

# Quality of Life Assessment in Palliative Surgery

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## Abstract

The conduct of surgical palliative care studies has largely mimicked the standards of oncologic surgery in the measurement of survival and perioperative morbidity as measures of success. Although these endpoints are familiar, success in palliative surgery may be better assessed by investigating Quality Of Life (QOL) endpoints such as relief of symptoms, pain control, and durability of symptom relief, minimizing hospitalization, and consideration of utilization of resources.

Palliative surgery carries a high degree of morbidity and mortality, 21-29% and 9-12% respectively. The occurrence of a major complication significantly reduces the rate of symptom improvement. Few papers assess QOL parameters and utilize validated research tools. Commonly used scales include the European Organization for Research and Treatment of Cancer, Functional Assessment of Cancer Therapy, Functional Living Index-Cancer, and Palliative Surgery Outcome Score.

As palliative surgery becomes increasingly recognized as a critical component of palliative care, well-designed studies utilizing quality metrics will be critical to better understanding, which patients may benefit from palliative surgery interventions in an era of aging population and increasingly limited health care resources.

**Keywords:** Palliative surgery; Palliative care; Quality of life

## Introduction

Palliative surgery is performed with the intent of improving quality of life or relieving symptoms in patients with advanced disease. The most common issues addressed by surgeons include pain, hemorrhage, and obstruction. An array of surgical procedures is available for the treatment of these problems and range from minor interventions to maximally invasive surgery. The choice of approach depends upon the patient's current state of health, the patient's medical and surgical history, prognosis, and goals of care. An example of this would be intestinal obstruction. To relieve the patient of nausea, vomiting, and pain, a simple procedure such as a decompressive gastrostomy tube may be used. However, in an appropriately selected patient, exploratory laparotomy with enteric bypass or stoma creation may be preferred.

Even before its acceptance as a board certified subspecialty in 2007 [1], practitioners of palliative medicine realized that establishing guidelines and preferred practice patterns were critical to legitimizing the field. In 2004, consensus guidelines were issued from The National Consensus Project for Quality Palliative Care, a consortium representing the five leading hospice and palliative care organizations in the United States [2]. These guidelines included eight aspects of quality including: structures and processes, physical, psychological and psychiatric, social, spiritual, cultural, ethical and legal aspects of care, and care of patients who are imminently dying. Based on these guidelines, The National Quality Forum (NQF) established its National Framework and Preferred Practices for Palliative and Hospice Care in 2006 [3]. Despite the growing role of invasive procedures for the care of this patient population, surgical practices are referred to only one time within the NQF consensus report--in reference to the need for further studies to determine its role in palliative care treatment [3]. Therefore, although palliative surgery has long been recognized as an integral component of palliative care, its role in the framework of quality, to date, is poorly defined.

Increasingly, health care systems are requiring quality standards to be analyzed in order to justify surgical interventions. One contemporary movement that has driven hospitals to address issues of safety, quality, and affordability is The Leapfrog Group. The three original "leaps" in quality included computerized prescriber order entry, intensive care

unit (ICU) physician staffing, and evidence-based hospital referral. A 2008 update on improvements resulting from the adoption of Leapfrog safety and quality standards showed that adoption of all three leaps at an urban hospital could save a total of 12.04 billion dollars and 57,903 lives per year [4]. As surgical palliation becomes an increasingly larger component of comprehensive cancer care, the same standards of excellence will need to be set by evidence-based studies. Establishing this foundation is crucial for ensuring patient safety, optimizing quality of care, setting expectations for families, aiding surgeons in complicated clinical decisions, and supporting the use of healthcare resources.

Although many curative-intent operations for cancer have established indications and quality parameters such as 5-year survival and perioperative morbidity, studies performed to establish similar guidelines for palliative surgery are currently lacking in the literature. The complexity of establishing a standard for palliative care interventions is multi-factorial and includes the inherent individualized goals of care for each patient, consensus end points for the determination of efficacy and success, and the diversity of the patient population undergoing these often complex surgical interventions. This paper will review the most commonly used Quality Of Life (QOL) tools within the literature, review the use of these metrics in the current literature, and outline the utility of these surveys in the surgical population.

