

# Clinical Research for Surgeons in Palliative Care: Challenges and Opportunities

Alexandra M Easson, MD, FRCSC, FACS, K Francis Lee, MD, Karen Brasel, MD, FACS, Robert S Krouse, MD

*To palliate: pallium (Latin) “affording relief, not cure . . . to reduce the severity of.”<sup>1</sup>*

Symptom management and palliative medicine have gained growing interest among physicians and other health care providers. One reason might be the profound shift in patient demographics and associated diseases. What was once a formidable condition, such as an acute coronary occlusion, for the most part follows a straightforward clinical protocol today with interventional cardiology and cardiac procedures. Sudden death from acute myocardial events among people in their sixth or seventh decade has become relatively uncommon. Instead, the elderly population is chronically plagued by heart failure, a condition present in nearly every other person more than 85 years of age.<sup>2</sup> In the younger population of 65 to 74 years of age, advanced cancer has surpassed heart disease as the most frequently cited cause of death.<sup>3</sup> We live in a rapidly aging society; 78% of people in the United States will live past their 65th birthday.<sup>4</sup> Congestive heart failure, advanced cancer, stroke, and dementia—the four formidable chronic morbidities—all share one common characteristic. There is no cure for their underlying disease process. Most current treatment modalities aim for disease control and symptom palliation rather than cure in the strict sense.

Surgeons might wonder how palliative care fits into their surgical practice. This might be because of the surgical myth that the principal role of the surgeon is to cure the patient and the business of palliation is deemed best relegated to the nonsurgeons. But the presumed delin-

ation between cure and palliation is becoming increasingly blurred because of the underlying patient demographics and associated disease processes that are fundamentally incurable, at least from today's vantage point.

In the end, it might be more constructive to consider the role of palliative care in surgery in terms of specific patient-oriented clinical outcomes, rather than in terms of the elusive cure versus palliation. In addition to survival, examples of patient-oriented clinical outcomes include functional status; relief from symptoms such as pain, dyspnea, and cachexia; and emotional and psychological well-being—all of which contribute to quality of life.

In the aforementioned context, there is a need to define what palliative surgery is, and what a palliative surgeon is. Palliative surgery is not to be construed as a type of surgery exclusive of any intent to cure. When cure is possible, palliative surgery is inclusive of curative intervention. In addition, palliative surgery does not connote any degree of diminishment or retrenchment of care. If anything, palliative surgery might provide more aggressive care, recognizing the value of medical, procedural, or other interventions leading to symptom relief and enhanced quality of life. Symptom palliation might even result in increased patient survival, whether or not cure is possible in the traditional sense.

What distinguishes palliative surgery is the palliative surgeon's expansion of clinical outcomes beyond surgical morbidity or mortality outcomes and recurrence of disease to include outcomes that are meaningful to the patient. Palliative surgeons acknowledge that death can be a natural and expected outcome of an advanced disease process, such as cancer and systemic atherosclerotic disease. They aim to set appropriate goals of care and to offer other clinical services for the total care of the patient and family.

For most patients with advancing atherosclerotic disease, malignancy, and dementia, relief from debilitating symptoms and quality of life might be just as or more important than the number of years lived. A concen-

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From the Division of Surgical Oncology, Princess Margaret Hospital, University Health Network, Toronto, Ontario, Canada (Easson) and the Departments of Surgery, Baystate Medical Center, Tufts University School of Medicine, Springfield, MA (Lee), Medical College of Wisconsin, Milwaukee, WI (Brasel), and Southern Arizona Veteran's Affairs Health Care System, and the University of Arizona, Tucson, AZ (Krouse).

Correspondence address: Alexandra M Easson, MD, FRCSC, Division of Surgical Oncology, Room 3-130, Princess Margaret Hospital, University Health Network, 610 University Ave, Toronto, Ontario M5G 2M9, Canada.

trated focus on quality-of-life outcomes in addition to quantity of life distinguishes the palliative surgeon and shapes the emergence of palliative surgery as a new surgical endeavor. Palliative surgery is not organ-specific or disease-specific. A palliative surgeon can arise from any surgical subspecialty, whether in trauma surgery, surgical oncology, pediatric surgery, or vascular surgery. Regardless of the subspecialty, the palliative surgeon's goal is to assess and address the appropriate goals of care specific to each patient. To this end, palliative surgery must base its interventions on rigorous clinical research using outcomes measurements of various surgical options, procedural or not. The purpose of the following discussion is to explore potential areas of clinical research as relevant to the palliative surgeon in clinical practice. In the end, a disciplined scientific investigation is necessary to determine the optimal course of intervention for most clinical situations, especially for patients whose goals of care include quality of life in addition to length of life.

### Areas of clinical research in palliative surgery (Table 1)

An important beginning is the study of the surgical decision-making process, beginning with the communication of patient preference. Because the goals of treatment are relief of suffering and improvement in quality of life, the patient's own perceptions and wishes are perhaps the most crucial determinants in procedure selection, yet the care provided to patients is often not consistent with their preferences and rather is associated with factors other than preferences or prognoses.<sup>5</sup> As is evident by data accumulated from studies on breast and prostate cancer, patient preferences are far more complex and dynamic than previously appreciated.<sup>6-8</sup> In critical care settings, surgeons are often brought in as consultants in dire emergencies in which the psychosocial conditions of stress and pain create a suboptimal environment for objective discussion. When surrogates are involved, additional distracting factors can influence the decision-making process.<sup>9-11</sup>

The above variables create a setting in which optimal informed consent and surgical decision making might not be possible. The patient's decision can be influenced by how the clinical issues are framed by the surgeon. It is difficult to ascertain the full range of the patient's preferences of outcomes when the patient and family have not addressed the issues before the illness. Patient-physician misperception, information overload, and

