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The National Comprehensive Cancer Network-Functional Assessment of Cancer Treatment (NCCN-FACT) Advanced Cancer Symptom Indices, the Need for Better Health-Related Quality of Life (HRQOL) Measuring in Palliative Care

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Abstract

There is a need for improved measurement of clinically significant advanced cancer-specific symptoms that are sensitive to intervention-related changes and that reflect the symptoms that both oncology clinicians and patients believe are most important to measure, given the growing importance placed upon Health-Related Quality Of Life (HRQOL) as an endpoint when evaluating advanced cancer treatment outcomes. The National Comprehensive Cancer Network-Functional Assessment of Cancer Therapy (NCCN-FACT) advanced cancer symptom indexes were created in response to this need for better HRQOL measurement using a strict, multi-step methodology that complies with regulatory guidance for patient-reported outcome measures. The most significant symptoms as identified by oncology doctors and people with advanced cancer were measured using eleven NCCN-FACT advanced cancer-specific symptom indices. In this study, we provide a brief overview of the NCCNFACT scales' development as well as a list of its benefits over earlier measures, such as their brevity, clinical relevance, and higher regulatory acceptance. We discuss the possible clinical and academic uses of these measures in palliative care as well as interpretability-related concerns. In order to demonstrate how results from the NCCN-FACT symptom indexes may be utilised and interpreted in clinical practise, we also provide the NCCN-FACT-Ovarian Symptom Index-18 (NFOSI-18) and its predecessor, the Functional Assessment of Cancer Therapy-Ovarian (FACT-O) Treatment Outcome Index (TOI). We recommend that published clinical trial data using cancer-specific FACT measures can inform planning for future use of the NCCN-FACT symptom indexes in research and clinical practise given the preliminary status of research reporting the use of the NCCN-FACT symptom indexes and their content overlap with precursor disease-specific measures from the FACT measurement system.

Keywords: Health-related quality of life; Patient-reported outcomes; Ovarian cancer; Advanced cancer; Palliative care

Introduction

The frequent absence of a survival benefit linked to a new medication, despite data suggesting there may be some utility to treatment, has made it difficult to interpret cancer clinical trials. New therapies may enhance surrogate endpoints like time to disease progression and progression-free survival, but they might not correspond with overall survival [1]. This may happen due to a variety of post-study therapies that are accessible to patients after they stop taking study medication, unequal crossover following study therapy, or the fact that these surrogate endpoints are poor substitutes for overall survival. Cancer symptom evaluation can offer an early signal of benefit that is directly relevant to patients' life, whether they are symptoms of the disease or side effects of therapy. Assessment of cancer symptoms can potentially foretell future events, such as tumour response, disease progression [2-5], and survival [6-9]. It may be really critical to properly appreciate the worth of new treatments if you comprehend the most significant symptoms and associated worries linked with advanced solid tumors. With ovarian cancer serving as a model illness to highlight the significance of this evaluation as a key component to determining treatment value, we present a method in this study for effectively evaluating the most significant symptoms and concerns of patients receiving advanced cancer treatment. Health-related quality of life (HRQOL) has increasingly become accepted as a clinical trial outcome; however, clinicians and regulatory organisations have been hesitant to incorporate HRQOL assessment into clinical research and practise [10-13] due to concerns about the use and interpretability of multi-item, multi-dimensional HRQOL measures. The Food and Drug Administration Oncology Drug Advisory Committee's Quality of life Subcommittee responded to concerns about HRQOL measurement in clinical trials by stating that pharmaceutical company claims of improved HRQOL must be specific to the QOL domain measured, with the recommendation that assessment of particular symptoms serve as a starting point for improved measurement of HRQOL domains [14].

Recent research sought to enhance currently validated cancer-related HRQOL and symptom measures in order to develop clinically-relevant symptom-specific measures that are sensitive to intervention-related changes and that reflect the symptoms thought to be most important to measure by both oncology clinicians and patients. This was done in recognition of the importance of assessing HRQOL and symptom improvement, particularly in the case of advanced cancer. Patients were asked to rank the most significant symptoms for 11 distinct forms of advanced cancer, and medical professionals determined whether the symptoms were mostly caused by the disease or the therapy.

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These findings were in agreement with previously released indices that assessed the most crucial symptoms, as judged by oncology experts. By a multi-step approach, advanced cancer symptom indices reflecting the symptoms given the greatest importance by patients and doctors were developed and initially validated [15]. The creation of these symptom indices shows increased adherence to FDA recommendations on patient-reported outcomes in addition to offering clinically useful tools for the assessment of the most significant symptoms to evaluate across 11 distinct forms of advanced cancer. It does this by guaranteeing the final questionnaire's content validity. The published results of closely related predecessor instruments with substantial content overlap can be used to infer validity in other areas. To give an example, that, using the FDA-recommended methodology, the number of new questions added to previous FACT-specific questionnaires ranged from 0 to 4, with new material never reaching 20% of the final index.

