

# Palliative Surgical Research-Challenges and Solutions

Brian D Badgwell\*

Department of Surgical Oncology, University of Arkansas for Medical Sciences, Little Rock, Arkansas, USA

## Abstract

Surgeons are frequently asked to evaluate advanced cancer patients with symptoms attributable to their disease or treatment. The frequency of these consultations varies but can represent up to 40% of all inpatient consultations at major cancer centers. As opposed to the standard outcome measures of survival and recurrence for potentially-curative cancer surgery, the appropriate outcome measures for palliative surgical oncology have not been fully defined. In addition, there are many challenges to performing palliative surgical research such as frequent and early death in the study population. This review article summarizes the current research in palliative surgical oncology with a focus on these challenges and barriers to research. Lastly, this article will review some of the work attempting to current these limitations and future areas of analysis.

Palliative surgery is typically defined as any procedure performed to reduce symptoms or improve quality of life in a patient with an advanced malignancy, excluding operations for potential cure [1-3]. Palliative surgery has been shown to represent 13% of all operations performed by surgical oncologists and over 1000 procedures per year at tertiary cancer centers [2,4]. The definition of palliative surgical consultation, similarly, is a consultation with patients with advanced malignancy who had symptoms attributable to their malignancy or complications/toxicity of treatment of their malignancy [5]. Palliative consultations have been reported to constitute 40% of all surgical consultations at a major U.S. cancer center [5]. These statistics demonstrate the frequency of palliative surgical consultations and surgery but fail to fully describe the clinically challenging nature of these scenarios, increased risk of surgery in this population, and lack of high-quality prospective research upon which to base treatment decisions.

The considerable morbidity and mortality rates associated with palliative surgery have been well described. Mortality rates of approximately 10% are standard, with rates as high as 21% for subgroups such as malignant bowel obstruction [2,5,6]. Morbidity has also been consistently described as 30-40% across several studies [2,5,7]. Morbidity and mortality rates are important in outlining the risk during preoperative discussions and informed consent, but are obviously only half of the risk-benefit ratio. The lack of clearly established outcome measures and thus benefit can lead to ambiguity in patient education and preoperative assessment. As a result, there has been a lack of evidence-based guidelines and algorithms for treatment. The challenges of future research are to break this cycle with clearly established outcomes and high-quality follow-up.

Clear evidence that the majority of recent literature focuses on the risk of surgery and infrequently on the benefit is outlined in a review of 348 articles published on surgical palliation of cancer [8]. The authors reported that few studies included outcome measures other than survival, morbidity, or mortality. Outcome measures noted in this review included morbidity and mortality in 61%, survival in 64%, physiologic response in 69%, need to repeat the intervention in 59%, quality of life in 17%, pain control in 12%, and cost in 2%. In addition, the majority of these studies were retrospective case series (72%) while a minority was prospective (9%). The remainders of the included articles in this analysis were either reviews (10%) or case reports (9%).

The simplest solution to the deficiencies noted in the current literature would seem to be corrected with prospective evaluation of quality of life measures. There has been a recent body of work that includes quality of life outcomes with a high rate of follow-up. Podnos et al. [9] reported a prospective study of 104 patients that underwent palliative surgery including outcome measures of physical,

psychological, social, and spiritual aspects. The authors found that improvement in symptoms, as measured by a distress severity score, were significant and durable but that quality of life continued to decline as a result of disease progression. Recognizing the heterogeneity of this study that included many different types of cancers and palliative operations, the authors went on to focus on surgical interventions for gastrointestinal cancers with similar results [10].

Other authors have addressed the difficulty in prospective analysis by prospectively identifying patients but then defining symptom improvement retrospectively. In the largest prospective study of this nature to date, over 1000 patients were identified over a one-year period [2]. The population included multiple types of cancers over many different specialties to include both operations and procedures involving the musculoskeletal, genitourinary, neurologic, and respiratory symptoms. Retrospective symptom improvement was noted in the majority of patients as defined utilizing pre-defined criteria and the absence of documented complaints in the medical record. An important finding was that symptom recurrence occurred in 25% and 29% suffered new symptoms that required further treatment.