## Morbidity and Mortality in Palliative Surgery

Palliative surgery carries a high degree of morbidity and mortality, 21-29% and 9-12% respectively [5,6] in two recent publications. As such, appropriate patient selection is integral in improving outcomes.

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**Received** January 08, 2013; **Accepted** February 06, 2013; **Published** February 09, 2013

**Citation:** de Rosa N, Blazer III D (2013) Quality of Life Assessment in Palliative Surgery. J Palliative Care Med S2: 005. doi:10.4172/2165-7386.S2-005

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In an American College of Surgeons National Surgical Quality Improvement analysis completed by Tseng et al. [7], patients with disseminated malignancy were found to have mortality rates as high as 18.4% for vascular procedures and 27.9% for emergent operations. Reoperation was performed in 9% of cases. Several factors were identified to be significant predictors of increased morbidity and mortality including: increased age, poor functional status, Do Not Resuscitate (DNR) status, impaired respiratory function, ascites, poor nutrition, renal insufficiency, and WBC aberrations. Using these factors, a nomogram was developed to predict 30-day morbidity and mortality [7]. In a study involving patients with malignant bowel obstruction, functional status as calculated by the Eastern Cooperative Oncology Group Score (ECOG) of 0/1 was the best predictor of survival [8]. A large prospective outcomes analysis of patients with advanced cancer undergoing operative and endoscopic interventions showed similar 30-day death and complication rates of 11% and 29%. This study went on to link the occurrence of a major complication with a reduced rate of symptom improvement by 17%. Factors associated with decreased survival included poor nutrition, poor functional status, significant weight loss, and lack of previous oncologic therapy [5].

Despite these studies identifying risk factors for poor outcomes, no formal guidelines exist to determine which patients should be considered candidates for palliative surgery. Given the significant morbidity and mortality associated with palliative surgery, additional prospective trials are needed to determine better inclusion criteria for these invasive procedures. These morbidity and mortality outcomes also suggest that other assessment tools may be critical in helping the surgeon to make better decisions about which patients should undergo procedures with oftentimes poor outcomes.

### Current Utilization of Quality of Life Tools

As evident above, the conduct of surgical palliative care studies has largely relied upon the standards of oncologic surgery in the measurement of survival and perioperative morbidity as measures of success. Although these endpoints are familiar, success in palliative surgery may be better identified by addressing aspects of QOL such as relief of symptoms, pain control, durability of symptom relief, minimizing hospitalization, and utilization of resources. In 1999, a review of the literature concerning the surgical palliation of cancer was conducted to evaluate the adequacy of available studies in supplying appropriate data for clinical decision-making. The endpoints focused upon were those intrinsic to palliative care including QOL, pain control, and cost effectiveness. Of the 348 largely retrospective studies reviewed, only 17% assessed QOL parameters and validated research tools were used only 40% of the time, most commonly the Karnofsky Performance Scale. Pain control was addressed in only 12% of studies with a minority (19%) using validated pain scales, most commonly the visual analog scale. Finally, cost analysis was least commonly addressed, assessed in only 2% of studies [9]. This study nicely demonstrates the paucity of literature on quality of life endpoints--which could aid surgeons in appropriate surgical decision-making--and suggests utilizing current standards in the medical oncology literature as a model to shape future surgical palliative study designs.

### Quality of Life Assessment Tools

Although there is a paucity of current palliative surgery studies that consider quality of life endpoints in patients, a variety of validated tools have existed in the literature for decades. Many of these tools were constructed for the medical oncology population in assessing the effect of noncurative drug and radiation regimens. These tools have been used

successfully to determine the benefit to patients of these interventions in the setting of clinical trials. Many share the characteristics of pain, physical function, emotional, and social assessments.