**Table 1.** Possible Areas of Clinical Research in Palliative Surgery

1. Surgical decision making
Communication of patient preference
Informed consent
Prognostication and the natural history of disease with and without surgical intervention
Breaking bad news
Defining goals of care
Family and surrogate decision-making
End-of-life decisions
Advance directives and DNR
Withdrawal of support
2. Symptom management
Pain
Chronic postoperative pain syndromes
Malignant neoplastic cancer syndromes
Geriatric pain syndromes
Pain in the surgical intensive care unit
Posttraumatic pain syndromes
Vascular pain syndromes
Nonpain symptoms
Nausea and vomiting
Dyspnea
Fatigue
Anorexia and cachexia
3. Palliative surgical procedures
Selection of ideal treatment modality
Morbidity of procedure versus morbidity of not doing procedure
Mode of death with and without surgical intervention
Suffering of patient and family with and without surgical intervention
Validated outcomes measures for surgical procedures
Quality of life
Relief of symptoms
Prevention of symptoms: obstruction, neurological complications, fractures
Assessment of new procedures
Minimally invasive procedures
Interventional radiology
4. Surgical education about palliative care
Undergraduate—medical student education
Graduate—surgical resident training
Postgraduate—continuing medical education

transference-countertransference during the communication process have been well described.<sup>12-14</sup> It is known that patient treatment choices are influenced by what the patient and family understands about the disease and prognosis. Weeks and associates<sup>15</sup> showed that the decision about whether or not cancer patients should have

aggressive therapy related to their perception of their own survival. Cancer patients tended to overestimate their survival; those who thought that there was at least a 10% chance that they would die within 6 months were more likely to favor less aggressive therapies. If patient preferences about the trade-offs between the risks and benefits associated with alternative treatment strategies are based on inaccurate perceptions of prognosis, then treatment choices might not reflect each patient's true values.

Communication can be particularly challenged in the setting of "breaking bad news." The patients or surrogates might not fully comprehend the finality of the news of advanced cancer, for example, and physicians are often loath to take away the last vestige of hope, so together they are susceptible to pursuing a course of therapy with unrealistic goals. Although much has been written about breaking bad news in clinical medicine, empiric data are lacking in terms of beneficial methods of communicating negative clinical results.<sup>16</sup>

Accurate assessment of prognosis is essential to determine the risk/benefit ratio before recommending a surgical intervention. Studies of the ability of physicians to predict prognosis have yielded mixed results. A prospective study found that clinicians estimated prognosis quite accurately when asked whether or not a patient with terminal cancer was expected to live 6 months.<sup>15</sup> In other studies, treating physicians tended to overestimate the survival of patients, and, in particular, failed to predict those who died early (within 2 months).<sup>17,18</sup> Several clinical prognostic indices have been developed for terminal patients that combine objective clinical criteria such as weight loss and performance status (patient function) with clinician estimates.<sup>19-22</sup> Objective clinical criteria perform as well (or as poorly) as clinician estimates.<sup>22,23</sup> The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT) found that recommended clinical prediction criteria were not effective in identifying patients with a survival prognosis of 6 months or less in seriously ill hospitalized patients with advanced chronic obstructive pulmonary disease, congestive heart failure, or end-stage liver disease.<sup>24</sup>

Other less well-defined factors also impact on prognosis. Extent of disease and quality of life together predicted survival better than each parameter alone in patients with breast cancer.<sup>25</sup> Symptom distress alone predicted survival in lung cancer patients.<sup>26</sup> Patients

with a low quality-of-life score were more likely to die within 6 months than those with higher scores, but low scores were not strong predictors of survival in individual patients.<sup>27</sup> An early example of a surgical prognostic index was the Child-Turcotte classification of portal hypertension.<sup>28</sup> It used five clinical and laboratory values to categorize patients before undergoing surgery for portal hypertension by a portosystemic shunt. Widely used, it proved to reliably estimate early preoperative mortality.<sup>29</sup> No similar index has been developed for the risk of surgical morbidity and mortality in patients with advanced disease such as cancer. Research that provides clinicians with a clearer understanding of patient prognosis and the risk-benefit ratio of specific surgical interventions is necessary for palliative patients.

Another aspect of the problem is that currently there are few outcomes data in the current surgical literature on which to base sound palliative surgical choices.<sup>30</sup> Improvement in quality of life and symptom relief should be the best measure of any palliative therapy.<sup>31-33</sup> These outcomes have not been a large part of traditional surgical thinking, which has tended to focus on quantity rather than quality of life, although this is slowly beginning to change.<sup>34</sup> Reports of outcomes after palliative surgery reveal conflicting results about quality of life and survival after palliative surgery, but very few prospective data are available.<sup>30,35-38</sup>

It would be valuable to understand more clearly the major variables that lead to surgical decisions that later become associated with patient or surrogate dissatisfaction or unnecessary use of health care resources. Clinical research in palliative surgery might focus on investigating tools that can enhance the ability of the surgeons to accurately determine patient and surrogate preferences and minimize the influence of compounding factors in decision making, such as emotional guilt, denial, cultural bias, and misunderstanding of prognostication. In end-of-life clinical settings, the need for such research is even greater because there appear to be considerable shortcomings with DNR orders, physicians' knowledge of patient preferences to forgo resuscitation, delay in withdrawal of support, and inadequate pain management.<sup>39</sup>

Another major potential area of surgical research is in improving resident and medical student skills related to palliative care. Communication between physician and patient has been recognized as a core competency of medical education. Requirement of competent interper-

sonal skills and communication, along with other core competencies, has been interpreted as a substantial initiative for surgical training.<sup>40</sup> The American Board of Surgery has included among its list of definitions of general surgical specialty one's ability to counsel patients and families.<sup>41</sup>

The *Surgical Resident Curriculum* has listed various communication skills as part of preoperative assessment of geriatric surgical patients. They include developing communication skills and relationships with the elderly, family, and other health care professionals, and understanding psychosocial aspects of the preferences of the patient, family, and referring physicians.<sup>42</sup> Surgical housestaff generally receive little formal training about death and dying. Although an experienced attending surgeon might serve as an educator in this area, only 50% of senior surgical residents reported ever discussing this topic with their attending surgeons.<sup>43</sup> Less than half of a group of surgical residents surveyed were competent in cancer pain management; of note, there was no improvement as the residents moved to more senior levels.<sup>44,45</sup> Most residents have had some formal training about death and dying in medical school; it is unknown what impact this has during their years of surgical training. In this context, the palliative surgeon should take leadership in training surgical residents and practicing surgeons to improve their communication skills. In the medical school curriculum, there is a role for the palliative surgeon to take the lead in the education of patient-physician communication, in both teaching and investigative capacities.