Palliative oncology

The relevance of using patient-reported HRQOL as an endpoint for assessing the efficacy of treatment is highlighted by the frequently constrained availability of curative treatment choices in late stage cancer. Many physical and mental symptoms may negatively impact HRQOL in people with advanced cancer. Hence, the major objectives of therapeutic trials in advanced cancer are symptom management, functioning preservation, and maintenance or enhancement of HRQOL. The focus on these endpoints in palliative interventions highlights the importance of psychometrically sound HRQOL assessment that provides clinically useful information, as well as HRQOL measurement that follows regulatory guidance by concentrating specifically on the symptoms important for that condition. The NCCNFACT symptom indices were developed using a strict, multi-step technique that uniquely qualifies them for use in clinical research and practise addressing palliative therapy for advanced cancer.

Clinical professionals and academics now have a new method for evaluating patients' symptom-specific responses to therapy thanks to the NCCN-FACT symptom indexes. The NCCN-FACT symptom indices provide a special blend of clinical relevance and succinctness. They may thus be particularly well-suited to circumstances and settings that call for a quick, clinically relevant, and change-sensitive evaluation of HRQOL. Because each index has between 16 and 24 questions, it may be easier to address long-standing issues with HRQOL adoption in clinical practise and research settings, such as patient burden, disruption of clinic workflow, and interpretability [16]. While patients may be more affected by fatigue and other symptoms in the palliative setting, which might prevent them from completing longer HRQOL evaluations, minimising patient burden may be especially crucial. The NCCN-FACT indexes are shorter than the original FACT cancer-specific measurements, which are lengthier and more labor-intensive to complete. This represents an improvement. The NCCN-FACT symptom indexes were created primarily to assess the most significant signs and symptoms for chemotherapy-treated patients with advanced (stages III and IV) cancer. They are thus particularly well adapted for clinical practise or clinical trials that aim to evaluate the concentrated symptom experience of patients with advanced disease as well as the impact of the illness and therapy on the symptom experience. The original FACT cancer-specific measures may be a preferable option in cases when healthcare practitioners and researchers want to look at the multidimensional HRQOL experience of people with advanced cancer or HRQOL in people with early stage cancer. The FDA's guideline on patient-reported outcomes was specifically taken into account while developing the NCCN-FACT symptom indexes, which may be a benefit in terms of their acceptance in a regulatory framework [17]. When analysing the impact of novel medicines on the symptoms deemed most essential across cancer types in clinical research including regulatory filing, they offer a suitable option for quantifying HRQOL. There is no other instrument or index that is more sensitive to the FDA Patient-Reported Outcome (PRO) Guidelines, for example, in the case of ovarian cancer. The Functional Assessment of Cancer Therapy-Ovarian Cancer (FACT-0) and the Quality of Life Instrument-Ovarian Cancer Patient Version (QOL-OVCA) are two currently accessible ovarian cancer-specific HRQOL assessments.

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Interpreting the NCCN-FACT symptom indexes

An essential measurement attribute is interpretability, which has an impact on both how the measure is used and how relevant the results are. Similar with all FACT/Functional Assessment of Chronic Illness Treatment [20] surveys, a total score may be calculated for the NCCNFACT symptom indexes, and higher scores suggest better outcomes than lower ones. At the level of the overall index, this can be clinically instructive, but a closer look at the individual subscales (such as disease-related, treatment side effects, and function and well-being) can provide more detail about how the target symptoms change over time or in response to an intervention. Given that the NCCN-FACT indexes are new, measures to ascertain their interpretability or significance have not yet been created, but they represent a significant field for future research. It is fair to expect that a significant change for the NCCNFACT indices would be in the region of 4-5 points based on the work of Yost and Eton [21]. This is in line with the previously mentioned, greater-than-four-to-five-point variances in NCCN-FACT ratings amongst Eastern Cooperative Oncology Group (ECOG) performance status groups [22]. The topic of how to interpret the NCCN-FACT symptom index scores in relation to the original FACT

measure scores may emerge given that many healthcare practitioners and researchers may have employed the original FACT cancer-specific HRQOL measurements. This may be particularly significant for clinicians and researchers who seek to switch to utilising the more recent NCCN-FACT symptom indices after previously using the earlier FACT measures longitudinally. The NCCN-FACT symptom index scores cannot be derived directly from the original FACT measures due to the fact that the more recent NCCN-FACT scales contain items that were not initially included in their original FACT equivalent. However, if more than 50% of the NCCN-FACT items are completed, the scores obtained using the original FACT measures can be prorated to be comparable to the NCCNFACT measures using the following established formula: (number of items in NCCN-FACT measure) x (sum of NCCN-FACT item responses)/(number of NCCN-FACT items completed) [23]. We have given the following example involving the NCCN-FACT Ovarian Symptom Index-18 (NFOSI-18) [24] for use as a potential outcome measure in evaluating the effectiveness of chemotherapy for advanced ovarian cancer in order to demonstrate how the NCCN-FACT symptom indexes can be applied when assessing the efficacy of palliative treatment for advanced cancer.

