Barriers to palliative care research for emergency department patients with advanced cancer

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Background Patients with advanced cancer often visit the emergency department (ED). Little is known about their willingness or ability to engage in palliative care research, although enrollment in clinical trials of other seriously ill ED patients – those with stroke, for example – has been shown to be feasible.
Objective To identify barriers to the enrollment of ED patients with advanced cancer in palliative care research.
Methods We prospectively tracked factors that affected patient accrual into a trial of palliative care for adults with metastatic solid tumors at an urban, academic ED. Research staff screened the electronic medical records for patients admitted to the hospital with metastatic solid tumors 8-12 hours a day, Monday through Friday. The ED attending of record and the patient's medical oncologist had to agree before research staff invited the patient to participate. Informed consent was obtained at the bedside in the ED, and patients were offered a $20 incentive to participate.
Results Attempts were made to enroll 150 eligible patients in the study, and 73 were enrolled (49% enrollment rate). Barriers to enrollment for the 77 patients who did not participate were deduced from the field notes and placed into the following categories: patient refusal (n = 38, 49%), diagnostic uncertainty regarding cancer stage (n = 11, 14%), symptom burden (n = 9, 12%), family refusal (n = 7, 9%), physician refusal (n = 7, 9%), and/or patient unaware of illness or stage (n = 5, 7%).
Limitations The findings are descriptive and do not test predetermined hypotheses.
Conclusion Patient refusal, symptom burden, and diagnostic disparities are common barriers encountered when recruiting ED patients with advanced cancer. Despite the barriers, recruitment was feasible for such ED patients.
Funding/sponsor This study was funded by a Mentored Research Scholar Grant from the American Cancer Society (Dr Grudzen), a Medical Student Training in Aging Research Grant from the American Federation on Aging (Mr Kandarian), and by a Mid-Career Investigator Award in Patient Oriented Research (K24 AG022345) from the National Institute on Aging (Dr Morrison).

For patients with advanced cancer, visits to the emergency department (ED) are common,[1,2] as are visits for older adults with other advanced illnesses at the end of life.[3] Despite this, little is known about the willingness or ability of such patients to engage in palliative care research. The ED is a unique setting in which to recruit patients with advanced cancer, but it is crowded and chaotic, with little privacy. Patients with advanced cancer and their families come to the ED because they are in physical and/or emotional crisis.[4-6] The patients often have a high symptom burden and are in significant distress, all of which can preclude participation in research. At the same time, enrollment of other seriously ill ED patients in clinical trials is feasible as demonstrated by important research in areas such as stroke.[7] Recruitment of advanced cancer patients in this environment is essential given the important decisions that are made about intensity of care, including whether or not to admit (and to what level of care) or whether to begin life-prolonging therapies. It is an important point at which to measure patient and caregiver stress and strain, symptom burden, goals of care, and to enroll patients in palliative care trials.[9,10]

Although barriers to palliative care recruitment for a range of life-limiting diseases have been studied, little is known about recruitment in the ED. The one study of barriers to recruitment into an ED study of palliative care showed that level of acuity was a barrier for some patients.[11] However, other barriers were similar for other settings and included concerns about consent and objection from family members. Compared with other fields, recruitment and retention for trials of palliative care are especially challenging because of patients' poor health status and

Accepted for publication September 24, 2013. Correspondence: Corita R Grudzen, MD, MSHS; corita.grudzen@nyumc.org. JCSO 2014;12:158-162. DOI 10.12788/jcso.0040.

high symptom burden.[12] As a result, clinical trials are difficult to conduct in this population and represent only a small proportion of the research done in palliative care.[13,14] Some researchers have argued that this population is difficult to engage because of ethical concerns regarding their already limited time and energy,[15] whereas others have argued that these patients are difficult to recruit because of "taboos" among some populations about discussing the end of life. Other documented barriers to recruitment include physician refusal[16] and symptom burden.[17]

The goal of this study was to track and quantify recruitment barriers and overall enrollment rate for patients who met inclusion criteria for a randomized controlled trial of palliative care for ED patients with metastatic solid tumors. In this way, we will be able to describe and categorize barriers to the enrollment of ED patients with advanced cancer so that others can use this information in future studies.

Methods and materials

We prospectively tracked factors that affected patient accrual into a single-blind, randomized, controlled trial of palliative care consultation for adults with metastatic solid tumors at an urban, academic ED located within a tertiary care referral center. Patients eligible for participation were those who presented to the study ED over an 18-month period beginning in June 2011 who had a known metastatic solid tumor, no previous palliative care consult, the ability to speak English or Spanish, and a score ≥ 4 on the Six-Item Screener for cognitive impairment, indicating they answered at most 2 questions incorrectly of the 6 questions asked.[18] Patients who were planning to be discharged home or to leave the immediate geographic area (ie, move to another state or country) were excluded. Patients were randomized through balanced block randomization by research staff with no role in study recruitment, analysis, or follow-up. Intervention patients received a comprehensive palliative care consultation by the inpatient team the same or the following day, including an assessment of symptoms, spiritual/social needs, and goals of care. Outcomes included quality of life at 12 weeks, survival, length of stay and direct costs for the index admission, and ED revisits and re-hospitalization at 30 and 180 days.