At the same time, there is a need to assess the effectiveness of various training modalities. Among lectures, workshops, small-group discussions, and role-plays, it is not clear which one or combination of various teaching methods would be best for educational training at each level of surgical professional development. This is fertile ground for educational research that the palliative surgeon might explore.

Another important area of clinical research is symptom management. The previous two decades have seen an explosion of clinical interest in pain management, most of which were led by pain specialists from anesthesiology. Clinical use of epidural catheters, neurolytic procedures, and neuroaugmentation technology has contributed to the establishment of acute pain service and outpatient centers for chronic pain management. It

is a mistake for surgeons to relinquish pain management altogether to another specialty.

Pain is a ubiquitous physical complaint, now a fifth vital sign mandated by the Joint Commission on Accreditation of Healthcare Organizations to be monitored on all patients. Between 30% and 75% of elderly patients live daily with chronic pain that contributes to their disability and morbidity because of inadequate relief.<sup>46</sup> Surgeons encounter pain as a formidable clinical dilemma in a number of clinical settings (Table 1). There is a need to explore the precise role of surgical intervention—whether by traditional open or minimally invasive surgical approaches—in many pain syndromes. There is potential for the role of thoracoscopic splanchnicectomy for malignant visceral pain, laparoscopic adhesiolysis for chronic postoperative abdominal pain, and neurectomies for refractory postoperative inguinal neuropathic pain.

A landmark example is a study by Lillemoe and colleagues,<sup>47</sup> from Johns Hopkins, who, in 1993, reported the results of a prospective, randomized, double-blind study of intraoperative chemical splanchnicectomy. They evaluated the effects of celiac plexus injection with 50% alcohol versus placebo injection in patients with unresectable pancreatic cancer. Mean pain scores were notably lower in the alcohol group at repeated followup, with no increased morbidity. In patients without preoperative pain, alcohol delayed or prevented the onset of pain. Alcohol injection markedly reduced existing pain for patients with considerable preoperative pain. Most unexpectedly, patients with preexisting pain who received alcohol showed a notable improvement in survival. Unfortunately, this exciting work has yet to be repeated in the surgical literature, and splanchnicectomy is currently not part of the routine management of patients with advanced pancreatic cancer at most institutions. A retrospective study from the Mayo Clinic in 1997 reported that only 15% of 292 patients with pancreatic cancer received neurolytic celiac plexus block, suggesting a major underuse of a well-described palliative procedure.<sup>48</sup>

To be sure, the literature evidence on the efficacy of these procedures is often equivocal. But the answer to the specific therapeutic efficacy might lie in further stratification of the affected patient population. Precise indications for surgical interventions must be delineated. For patients with considerable comorbidities whose longterm survival is tenuous, the palliative surgeon's

ability to offer symptom relief through intensive medical or procedural intervention might add a third alternative to the traditional dichotomy of “surgery-or-no-surgery” options. The management of nonpain symptoms—such as dyspnea, nausea, and cachexia—are also fertile ground for palliative surgical research.

Whether the focus of clinical investigation is symptom relief or patient–physician communication, careful outcomes measurement is vital to a successful research agenda. In surgical oncology, for example, outcomes measures of quality of life are becoming fundamental to clinical research. In surgical ICUs from which critically ill patients are discharged either alive or dead in a relatively short time, analyzing the process of care—ie, the quality of care—is a valid focus of clinical investigation in and of itself.

#### **Palliative surgical research in surgical oncology: Quality-of-life outcomes**

Surgery has a long tradition of cancer palliation; well before surgeons had a modern understanding of DNA mutations or apoptosis, they performed procedures to alleviate the pain and suffering from cancer. Clinical surgical research has only recently begun to refocus on these outcomes.<sup>34</sup> This is not unique to surgery. Medical oncology research underwent a fundamental change in 1996 when the FDA approved the use of gemcitabine for advanced pancreatic cancer because the authors demonstrated that the main benefit of the drug was the relief of symptoms.<sup>31,49</sup> Radiation oncology, in contrast, has a wealth of research into palliative treatments, as in the relief of shortness of breath in lung cancer, and the relief of pain from bone metastases.<sup>50,51</sup>

There are a variety of surgical procedures available to manage pain and other symptoms in cancer patients that span the spectrum of invasiveness, from percutaneous interventions under radiologic guidance to open surgery.<sup>52</sup> Other options for management are often available, such as chemotherapy, radiation, and other modalities. It is only by applying rigorous clinical research techniques to assess and compare these modalities that we are able to recommend the treatment that will provide the best quality of life for our patients.

Few palliative surgical cancer procedures have been subjected to rigorous scientific assessment. One example in which clinical research has been done is the management of biliary obstruction for unresectable cancer patients. The results of four randomized trials comparing

endoscopic stent insertion versus surgical bypass allow for some broad conclusions to be made.<sup>53</sup> Both techniques are effective in initial drainage of the biliary tree and improvement of symptoms. Endoscopic stenting has a lower early morbidity and mortality rate compared with surgical bypass, and so is more suitable for sick and debilitated patients. But late complications of cholangitis and recurrent jaundice are high with endoscopic stenting, so repeat procedures might be required every 3 to 6 months. So patients expected to live longer than 6 months might be more suitable for surgical bypass, although this prognostication is difficult.<sup>54</sup>

An example of the current state of palliative surgical research is the study of surgical management of malignant bowel obstruction, recently reviewed in the July issue of this journal.<sup>55</sup> Feuer and associates<sup>38</sup> published a Cochrane literature review of the subject in 2000. The authors were unable to draw any conclusions and identified the following problems with the available literature. All studies were retrospective, and there was little uniformity or clarity about which patients were entered into the studies. When symptom control was used as an outcomes measure, it was unclear how symptoms were measured and whether the symptom scores used were validated. Even when postoperative morbidity and mortality were used as the outcomes measures, definitions of these outcomes were unclear and varied among many of the papers. The research question must be clearly defined by careful identification of the target population and use of validated outcomes measures before meaningful conclusions can be made from clinical research.