A similar methodological approach was utilized in a study including patients managed with surgery and also patients managed with non-operative management [11]. The authors found that symptom improvement was obtained in the majority of patients regardless of whether management was surgical or non-surgical. Surgery was associated with symptom improvement as defined retrospectively for the various indications for consultation. Median overall survival for all patients was 4.2 months and highlights one of the difficulties in obtaining follow-up data. Another study found a median overall survival of 2.9 months and follow-up intervals in future studies will therefore need to be short and frequent to address this limited survival [5]. In fact, in one of the few prospective observational studies of patients undergoing surgery and non operative treatment to include quality of life assessment, death was found to be a significant factor

**\*Corresponding author:** Brian D Badgwell, Department of Surgery, Winthrop P Rockefeller Cancer Institute, University of Arkansas for Medical Sciences, 4301 W Markham St, #725, Little Rock, Arkansas 72205-7199, USA, Tel: 501-686- 5547; Fax: 501-686-7861; E-mail: [badgwell@uams.edu](mailto:badgwell@uams.edu)

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in limiting adequate follow-up assessment [12]. This study from the University of Arkansas prospectively enrolled 77 patients with plans for follow-up at 1 and 3 months utilizing the Functional Assessment of Cancer Therapy-General Survey. A total of 31 patients (40%) died before the 3 month study endpoint. Many patients were also too ill to complete the questionnaires and therefore follow-up questionnaires were only obtained at 1 month and 3 months in 48% and 15%, respectively. On an extensive analysis to identify variables associated with questionnaire completion, only death was significantly associated with questionnaire response. It should be noted that this population included patients managed without surgery which tend to represent a more deconditioned and ill population. Other studies that focused exclusively on patients managed with surgery had better response rates and follow-up survey administration can be obtained at routine post-operative follow-up visits.

Another study from Walter Reed Army Medical Center utilized a novel approach of outcome assessment focused on quality of life, functional performance, and pain perception [13]. Interviews with the patient, significant family member, and attending surgeon added expectations about the outcome and durability of the procedure. Twenty-six patients were enrolled and the planned postoperative monthly assessment was achieved in 69%. After palliative surgery, 54% of the patients did not show clinical improvement, with post-operative complications likely playing a role as patients with complications were unlikely to be discharged from the hospital. For those patients demonstrating clinical improvement, family members and surgeons concurred over improvement in every case highlighting the importance of involving family members in outcomes assessment. Involvement of family members may also be an opportunity to obtain follow-up assessment when patients are too ill to answer questionnaires or even perform telephone survey administration. The issues surrounding achieving follow-up near the end of life were also prominent in this study as median survival for all patients was only 108 days and mean length of hospital stay was two weeks.

The heterogeneous population of patients undergoing palliative surgery or surgical consultation is another challenge that will require focused efforts to address. Common indications for consultation or surgery include bowel obstruction, gastrointestinal bleeding, bowel perforation, inability to eat/request for feeding tube placement, and obstructive jaundice [5,12,14]. Bowel obstruction is the most common indication for palliative surgical consultation and has been suggested as a good diagnosis for a prospective randomized trial in palliative surgery. An international conference on malignant bowel obstruction was convened to advance palliative care clinical trials with malignant bowel obstruction as a model to develop a research protocol [15]. Leaders in quality of life research, ethnocultural variability, and palliative medical and surgical care attained a consensus on methodological approaches with a clear outcome supported by sample size calculation and disseminated in a supplement of *The Journal of Pain and Symptom Management* [16]. Despite such efforts, clinical trials in palliative care are exceedingly rare and reflect a lack of equipoise in surgical decision-making, the difficulty of informed consent at the end-of-life, and the heterogeneous clinical scenarios that make inclusion criteria complex.

In summary, the greatest challenges to palliative surgical research include the lack of clearly defined endpoints, frequent and early death limiting follow-up evaluation, and the heterogeneous patient population. Therefore the first step in answering these challenges will

be a consensus on the appropriate outcome for each diagnosis. Second, administration of a formal validated quality of life measure is difficult and it is likely that follow-up will be much improved with an outcome measure that can be obtained easily with minimal patient involvement such as days outside of the hospital or the ability to tolerate oral intake, as in the example of malignant bowel obstruction. Third, multi-institutional collaboration will be a key-factor in obtaining adequate patient numbers to identify variables associated with improved outcomes. Lastly, and as in all surgical research, prospectively collected data will be much more reliable than retrospective analysis and certainly retrospective determination of symptom improvement. Clinical trials, for now, will need to await high-quality prospective observational data to identify the appropriate patient populations and inclusion criteria for collaborative group trial approval.

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