In 1986, the European Organization for Research and Treatment of Cancer (EORTC) initiated a program to develop an approach for evaluating the quality of life in patients participating in international clinical trials. This program was recently updated in 1993, electing to discard items deemed noninformative and to revamp its emotional functional scale which previously had poor reliability, resulting in the EORTC QLQ-C30 [10]. The EORTC QLQ-C30 is an 11-minute self-administered questionnaire that includes nine aspects of well-being: five functional scales (physical, role, cognitive, emotional, and social); three symptom scales (fatigue, pain, and nausea and vomiting); and a global health and quality-of-life scale. Additional clinical variables used in this survey were disease stage, weight loss, performance status, and treatment toxicity. The purpose of this international study was to create a core questionnaire generalizable to a heterogeneous group of cancer patients, similar to the Canadian system of QOL measurement in which a core survey is augmented by a cancer-specific survey [11]. It also sought to establish a model that would be useful among diverse cultural backgrounds.

Statistically significant changes in the trend of physical functioning, global quality of life, fatigue, nausea and vomiting for patients whose performance status had improved or declined during treatment were observed. Additionally, the reliability and validity of the survey were consistent across various patients from 12 countries including Northern Europe, Western Europe, and Australia, making it an excellent tool to be used across a multicultural population. It is also unique in its consideration of the financial impact of treatment, an important yet underrepresented factor in QOL studies in the literature.

Although this study initially sought to develop a generalizable survey, it was validated only on patients with one disease, unresectable lung cancer. This disease is aggressive and was used purposefully to be able to detect QOL changes in the population over a short period of time. Despite this, a statistically significant change in QOL from pre-treatment to on-treatment parameters was seen in only two variables, nausea and vomiting. Therefore, this tool may lack sensitivity in detecting degrees of dysfunction in patients over time. Women were significantly underrepresented in this cohort, consisting of only 24% of the group. Therefore, this tool may not accurately represent the concerns or experiences of women.

In 1993 the Functional Assessment of Cancer Therapy survey was validated [12]. This study was undertaken with the understanding that much of the chemotherapy and radiation used is not curative and that the toxicity and effect on lifestyle of new therapies needed to be balanced with their utility in treating the disease. The first version of FACT was a 33-item survey derived from interviews with 854 patients with breast, lung, or colon cancer. The scale was then refined into a 28-item scale called the FACT-general (FACT-G) that could on average be completed within 5 minutes without assistance. In addition to a total score encompassing quality of life, separate scores for physical, functional, social, emotional well-being, and satisfaction with the treatment were calculated. The reliability and validity of this scale were uniformly high. When given repeatedly over time, there was a high degree of sensitivity for change, unlike the EORTC QLQ-C30 trial.

This tool can be easily administered and is brief, reliable, and fairly inclusive of multiple aspects of a patient's well-being. Since its conception, several cancer specific subtypes have been validated in the literature not limited to the FACT-L for lung cancer and the

FACT-B for breast cancer [13,14]. This need for further specialization of QOL questionnaires addresses the unique concerns seen within cancer subtypes and the complexity of generalizing the palliative care population.

In 1984, the Functional Living Index-Cancer (FLIC), a 22-item questionnaire designed for easy, repeated patient self-administration, was published [15]. This study was conceived as a response to the inherent limitations of the Karnofsky and ECOG scores which encompass only the medical-physical aspects of illness instead of the overall functioning of patients. This 10-minute survey evaluates the physical and emotional well-being of patients, taking into account physical ability, emotional state, sociability, family situation, and nausea. The survey is derived from an original set of 250 questions identified by a small but diverse panel of 11 people including patients, spouses, doctors, nurses, and psychologists and is designed to measure the overall global function of the patient. As hypothesized, functional well-being measured by the FLIC did not always correlate with social or psychological well-being. This is important in that patients undergoing therapy may make some physical improvements, but may still be socially and emotionally debilitated having a poor overall QOL. The FLIC was thoughtfully constructed to omit confounders of social desirability. With the assumption that patients often answer surveys with a goal of pleasing their physicians, the FLIC questions were analyzed to be free of this bias.