There are a number of validated quality-of-life and symptom outcomes measures available for interventional research in cancer patients (Table 2). Three were created for palliative populations,<sup>56-58</sup> and several others have undergone at least some validation when applied to this population.<sup>59-64</sup> When used to measure the effects of an intervention, the ideal measure should have the following characteristics. The measurement tool should ideally be rated by the patient rather than by a health professional because it is patients' perceptions of their experience that is most valuable. The measure should be short and easy to complete because it will be need to be readministered on a regular basis (eg, before and after the intervention, longterm followup). These patients will become more debilitated as their disease progresses, and they will not be able to complete a complex questionnaire. A more complete list of measurement tools used to

**Table 2.** Validated Outcomes Measures of Quality of Life and Symptom Control for Cancer Patients Potentially Applicable to the Palliative Population

Measure	Characteristics
Quality of Life Index <sup>93</sup>	Physician-rated scale with 5 subscales: activity, daily living, health, support, outlook. Tentative utility weights available <sup>94</sup>
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (QLQ-C30) <sup>59</sup>	33-item tool with 9 subscale domains, including physical, social, disease symptoms, global quality of life. Cancer site-specific modules available
Functional Living Index-Cancer (FLIC) <sup>95</sup>	22-item scale, “global construct of functional quality of life,” total score only
Functional Assessment of Cancer Therapy (FACT) <sup>63</sup>	28 items generic core, multiple specific subscales, including symptoms
Linear Analogue Self-Assessment Scale (LASA)	Symptom, mood, physical, social domains: advanced breast cancer, <sup>96</sup> colostomy patients <sup>97</sup>
Quality-Adjusted Time Without Symptoms and Toxicity (Q-TWiST) <sup>98</sup>	Utility-based, discounts survival time, operable breast cancer
Gastrointestinal Quality of Life Index (GQLI) <sup>99</sup>	36-item index specific to gastrointestinal disorders
McGill Quality of Life Questionnaire (MQOL) <sup>56</sup>	16 items, 4 domains: physical, psychological, existential well-being, support. Created for a palliative care population
Missoula-Vitas Quality of Life Index—Advanced Illness <sup>57</sup>	25 items, created for a terminally ill population
Medical Outcomes Survey-Short Form (MOS-SF-36) <sup>68</sup>	36-item questionnaire, validated in many different populations
Spitzer Uniscale <sup>93,100</sup>	Single item: overall quality of life
Edmonton Symptom Assessment Scale (ESAS) <sup>58</sup>	10 items, numeric, for repeated use. Created for a palliative care population
Memorial Symptom Assessment Scale <sup>61,62</sup>	32-item scale that contains physical, psychological, and global distress subscales
Rotterdam Symptom Checklist <sup>64</sup>	34-item symptom scale

evaluate quality of care at the end of life and an evaluation of the tools themselves, can be found at <http://www.chcr.brown.edu/pcoc/toolkit.htm>.

When investigating a specific symptom intervention, the tool must be specific enough to include the symptom(s) of interest, and sensitive enough to distinguish change in this symptom over and above the other symptoms that the patient is experiencing. Few such symptom-specific tools exist; most measurement tools available for this use are disease-based and contain within them specific symptom subscales (eg, shortness of breath in lung cancer.<sup>51</sup> Most importantly, it must be responsive or sensitive to changes over time, to measure the effects of an intervention. Before these measures are used for a surgical study, they need to be validated for the population to be studied.

### **Palliative surgical research in the surgical intensive care unit: Process-of-care outcomes**

Initially, the focus of care in an ICU patient is on the use of highly invasive, technologically advanced procedures designed to support, save, and prolong life. Outcomes measures evaluating ICU care from this perspective as-

sess the number and quality of “successes,” or survivors. But if and when the focus of care includes the provision of palliative care, a successful outcome must be redefined. The process of care and satisfaction with care, rather than mortality and longterm quality of life, become the primary outcomes of interest. Both types of outcomes can help health care providers improve the quality of palliative care in the ICU and might be part of a research agenda for the palliative surgeon.

### **Morbidity and mortality**

Traditional measures of morbidity and mortality as outcomes are familiar to surgeons. Application of these measures in the high-tech “rescue environment” of the ICU reflects the high acuity of the patients encountered. Knowing the likelihood of survival for a particular patient population might help guide the discussion about appropriateness of continuing care.<sup>65,66</sup> These outcomes do not allow us to measure the care we give at the end of life to nonsurvivors.

### **Quality of life**

Functional quality-of-life scales have been studied in the ICU population. For survivors of ICU care, Sickness

Impact Profile scores worsen initially, but return to baseline or lower 1 year after discharge, indicating improvement in quality of life.<sup>67</sup> This improvement might be both variable and difficult to measure because the change in Medical Outcomes Survey-Short Form (MOS-SF-36)<sup>68</sup> scores 1 year after surviving ICU discharge is much less pronounced.<sup>69</sup> Although this quality-of-life information is more informative than crude morbidity and mortality rates, it does not inform about the quality of palliative care in the ICU. As with morbidity and mortality, these outcomes provide information about prognosis that can guide discussions with patient and family. But they must be used carefully. More than 80% of patients would be willing to undergo critical care again, despite a poorer longterm functional status than at baseline, reporting good to fair quality of life.<sup>70</sup> And perhaps contrary to prevailing opinion, future quality of life might not have as great an impact on reasons for withdrawal of care in all patient populations.<sup>71</sup>

### **DNR orders**

DNR orders are one aspect of the process of palliative care and are the easiest to measure. It seems reasonable to use the presence of a DNR order as a minimal outcomes measure for palliative care, because it is unlikely that patients receiving palliative care would not have DNR orders. Currently, more than 90% of all hospitals have some type of policy for DNR orders. Implementation of such a policy might improve documentation and provide clarity regarding specific interventions without altering the total number of DNR orders.<sup>72</sup>

DNR orders used as an outcomes measure for palliative care are a surrogate for a discussion about goals of therapy. The assumption is made that if the order is present, the discussion has occurred and the goals will be met. Between 9% and 13% of ICU patients will have a DNR order written at some point during their stay.<sup>73</sup> Unfortunately, the majority of studies about DNR orders are retrospective and do not suggest that the presence or timing of DNR orders in ICU patients provide relevant information about the quality of care.<sup>39,65,66,72-74</sup> Studied prospectively by SUPPORT investigators, physicians know patient preferences about life-sustaining treatment less than 40% of the time.<sup>39</sup>