Analyze the results of advanced ovarian cancer treatment

With approximately three-fourths of women presenting with advanced stage (stage III-IV) illness, ovarian cancer is the second most frequent and deadliest gynecologic malignancy in the United States [25]. Increasing progression-free and overall survival rates as well as reducing the number of symptoms brought on by the illness and therapy have historically been the main objectives of ovarian cancer treatment. Nevertheless, recent studies looking at clinically significant patient-centered outcomes have become more and more interested in optimising HRQOL as a crucial end-point. Research has increasingly noticed the effect of disease and therapy on HRQOL as it has placed a larger emphasis on HRQOL. The balance between efficacy and safety, or benefit and damage, is frequently taken into account while choosing a course of therapy for ovarian cancer since certain clinical advantages may degrade HRQOL. In contrast, a therapeutic benefit may also enhance HRQOL, so elevating the therapeutic benefit above and above the clinical outcomes of response, disease-free survival, progression-free survival, and overall survival. As a result, ovarian cancer offers a pertinent backdrop for discussing how the NFOSI-18 is applied to assess treatment results in advanced ovarian cancer. The NFOSI-18 was created as a component of a broader cross-sectional research that created symptom indices for 11 various forms of advanced cancer (before reported). While treating advanced ovarian cancer, 51 women with the disease evaluated which symptoms were most crucial, and 10 gynecologic oncologists determined whether these symptoms were mostly caused by the disease or the therapy. An 18-item symptom index for advanced ovarian cancer was created by combining the patient-rated priority symptoms with previously reported clinician-rated priority symptoms. The NFOSI-18 showed strong initial reliability, with subscale reliability ranging from =0.55 (Treatment side effects) to =0.64 (Function and Well-Being) and whole scale internal consistency reliability (16 items with data) of =0.80. The NFOSI-18's preliminary validity was also strong; there were notable variations in scores between performance status groups as determined by the ECOG measure of performance status, and lower NFOSI-18 scores were linked to lower performance status. The differences in NFOSI-18 scores between ECOG performance status groups exceeded the range of 4 to 5 points discussed in previous research to establish standards for clinically meaningful differences in measures from the FACIT measurement system, even though more research is required to define what constitutes a clinically meaningful difference and change on the NFOSI-18. The Functional Assessment of Cancer Therapy-Ovarian (FACT-O) HRQOL assessment and the NFOSI-18 are extremely redundant. The 26-item FACT-O Trial Outcome Index was the most popular clinical trial endpoint in advanced ovarian cancer clinical trials prior to the development of the NFOSI-18 (TOI). It contrasts the item content of the FACT-O TOI with the NFOSI-18, which was created in response to the U.S. FDA PRO Guideline on content validity (built to be more inclusive of HRQOL considerations beyond the most important symptoms and concerns). The majority of the NFOSI-18 questions (n=14) are also in the TOI, indicating that the published data on the TOI would offer reliable and pertinent evidence for the NFOSI-18's expected performance in upcoming trials. The NFOSI-18 therefore differs from the FACT-O in a number of ways, including its brevity, focus on symptom measurement for advanced ovarian cancer, and improved satisfaction with regulatory guidance. However, given the NFOSI-18's recent development, we must extrapolate much of its validity from its strikingly similar predecessor, the TOI.