Although medical oncologists have long used surveys to assess the risk/benefit ratio of palliative chemoradiation, metrics specific to surgical patients remain a rarity. A recent QOL measure that is specific for the surgical patient is the Palliative Surgery Outcome Score (PSOS) [16]. The PSOS is a prospective measure of the impact of palliative surgery, using the absence of a postoperative complication requiring hospitalization, as part of a measurement for QOL. It is calculated by using the following equation: Number of Symptom-free, Non-hospitalized Days/Number of Postoperative Days of Life (up to 180 days). The numerator is an indicator of the durability of symptom relief and relief from major surgical complication and the denominator is a function of days hospitalized after the operation and any additional days hospitalized to monitor surgical complications or recurrent symptoms. A PSOS value of 0.7 was identified by patients and families who had good to excellent palliation as an acceptable outcome score. A major strength of this study is that, unlike other surgical studies that often classify patients as palliative after failed complete extirpation of cancer, this study specifically classifies palliative patients a priori. This concept is critical to accurately define palliative success because patients who undergo surgery with curative intent may not have symptoms, making it unlikely to improve QOL by surgery.

There have been many reports generated on the comparison of QOL tools for cancer patients. In one such study by Kemmler et al. the FACT-G was compared with the EORTC QLQ-C30 [17]. This study was performed on 244 patients with either breast cancer or Hodgkin's disease. Patients completed both the EORTC QLQ-C30 and the FACT-G during the same session. Overall agreement between the two tests was only moderate. Of the five FACT-G subscales, only physical well-being was well represented by the EORTC QLQ-C30 subscales. Only three of eight EORTC QLQ-C30 subscales (physical functioning, global QOL, general symptoms) were represented well by FACT-G subscales.

This question of extrapolation of results among differing questionnaires is an important one in properly analyzing the literature. Clearly, the EORTC QLQ-C30 and the FACT-G were validated in different populations. Each of these surveys also represented only one

component in the assessment of QOL in cancer patients. Both models subscribe to a core evaluation of QOL generalizable amongst the cancer population augmented by a cancer specific tool. It may be that multiple QOL tools are needed to delineate the broad range of concerns in this highly diverse population.

## Future Directions

The complexity of establishing standard algorithms for palliative surgery is multi-factorial and includes the inherent individualized goals of care for each patient, the lack of agreed upon outcomes to determine success, and the diversity of the patients themselves. For those QOL surveys that already exist, many may be helpful in determining QOL changes in patients after palliative operations. However, further studies are needed to validate tools, such as the PSOS, that are specific to the surgery patient. Furthermore, the optimal timing of patient evaluation has yet to be determined. In the immediate post-operative period, patients are often less functional than at baseline and determining the most representative time for assessment of symptom relief may be difficult. Additionally, when constructing prospective trials, researchers should strictly adhere to the pre-operative designation of procedures as palliative in order to avoid inclusion of asymptomatic patients who may not benefit from a QOL perspective.

Despite the fact that palliative surgery is becoming increasingly recognized as a critical component of palliative medicine, availability of quality of life metrics in palliative surgery still lags other palliative care components and studies utilizing the available metrics in palliative surgery are few. The use of existing quality of life metrics and development of more robust metrics is critical to evaluate the impact of palliative surgery in relieving symptoms and improving QOL. These metrics will help patients make better decisions about complex surgical options, will help surgeons better manage expectations for themselves and their patients, and will aid in the distribution of healthcare resources in an era of escalating health care costs.

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This article was originally published in a special issue, [Palliative Surgery](#) handled by Editor. Dr. Paul J Mosca, Duke University, USA