Predictive models identify age, race, chronic health conditions, acuity (measured by the acute physiology score), coma, and primary disease process as important factors that determine the likelihood of a DNR order

during admission to the ICU. In-depth study of different ICUs shows a distinct difference in observed and expected DNR orders. This difference did not seem to correlate with qualitative assessment of DNR practices, highlighting the difficulty in using the presence of DNR orders as a relevant outcomes measure of quality end-of-life care.<sup>74</sup>

### **Symptom control**

Involvement of palliative care teams in the care of ICU patients is a "process" outcome that is measurable and has some face validity in improving the quality of palliative care for these patients. This approach is used in some ICUs that care primarily for medical patients. But, a considerable number of patients in these units still have poor symptom control at the end of life. In a group of cancer patients with a 32% ICU mortality and 55% in-hospital mortality, 56% reported moderate-to-severe pain. Discomfort, unsatisfied thirst, difficulty sleeping, and anxiety occurred even more frequently.<sup>75</sup> This study, which assessed concurrent symptoms prospectively, confirmed previous studies that relied on symptom recall.<sup>76,77</sup> Patient-reported pain scores differ markedly from those reported by physicians and nurses, confirming the importance of this outcomes measure as a valid indicator of the quality of palliative care in the ICU.<sup>78</sup>

### **Communication**

In contradistinction to physician practice, the majority of patients wish to discuss preferences about resuscitation options. Unfortunately, these discussions are often held with surrogate decision makers, perhaps because they are postponed until the patient is unable to participate. Problems with surrogate decision makers include their availability, knowledge of patient desires, and an overestimation of patient's wishes for resuscitation.<sup>79</sup>

Communication relevant for study includes communication between family and physician and between all members of the health care team. Lack of standard approaches to palliative care and withdrawal of care, such as the lack of a ventilator withdrawal policy, leads to inconsistencies, confusion, and frustration. A structured approach eliminates many of these problems, and has the benefit of allowing all staff members to be more comfortable discussing palliative care decisions with patients and family members.<sup>80</sup> Use of the family conference in a structured way is one method to improve communication and satisfaction with palliative ICU care.<sup>81</sup>

The palliative surgeon can evaluate ICU palliative

care by investigating the quality of the patient's and the family's experience with the care delivery system. Measurable outcomes might include various endpoints reflecting the patient's and family's emotional, psychological, and spiritual experience, and the patient's physical suffering from various treatable symptoms. Another important area of research might focus on the health care providers' experience in similar dimensions. Factors that personally influence health care professionals can impact their ability to provide quality care, so their professional experiences might in and of themselves be a valid subject for palliative care research. Studies that address the unique characteristics of palliative care research will be particularly helpful.

### **Unique characteristics, ethical considerations, and barriers to palliative surgical research**

The study of the care of patients who are dying from their disease offers its own set of challenges. The disease course is frequently characterized by constantly changing symptoms and a relatively short period of final illness. Longterm followup is not an important factor. But difficulty in predicting time to death makes decision making and patient assessment harder. Although the best assessment of the patient's quality of life comes from the patient, this is difficult if not impossible to obtain as the patient approaches the terminal phase of illness.

Ethical challenges, while paramount in all research, can be especially complex for clinical research for patients in the terminal phase of their illness.<sup>82,83</sup> Although some of these issues are not unique to patients at end of life, they are often magnified in the population.<sup>84</sup> Causes of dilemma can include a vulnerable population, an inadequate consent process, and the difficulty a researcher–clinician has in balancing roles.<sup>85</sup> Evaluation for clinical trial eligibility can be unduly invasive, and a greater number of various tests might be required for followup than are usually performed in standard clinical practice.

Ethical dilemmas that differ from those in other types of clinical research can include the difficulty in assessing risks and benefits, randomization (especially if there is a “no treatment arm”), and the unstable mental status of patients with terminal illnesses. Finally, surgical issues mandate special consideration.<sup>86,87</sup> Dilemmas consist of the invasiveness of a surgical procedure, the possible loss of decision-making control, unclear clinical equipoise when comparing a surgical approach with a nonsurgical

approach, and the inability to withdraw from a surgical procedure, especially if general anesthesia is used.

There are multiple barriers to palliative care research. A major barrier might be clinician bias. This could lead to few referrals based on the argument that research on patients facing the end of life might not be morally justifiable.<sup>88</sup> In addition, many researchers might be unwilling to participate in palliative care trials; even experienced researchers have expressed difficult psychological and emotional concerns with the complexities of palliative care research.<sup>89</sup> Barriers to palliative care research to surgeons include patient's and family's reluctance to undergo surgery, financial constraints for care, patterns of referral to surgeons (or other palliative care specialists), and cultural factors influencing palliative care.<sup>86</sup> Funding deficiencies are also major barriers to palliative research. For example, only 0.9% of the total 1999 National Cancer Institute budget went to palliative and hospice care research.<sup>90</sup> Finally, the limited numbers of palliative care services and hospices ultimately result in fewer opportunities for palliative care research.<sup>91</sup>

An article that will explore the unique ethical considerations in surgical palliative care research in greater depth is planned for this series in the future.

In conclusion, the study of the care of patients who face a terminal disease is especially relevant in a rapidly aging society such as that in North America, but it offers its own unique set of challenges and opportunities. Care based on appropriate patient-centered outcomes is the focus of the palliative surgeon, regardless of the surgeon's specialty background. In addition to survival, palliative surgical outcomes worthy of clinical investigation include symptom relief and quality of life, communication and surgical decision making, quality of process of care, and effectiveness of surgical education. Recognizing the current deficiencies in palliative surgical care, surgeons can aim for improvement by questioning the appropriate goals of treatment. True innovations in surgical care will require rigorous clinical investigation using pertinent outcomes measures. A research agenda has already been developed for future end-of-life care in the ICU.<sup>92</sup> This discussion attempts to begin to address a clinical research agenda for the future of palliative surgery.

It is a privilege for surgeons to be requested to become intimately involved in patients' lives at the time that they are most vulnerable. It is important in such settings to determine the appropriate clinical endpoints and to use them rigorously to assess the role of surgical interven-



tion. By participating in properly designed clinical studies, surgeons will increase their understanding of the variables that influence the end-of-life experience, and improve the quality of the care delivered to our palliative surgical patients.