Research staff screened the electronic medical records for patients with metastatic solid tumors 8-12 hours a day Monday through Friday. The ED attending of record and the patient's medical oncologist had to agree before research staff invited the patient to participate. Informed consent was obtained at the bedside in the ED, and patients were offered a $20 incentive to participate. Data from patients who qualified for the study but did not enroll were anonymously recorded and grouped into standard categories based on the Consolidated Standards for Reporting of Trials (CONSORT) statement, with as much detail as possible.[19,20] Patients who did not meet the inclusion criteria for the trial were excluded from this analysis. The Institutional Review Board approved all study procedures.

Results

We tried to enroll 150 eligible patients in the study, and 73 were successfully enrolled (49% enrollment rate). Barriers to participation for the remaining 77 patients are categorized and quantified in Table 1, and examples xamples within each category are delineated in Table 2 (p. 160).

Patient refusal

The most common barrier to enrollment was patient refusal (n = 38, 49%). Common reasons for not participating included: not being interested in the study, satisfied with current care, or not ready for palliative care. One patient stated, "I don't want to be a guinea pig for your little study", and expressed fears of being "experimented on." Another stated he'd been undergoing "too many tests" recently and didn't "have the energy" to participate in the research.

Diagnostic disparity regarding cancer stage

The second most common reason patients were not enrolled was because of a disparity regarding their cancer stage (n = 11, 14%). In these cases, one source listed the patient as having a metastatic solid tumor but another reported a less advanced cancer stage. Discrepancies included: doctor's notes and pathologic/radiologic stage (n = 9), and oncologist understanding and pathologic/radiologic stage (n = 2). In one case, a patient had multiple notes, pathology, and radiology reports stating the patient's cancer had metastasized, but the oncologist disagreed, stating the patient's cancer was not advanced and thus did not qualify for the study.

Symptom burden

Another common barrier was the severity of patients' current symptoms (n = 9, 12%). Symptoms encountered include dyspnea (n = 3), pain (n = 3), and sedation after analgesic administration (n = 3).

Family refusal

Some patients were excluded because a family member refused for them (n = 7, 9%). Reasons included religion (n = 1), a family member not wanting the patient to know he or she had cancer (n = 2), and satisfaction with current care (n = 4). In some cases, family members declined the study without speaking with the patient. In one case, a patient's sister stated the patient was "not at that point yet" when referring to palliative care and ended the conversation by stating she only wanted her sister to "speak with physicians."

Physician refusal

Physician refusal was another barrier to patient enrollment

(n = 7, 9%). Reasons included not wanting patient to be in a study (n = 2), a physician thinking a patient was not ready for palliative care (n = 4), or a physician being unclear on inclusion criteria for the study (n = 1). In one case, a patient who qualified for the study was not enrolled because the ED attending stated the patient didn't quality for the study when, based on further chart review, they actually did. In another case, a physician refused, stating that his patient was "young and hopeful' and that "she wouldn't take well to the idea of palliative care." A total of 6 of the 7 physicians who refused were oncologists.

Patient unaware of cancer or stage

Another reason patients were not enrolled was that some were unaware of their cancer (n = 5, 7%). In one case, a patient believed he or she had "tumors" but denied having cancer, despite qualifying for the study based on his medical record. In another case, a patient with metastatic cancer, according to her chart, asked why she would need an oncologist when she didn't have cancer.

Discussion

In our study to determine barriers to palliative care research for ED patients with advanced cancer, we found patient refusal, severity of symptom burden, and diagnostic disparities were the most common barriers to enrolling qualified ED patients with life-limiting cancer. Patient awareness of his or her own cancer, and refusal by either the patient's family or physician, were less common but significant barriers we encountered in recruiting eligible patients. The barriers to recruitment we encountered were not dissimilar to those found in other palliative care patients in ambulatory, inpatient, or hospice settings.[21-23]

Patient refusal alone was by far the most common barrier to enrollment, accounting for about half of eligible patients not enrolling in the trial. Mill and colleagues examined barriers that patients refused to participate for similar reasons to our own study, such as feeling "experimented on," seeing no benefit in the intervention or trial, and uncertainty regarding treatment group.[24] In a study evaluating the use of routine screening questions to identify eligible cancer patients for a palliative care intervention trial, patients were more interested in enrolling in disease-modifying than symptom-modifying research.[25] In the case of our study, patients might have interpreted our offer of palliative care intervention as something additional and unnecessary in addressing the management of their cancer diagnosis. A number of patients declined without explanation, even when probed for reasons, approached at a more convenient time, and offered a further description of the service offered. This may reflect the patients' focus on addressing their presenting complaint in the ED and rejecting services that may not seemingly address the pressing symptom or issue at hand.

