concealment (i.e. that investigator could not manipulate patient assignment to different groups) [24]. Such manipulations are also likely to result in systematic imbalances in prognostic factors that are known to influence outcomes. Sample size calculations [25] were not provided in 2 studies [14,15], which undermines confidence in the power of the studies to detect or exclude clinically important differences.

Four of the studies [14–16,19] did not report all the details, as indicated by the CONSORT guidelines for reporting RCTs, which further hampers interpretation of these findings (i.e. were all randomized patients included in the analysis; were there losses to follow [see below]) [26].

Due to the nature of these interventions, patients and healthcare providers cannot be blinded. This can result in a number of problems including biased outcome assessment, differential use of co-interventions, and contamination of the control arm with the intervention. To overcome the problem of biased outcome assessment, two studies had assessment of clinic visit audio tapes by assessors who were blinded to the patient allocation [17,18].

Contamination of the control arm could occur if use of the questionnaire in the intervention arm lead to physicians paying closer attention to assessment of QoL issues in the control arm. Intention-to-treat analysis [27] was conducted in two trials [17,18]. This was difficult to ascertain on the other four trials since “as treated” group analysis was provided.

All of the studies; except one [15] had more than 20% of subjects lost to follow up. It was usually not clear if the loss to follow-up was due to death from the cancer, or if it was due to other causes.

Overall evaluation of the studies

Based on the six studies; the evidence for or against routine use of questionnaires (or other QoL instruments) in medical oncology clinics is of low quality [28]. Using the GRADE approach to assessing quality, the main limitations are the potential for bias (lack of blinding, possible lack of concealment, large and poorly explained losses to follow-up) and imprecision (wide confidence intervals on estimates and uncertainty around power calculations). However, even with the potential for bias that would be expected to favour the intervention, only two
out of the six studies [14,17,29,30] suggested any benefit from routine administration of QoL questionnaires. In addition, this practice is expected to be associated with considerable resource utilization and cost (not formally assessed in any of the studies) and it might be even harmful (causes stress for patients).

The findings of the six studies in a formal meta-analysis could not be done because of major heterogeneity between studies in terms of clinical differences between patients, study design and the outcomes that were assessed.

Discussion

There are many issues related to strengths and limitations of using QoL instruments in routine practice in oncology. These issues can be classified [31] as related to the (1) scale, (2) clinician, (3) patient and (4) the health care system.

Scale issues

Important scale issues include: (1) suitability for use in a wide range of clinical settings; (2) ease of use; and (3) scale responsiveness.

It is unclear what is the most suitable scale to be used, most of the literature support the use of EORTC QLQ-30C but this not consistent with across physicians and patients [32].

Most currently used QoL scales were developed using classical test theory (CTT) and generalizability theory [33] which might not be optimized to solve the above issues. These techniques have serious limitations as those methods were optimized to average the responses for different patients and were used commonly to compare groups rather than differences among individuals. This will limit the ability of the scale to detect change for the individual score unless it is large difference [34]. To use one scale in different clinical scenarios it would need to assess a wide variety of domains (i.e. to be multi-faceted/multi-dimensional questionnaire). It is also important to keep QoL questionnaires brief for ease of completion [35].

Item response theory (IRT) might represent a solution for some of the above mentioned limitations of QoL scales [36]. This allows for the development of computerized adaptive testing which is gauged for each individual and allow for better comparisons between patients. IRT-driven questionnaires in oncology require extensive testing with large populations (item banking) and special expertise, and only a few such studies have appeared in the literature [37].

Clinician issues

The value of administering QoL scales in routine clinical practice has been questioned by clinicians who feel that they are better able to obtain the same information by talking to the patients in a less structured way during clinic visits [16,37].

Presentation and analysis of routinely collected QoL data is another issue that needs to be considered [38]. Should physicians pay attention to the current score or to the trend, and what constitutes an important difference? In four of the above reviewed trials [14–16,19] no formal training was given to the health care providers to guide them on how to interpret the QoL data, which further limits the utility of this data. One way to help with the interpretability of QoL data on an individual level is to establish minimal important difference [40]. This is achieved by two methods: distribution based, or the anchoring method [38,41].

Patient related issues

The acceptability of such intervention needs to be established by determining if patients believe that they are of value to them or are an excessive burden. Acceptability is influenced by multiple issues such as the length of the scale, availability of translated validated versions, and belief that the scale addresses issues that patient’s value.

Patient anxiety is another potential disadvantage of routinely administering QoL questionnaires. In recent studies, patients with terminal cancer have been shown to have an increased level of anxiety [39], and possibly lengthening of consultation time [41], when they are provided with a prompt list compared to receiving standard care. Despite the prompt list being different than the QoL questionnaires, they do share many domains. However, as noted above, consultation time was not affected by administration of the QoL questionnaires in three randomized controlled trials.

Health care system issues

In order to integrate QoL questionnaires into routine clinical practice, it is important to have the resources to capture, register and review the QoL data [42]. It is important to have both pen and paper versions and computer versions available for the ease of use and archiving the scores with ease of accessibility. However, elderly patients may have difficulty with interpretation of questions, or recording of answers [44]. Few programs like Cancer Care Ontario captures symptoms questionnaire data (ESAS) and assumes that completeness of this process is indicative of quality but, until it is proven that capturing this data improves outcomes for the patients; this assumption may not be justified.

Conclusion

Evidence for the use of symptom questionnaires or QoL scales in daily clinical practice is limited. There is some evidence suggesting that this might improve communication between patients and health caregivers but, because this evidence is of low quality, this is also uncertain. Currently, there is no good evidence that routine administration of QoL questionnaires improve patient’s QoL or changes management. In addition, QoL questionnaires is associated with costs, may be stressful for patients. Consequently, the overall impression is that routine administration of questionnaires in medical oncology outpatient clinics is currently hardly justified.

Before further implementing such an intervention on a large scale, RCTs need to confirm its benefits. One potential design to confirm the usefulness of in routine practice might require a cluster randomization [43].

Disclosures

I, Dr. Khalid Al-Saleh, indicate that for the article entitled “Routine administration of standardized questionnaires that assess aspects of patients’ quality of life in medical oncology
clinics: A Systematic review”, have no relevant financial relationship or conflict of interest. This research received no external funding. I have full control of all primary data and agree to allow the journal to review the data if requested.

References