## REFERENCES

- Friel JP. *Dorland's illustrated medical dictionary*. 26th ed. Philadelphia: WB Saunders; 1985.
- Lye M. Chronic cardiac failure in the elderly. In: Tallis R, Fillit H, Brocklehurst J, eds. *Brocklehurst's textbook of geriatric medicine and gerontology*. Edinburgh: Churchill Livingstone; 1998:288–312.
- Deaths: Leading causes for 1999, National Vital Statistics Report. Accessed on 9/25/02 from: [www.cdc.gov/nchs/data/nvsr/nvsr49/nvsr49\\_11.pdf](http://www.cdc.gov/nchs/data/nvsr/nvsr49/nvsr49_11.pdf). 2001.
- Lynn J. Learning to care for people with chronic illness facing the end of life. *JAMA* 2000;284:2508–2511.
- Covinsky KE, Fuller JD, Yaffe K, et al. Communication and decision-making in seriously ill patients: findings of the SUPPORT project. The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments. *J Am Geriatr Soc* 2000;48(5 Suppl):S187–S193.
- Mandelblatt JS, Hadley J, Kerner JF, et al. Patterns of breast carcinoma treatment in older women: patient preference and clinical and physical influences. *Cancer* 2000;89:561–573.
- Hayman JA, Fairclough DL, Harris JR, Weeks JC. Patient preferences concerning the trade-off between the risks and benefits of routine radiation therapy after conservative surgery for early-stage breast cancer. *J Clin Oncol* 1997;15:1252–1260.
- Mazur DJ, Merz JF. How the manner of presentation of data influences older patients in determining their treatment preferences. *J Am Geriatr Soc* 1993;41:223–228.
- Terry PB, Vettese M, Song J, et al. End-of-life decision making: when patients and surrogates disagree. *J Clin Ethics* 1999;10:286–293.
- Levine RS. Avoiding conflicts of interest in surrogate decision making: why ethics committees should assign surrogacy to a separate committee. *J Clin Ethics* 1998;9:273–290.
- Rogers J, Ridley S, Chrispin P, et al. Reliability of the next of kins' estimates of critically ill patients' quality of life. *Anaesthesia* 1997;52:1137–1143.
- Haidet P, Hamel MB, Davis RB, et al. Outcomes, preferences for resuscitation, and physician-patient communication among patients with metastatic colorectal cancer. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments. *Am J Med* 1998;105:222–229.
- Jacobs TJ. On misreading and misleading patients. Some reflections on communications, miscommunications and countertransference enactments. *Int J Psychoanal* 2001;82:653–669.
- Shiminski-Maher T. Physician-patient-parent communication problems. *Pediatr Neurosurg* 1993;19:104–108.
- Weeks JC, Cook EF, O'Day SJ. Relationship between cancer patients prediction of prognosis and their treatment preferences. *JAMA* 1998;279:1709–1714.
- Ptacek JT, Eberhardt TL. Breaking bad news. A review of the literature. *JAMA* 1996;276:496–502.
- Vigano A, Bruera E, Jhangri GS, et al. Clinical survival predictors in patients with advanced cancer. *Arch Intern Med* 2000;160:861–868.
- Christakis NA, Lamont EB. Extent and determinants of error in doctors' prognoses in terminally ill patients: prospective cohort study. *Br Med J* 2000;320:469–472.
- Sloan JA, Loprinzi CL, Laurine JA, et al. A simple stratification factor prognostic for survival in advanced cancer: the good/bad/uncertain index. *J Clin Oncol* 2001;19:3539–3546.
- Morita T, Tsunoda J, Inoue S, Chihara S. The Palliative Prognostic Index: a scoring system for survival prediction of terminally ill cancer patients. *Support Care Cancer* 1999;7:128–133.
- Maltoni M, Nanni O, Pirovano M, et al. Successful validation of the palliative prognostic score in terminally ill cancer patients. *J Pain Symptom Manage* 1999;17:240–247.
- Knaus WA, Harrell FE Jr, Lynn J, et al. The SUPPORT prognostic model. Objective estimates of survival for seriously ill hospitalized adults. *Ann Intern Med* 1995;122:191–203.
- Vigano A, Dorgan M, Buckingham J, et al. Survival prediction in terminal cancer patients: a systematic review of the medical literature. *Palliat Med* 2000;14:363–374.
- Fox E, Landrum-McNiff K, Zhong Z, et al. Evaluation of prognostic criteria for determining hospice eligibility in patients with advanced lung, heart, or liver disease. *JAMA* 1999;282:1638–1645.
- Seidman AD, Portenoy R, Yao TJ, et al. Quality of life in phase II trials: a study of methodology and predictive value in patients with advanced breast cancer treated with paclitaxel plus granulocyte colony-stimulating factor. *J Natl Cancer Inst* 1995;87:1316–1322.
- Degner LF, Sloan JA. Symptom distress in newly diagnosed ambulatory cancer patients and as a predictor of survival in lung cancer. *J Pain Symptom Manage* 1995;10:423–431.
- Addington-Hall JM, MacDonald LD, Anderson HR. Can the Spitzer Quality of Life Index help to reduce prognostic uncertainty in terminal care? *Br J Cancer* 1990;62:695–699.
- Child CG, Turcotte JC. Surgery and portal hypertension. In: Child CG, ed. *Major problems in clinical surgery: the liver and portal hypertension*. Philadelphia: WB Saunders; 1964:1–85.
- Turcotte JG, Raper SE, Eckhauser FE. Portal hypertension In: Greenfield LJ, Mulholland MW, Oldham KT, Zenelock GB, eds. *Surgery, scientific principles and practice*. Philadelphia: JB Lippincott Co; 1996:887–908.
- Miner TJ, Jaques DP, Tavaf-Motamen H, Shriver CD. Decision making on surgical palliation based on patient outcome data. *Am J Surg* 1999;177:150–154.
- Michael M, Tannock IF. Measuring health-related quality of life in clinical trials that evaluate the role of chemotherapy in cancer treatment. *CMAJ* 1998;158:1727–1734.
- Osoba D. Rationale for the timing of health-related quality-of-life (HQL) assessments in oncological palliative therapy. *Cancer Treat Rev* 1996;22(Suppl A):69–73.
- Seely JF, Mount BM. Palliative medicine and modern technology. *Can Med Assoc J* 1999;161:1120–1121.
- McLeod RS. Quality-of-life measurement in the assessment of surgical outcome. *Adv Surg* 1999;33:293–309.
- Shekarriz B, Shekarriz H, Upadhyay J, et al. Outcome of palliative urinary diversion in the treatment of advanced malignancies. *Cancer* 1999;85:998–1003.