Clinical trial outcomes

In a recent prospective phase II randomised clinical study, women with platinum-sensitive recurrent ovarian cancer were randomly assigned to receive either docetaxel plus carboplatin or docetaxel alone, followed by carboplatin, with HRQOL being assessed as a secondary outcome. Overall survival did not vary, but the combination arm had substantially longer progression-free survival, greater neurotoxicity, and more neutropenia. The sequential therapy, however, had a much less effect on the results for HRQOL. Particularly, compared to the combination arm, the sequential arm had less of an effect on the FACT-O TOI during the duration of the experiment. From baseline to trial completion, the TOI in the combination arm reduced by 4.9 points, but it increased by 1.4 points in the sequential arm. The median time to TOI worsening did not differ across groups, albeit. The NFOSI-18 therefore differs from the FACT-O in a number of ways, including its brevity, focus on symptom measurement for advanced ovarian cancer, and improved satisfaction with regulatory guidance. However, given the NFOSI-18's recent development, we must extrapolate much of its validity from its strikingly similar predecessor, the TOI. Women with advanced ovarian cancer had a higher chance of survival while receiving intraperitoneal (IP) treatment. The FACT-O TOI was significantly lower in the IP group compared to the IV group before cycle four (10 point difference) and three to six weeks after treatment (7 point difference), despite a phase III randomised trial finding that intravenous (IV) paclitaxel plus IP cisplatin and paclitaxel significantly increased progression-free and overall survival when compared to IV-only paclitaxel and cisplatin. As compared to patients receiving IV therapy, patients receiving IP therapy reported considerably and clinically meaningfully more physical, functional, and ovarian cancer-specific issues both during and immediately after treatment. Notably, both groups reported improving TOI over time, with no differences between the IP arm and the IV arm at one year, with the exception of the IP group prior to cycle four. In particular, the TOI increased in the IV arm from 70.0 (baseline) to 83.2 (12 months) and in the IP arm from 64.5 (baseline) to 82.2 (12 months). These results emphasise the need to balance possible survival benefits of IP chemotherapy with its short-term HRQOL impairments in talks regarding treatment decision-making. Also, the size of variations in TOI scores across treatment groups and longitudinally over time may offer suggestions for future clinical trials that may use the NFOSI-18 to evaluate HRQOL outcomes.

A quest for new therapeutic agents, such as innovative biologic medicines, has been spurred by the limited number of curative therapy choices for women with advanced ovarian cancer, despite advancements in surgical and chemotherapeutic treatment regimens. The selective oral epidermal growth factor receptor tyrosine kinase inhibitor ZD1839 was tested in two Phase I studies among patients with advanced ovarian cancer and other advanced solid tumours, and is one of the innovative biologic treatments being developed and investigated. ZD1839 works by obstructing signalling pathways that are crucial for the development of tumours. LoRusso et al. note that while this was not the case for other solid tumour types in the study, the median TOI for patients with advanced ovarian cancer decreased with time from baseline in both Phase I trials of ZD1839. The total TOI median decline from baseline in the European/Australian experiment was -4.50. Interpretability of TOI change over time is constrained by the small number of ovarian subjects in the U.S. experiment. These results emphasise the need of considering HRQOL together with safety and tolerability when evaluating innovative medicines. Future trials using the NFOSI-18 as an HRQOL outcome measure in trials looking at innovative biologic therapy may be able to put the NFOSI-18's significant change in the TOI among ovarian cancer patients into context.

Discussion

Researchers and clinical professionals now have a new tool for assessing how well advanced ovarian cancer patients respond to treatment thanks to the NFOSI-18. The shortness of the NFOSI-18, focused evaluation of the key symptoms unique to advanced ovarian cancer, and improved adherence to FDA regulatory advice are all advantages. As a result, it could be especially tempting for usage in clinical settings where reducing patient and provider burden is important as well as clinical research where following regulatory instructions is crucial. The NFOSI-18 is patient-centered, which sets it apart from previous HRQOL measures for ovarian cancer. Patients, in addition to doctors, participated in item development and selection by ranking the most significant symptoms.

Conclusion

The preliminary nature of research reporting on the usage of the NFOSI-18 is its main drawback. We do, however, believe that published results using item subsets common to both the FACT-O and the NFOSI-18 can be used to aid in the development of future research using the NFOSI-18 as an advanced ovarian cancer specific HRQOL measure due to its redundancy with the FACT-O, which has been used in a number of published studies. The validity and interpretability of the NFOSI-18 will be further improved by more study employing it. The NFOSI-18 and other NCCN symptom indexes are also thought to be short in nature, but further study is required to see if it's necessary to modify them in order to lessen patient burden in both clinical research and therapeutic therapy contexts. There is currently little data available about how widely the NCCN symptom indices are used in clinical practise settings, both domestically and abroad. It is predicted that when these measurements become more well known, they will be used more often in clinical and research settings. Therefore, ongoing assessment of these measures' adaptability to change, generalizability to patient samples from a wider range of backgrounds, and generalizability across administration contexts (e.g., clinical trials versus clinical practise) represent crucial steps in the future development and establishment of these measures' psychometric properties. Moreover, it will be crucial to regularly update the scales to make sure that they continue to reflect the current priority symptoms given changes in symptom profiles as new treatment and supportive care strategies emerge.

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Conflict of Interest

Author declares no conflict of interest.

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