36. Prat F, Chapat O, Ducot B, et al. Predictive factors for survival of patients with inoperable malignant distal biliary strictures: a practical management guideline. *Gut* 1998;42:76–80.
37. Bolder U, Brune A, Schmidt S, et al. Preoperative assessment of mortality risk in hepatic resection by clinical variables: a multivariate analysis. *Liver Transpl Surg* 1999;5:227–237.
38. Feuer DJ, Broadley KE, Shepherd JH, Barton DP. Surgery for the resolution of symptoms in malignant bowel obstruction in advanced gynaecological and gastrointestinal cancer. *Cochrane Database Syst Rev* 2000;4:CD002764.
39. SUPPORT Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients. The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT). *JAMA* 2000;274:1591–1598.
40. Leach D. The ACGME competencies: substance or form? Accreditation Council for Graduate Medical Education. *J Am Coll Surg* 2001;192:396–398.
41. The American Board of Surgery: Booklet of information. July 2002–June 2003. Philadelphia, PA: The American Board of Surgery Inc; 2002.
42. Cox S, Pories W. Surgical resident curriculum. 3rd edition. Arlington, VA: The Association of Program Directors in Surgery; 1999.
43. Rappaport W, Prevel C, Witzke D, et al. Education about death and dying during surgical residency. *Am J Surg* 1991; 161:690–692.
44. Sloan PA, Donnelly MB, Schwartz RW, Sloan DA. Residents' management of the symptoms associated with terminal cancer. *Hospice J* 1997;12:5–15.
45. Sloan PA, Donnelly MB, Schwartz RW, Sloan PA. Cancer pain assessment and management by housestaff. *Pain* 1996;67:475–481.
46. Helme RD, Gibson SJ. The epidemiology of pain in elderly people. *Clin Geriatr Med* 2001;17:417–431.
47. Lillemoie KD, Cameron JL, Kaufman HS, et al. Chemical splanchnicectomy in patients with unresectable pancreatic cancer. A prospective randomized trial. *Ann Surg* 1993;217: 447–455.
48. Brown DL, Caswell RE, Wong GY, et al. Referral of patients with pain from pancreatic cancer for neurolytic celiac plexus block. *Mayo Clin Proc* 1997;72:831–834.
49. Rothenberg ML, Moore MJ, Cripps MC, et al. A phase II trial of gemcitabine in patients with 5-FU-refractory pancreas cancer. *Ann Oncol* 1996;7:347–353.
50. Ferris FD, Bezjak A, Rosenthal SG. The palliative uses of radiation therapy in surgical oncology patients. *Surg Oncol Clin N Am* 2001;10:185–201.
51. Aucter RM, Scholtens D, Adak S, et al. Quality of life assessment in advanced non-small-cell lung cancer patients undergoing an accelerated radiotherapy regimen: report of ECOG study 4593. Eastern Cooperative Oncology Group. *Int J Radiat Oncol Biol Phys* 2001;50:1199–1206.
52. Easson AM, Asch M, Swallow CJ. Palliative general surgical procedures. *Surg Oncol Clin North Am* 2001;10:161–184.
53. Gouma DJ, van Geenen R, van Gulik T, et al. Surgical palliative treatment in bilio-pancreatic malignancy. *Ann Oncol* 1999;10S4:269–272.
54. Cubiella J, Castells A, Fondevila C, et al. Prognostic factors in nonresectable pancreatic adenocarcinoma: a rationale to design therapeutic trials. *Am J Gastroenterol* 1999;94:1271–1278.
55. Krouse RS, McCahill LE, Easson AM, Dunn GP. When the sun can set on an unoperated bowel obstruction: management of malignant bowel obstruction. *J Am Coll Surg* 2002;195: 117–128.
56. Cohen SR, Mount BM, Strobel MG, Bui F. The McGill Quality of Life Questionnaire: a measure of quality of life appropriate for people with advanced disease. A preliminary study of validity and acceptability. *Palliat Med* 1995;9:207–219.
57. Byock IR, Merriman MP. Measuring quality of life for patients with terminal illness: the Missoula-VITAS quality of life index. *Palliat Med* 1998;12:231–244.
58. Bruera E, Kuehn N, Miller MJ, et al. The Edmonton Symptom Assessment System (ESAS): a simple method for the assessment of palliative care patients. *J Palliat Care* 1991;7:6–9.
59. Aaronson NK, Ahmedzai S, Bergman B, et al. The European organization for research and treatment of cancer QLQ-C30: a quality of life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993;85:365–376.
60. Kyriaki M, Eleni T, Efi P, et al. The EORTC core quality of life questionnaire (QLQ-C30, version 3.0) in terminally ill cancer patients under palliative care: validity and reliability in a Hellenic sample. *Int J Cancer* 2001;94:135–139.
61. Portenoy RK, Thaler HT, Kornblith AB, et al. The Memorial Symptom Assessment Scale: an instrument for the evaluation of symptom prevalence, characteristics and distress. *Eur J Cancer* 1994;30A:1326–1336.
62. Chang VT, Hwang SS, Feuerman M, et al. The memorial symptom assessment scale short form (MSAS-SF). *Cancer* 2000;89:1162–1171.
63. Cella DF, Tulsky DS, Gray G, et al. The functional assessment of cancer therapy scale: development and validation of the general measure. *J Clin Oncol* 1993;11:570–579.
64. de Haes JC, van Knippenberg FC, Neijt JP. Measuring psychological and physical distress in cancer patients: structure and application of the Rotterdam Symptom Checklist. *Br J Cancer* 1990;62:1034–1038.
65. Murphy DJ, Burrows D, Santilli S, et al. The influence of the probability of survival on patients' preferences regarding cardiopulmonary resuscitation. *N Engl J Med* 1994;330:545–549.
66. Emanuel LL, Barry MJ, Stocckle JD, et al. Advance directives for medical care—a case for greater use. *N Engl J Med* 1991; 324:889–895.
67. Lipsett PA, Swoboda SM, Dickerson J, et al. Survival and functional outcome after prolonged intensive care unit stay. *Ann Surg* 2000;231:262–268.
68. Haley SM, McHorney CA, Ware JE Jr. Evaluation of the MOS SF-36 physical functioning scale (PF-10): I. Unidimensionality and reproducibility of the Rasch item scale. *J Clin Epidemiol* 1994;47:671–684.
69. Lipsett PA, Swoboda SM, Campbell KA, et al. Sickness Impact Profile Score versus a Modified Short-Form survey for functional outcome assessment: acceptability, reliability, and validity in critically ill patients with prolonged intensive care unit stays. *J Trauma* 2000;49:737–743.
70. Fakhry SM, Kercher KW, Rutledge R. Survival, quality of life, and charges in critically ill surgical patients requiring prolonged ICU stays. *J Trauma* 1996;41:999–1007.
71. Keenan SP, Busche KD, Chen LM, et al. A retrospective review of a large cohort of patients undergoing the process of withholding or withdrawal of life support. *Crit Care Med* 1997;25: 1324–1331.

72. Mittelberger JA, Lo B, Martin D, Uhlmann RF. Impact of a procedure-specific do not resuscitate order form on documentation of do not resuscitate orders. *Arch Intern Med* 1993;153:228–232.
73. Rapoport J, Teres D, Lemeshow S. Resource use implications of do not resuscitate orders for intensive care unit patients. *Am J Respir Crit Care Med* 1996;153:185–190.
74. Jayes R, Zimmerman J, Wagner D, Knaus W. Variations in the use of do-not-resuscitate orders in the ICU: findings from a national study. *Chest* 1996;110:1332–1339.
75. Nelson JE, Meier DE, Oei EJ, et al. Self-reported symptom experience of critically ill cancer patients receiving intensive care. *Crit Care Med* 2001;29:277–282.
76. Desbiens NA, Wu AW, Broste SK, et al. Pain and satisfaction with pain control in seriously ill hospitalized adults: findings from the SUPPORT research investigations. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment. *Crit Care Med* 1996;24:1953–1961.
77. Puntillo KA. Pain experiences of intensive care unit patients. *Heart Lung* 1990;19:526–533.
78. Whipple JK, Lewis KS, Quebbeman EJ, et al. Analysis of pain management in critically ill patients. *Pharmacotherapy* 1995;15:592–599.
79. Uhlmann RF, Pearlman RA, Cain KC. Physicians' and spouses' predictions of elderly patients' resuscitation preferences. *J Gerontol* 1998;43:M115–M121.
80. Koch KA, Rodeffer HD, Wears RL. Changing patterns of terminal care management in an intensive care unit. *Crit Care Med* 1994;22:233–243.
81. Curtis JR, Patrick DL, Shannon SE, et al. The family conference as a focus to improve communication about end-of-life care in the intensive care unit: opportunities for improvement. *Crit Care Med* 2001;29(2 Suppl):N26–N33.
82. Casarett DJ, Karlawish JH. Are special ethical guidelines needed for palliative care research? *J Pain Symptom Manage* 2000;20:130–139.
83. Janssens R, Gordijn B. Clinical trials in palliative care: an ethical evaluation. *Patient Educat Counsel* 2000;41:55–62.
84. Kristjanson LJ, Hanson EJ, Balneaves L. Research in palliative care populations: ethical issues. *J Palliat Care* 1994;10:10–15.
85. Lawton J. Gaining and maintaining consent: ethical concerns raised in a study of dying patients. *Qual Health Res* 2001;11:693–705.
86. McCahill LE, Krouse RS, Chu DZ, et al. Decision making in palliative surgery. *J Am Coll Surg* 2002;195:411–422.
87. McLeod RS. Issues in surgical randomized controlled trials. *World J Surg* 1999;23:1210–1214.
88. de Raeye L. Ethical issues in palliative care research. *Pall Med* 1994;8:298–305.
89. Clark D, Ingleton C, Seymour J. Support and supervision in palliative care research. *Palliat Med* 2000;14:441–446.
90. Foley KM, Gelband H, eds. Improving palliative care for cancer, summary and recommendations. National Cancer Policy Board, Institute of Medicine and National Research Council. Washington, DC: National Academy Press; 2001.
91. Rhymes JA. Barriers to palliative care. *Cancer Control* 1996;3:230–23.
92. Rubenfeld GD, Randall CJ. End-of-life care in the intensive care unit: a research agenda. *Crit Care Med* 2001;29:2001–2006.
93. Spitzer WO, Dobson AJ, Hall J, et al. Measuring the quality of life of cancer patients: a concise QL-index for use by physicians. *J Chronic Dis* 1981;34:585–597.
94. Weeks JC, O'Leary J, Fairclough D, et al. A new tool for assessing health-related quality of life and utilities in clinical trials and clinical practice. *Proc Am Soc Clin Oncol* 1994;13:436.
95. Schipper H, Clinch J, McMurray A, Levitt M. Measuring the quality of life of cancer patients: The Functional Living Index-Cancer: development and validation. *J Clin Oncol* 1984;2:472–483.
96. Baum M, Priestman T, West RR, Jones EM. A comparison of subjective responses in a trial comparing endocrine with cytotoxic treatment in advanced carcinoma of the breast. *Eur J Cancer* 1984;2(Suppl 1):223–226.
97. Padiilla GV, Grant MM. Quality of life as a cancer nursing outcome variable. *Adv Nurs Sci* 1985;8:45–60.
98. Gelber RD, Goldhirsch A, Cole BF. Evaluation of effectiveness: Q-TWiST. The International Breast Cancer Study Group. *Cancer Treat Rev* 1993;19(Suppl A):73–84.
99. Eypasch E, Williams JI, Wood-Dauphinee S, et al. Gastrointestinal Quality of Life Index: development, validation and application of a new instrument. *Br J Surg* 1995;82:216–222.
100. Sloan JA, Loprinzi CL, Kuross SA, et al. Randomized comparison of four tools measuring overall quality of life in patients with advanced cancer. *J Clin Oncol* 1998;16:3662–3673.