A total of 9 patients who were eligible for our study could not participate because of the severity of presenting

TABLE 1 Number of patients excluded for each barrier (n = 77)

Barrier type	Patients, no. (%)
Patient refusal	38 (49)
Diagnostic uncertainty about cancer stage	11 (14)
Severity of symptoms preclude participation	9 (12)
Family refusal	7 (9)
Physician refusal	7 (9)
Patient unaware of cancer or stage	5 (7)

TABLE 2 Reasons qualified patients failed to enroll in study

Categories	Examples of reasons given
Patient refusal	Doesn't want to be experimented on ('guinea pig') Satisfied with cancer care More interested in disease-targeted (eg, experimental drugs) than symptom-targeted therapies
Diagnostic uncertainty regarding cancer stage	Two separate cancers versus metastasis Awaiting biopsy
Severity of symptomspreclude participation	Severe pain, visibly uncomfortable Too short of breath to answer questions, appears distressed
Family refusal	Refusal to let research staff speak with patient Family refuses to tell patient he/she has cancer
Physician refusal	Emergency medicine attending refused (patient 'young,' 'hopeful') Oncologist refused (patient 'not ready')
Patient unaware of cancer or stage	'Tumors,' not cancer Thought to be in remission

symptoms. For symptoms such as pain and dyspnea, patients were at times unable to listen to the details of our study or too lethargic to give full informed consent. One study found similar difficulties in enrolling eligible patients, especially among those with higher symptom intensity scores.[22] Such a barrier might be expected in the ED, where patients may defer precisely because of their acute presenting complaint and associated symptoms.

A review of 7 diagnostic studies involving minimal risk done in minority, pediatric, and geriatric patients in an ED at a large academic medical center found an overall enrollment rate of 74% for those who met eligibility criteria and were able to consent to participate.[26] Although that enrollment rate is higher than our 49%, the investigators found a significantly lower rate in pediatric, geriatric, and other vulnerable populations. Compared with the patients in their study, our patients were likely to have a higher average symptom burden and to be sicker on average than the general ED population. In addition, our request to engage patients in a randomized controlled trial, as opposed to a minimal risk diagnostic study, may also have contributed to our higher rate of refusal. Strategies such as emergency consent, which is in use in resuscitation research, or other ways of engaging families and caregivers (along with patients) may need to be used to include this pool of eligible patients in future palliative care studies.

It was often difficult to identify whether or not patients met our exclusion criteria because of the diagnostic disparities between physician understanding and medical records regarding cancer stage. This has numerous implications for quality improvement in cancer, and highlights the need for enhanced patient-physician communication, a universal electronic medical record system, and care coordination between hospitals, hospital staff, and departments within hospitals. In one instance, an oncologist denied the presence of metastatic cancer in a possible trial enrollee despite a past pathology report documenting otherwise. In 2 instances, the patient's oncologist was unknown or unreachable, with no way to corroborate the diagnosis. Although we had an electronic medical record system to access patients who were known to our hospital, we encountered problems enrolling patients who received clinical management outside of our system. Ability to access regional health information exchanges would decrease the potential discrepancies in diagnostic information for patients seeking care at multiple locations. Furthermore, better care coordination would ensure that all providers, from oncology to emergency medicine, are as up to date as possible with regard to a patient's cancer stage. Research standards and the developments of collaborations would also help improve the rate of recruitment. The formation of palliative care research cooperatives and collaborations has been useful in gathering clinical sites and multidiscipline specialists, standardizing methodology, and broadening recruitment sources.[27,28]

Finally, it is important to recognize that a patient's physician and caregiver(s) are involved not only in treatment decisions but also in patient enrollment and participation in research. Physician and caregiver "gatekeeping," or refusal to allow an eligible patient to participate in a study, is a well-known obstacle to conducting palliative care research,[29,30] and our study was no exception. We encountered gate-keeping from family members rather than physicians; in some cases, the respective caregiver prevented us from directly approaching the patient. Studies in the past have shown that both caregivers and referring physicians can facilitate patient enrollment when briefed and involved in the research process.[17,31]

Barriers to enrollment in clinical trials are well recognized. A large study tracking recruitment in 41 clinical trials determined that 34% recruited less than 75% of their anticipated sample size.[8] The effect of reducing the sample size is to reduce the statistical power of the study and is one of the main causes of trials being abandoned.[9] A review was conducted in 1999 to determine the barriers to enrollment in 71 clinical trials.[10] Patient barriers included: the additional demands of a trial; patient preferences for a particular treatment (or no treatment); worry caused by uncertainty about treatments; and concerns about information and consent.

Despite the barriers we encountered, we managed to recruit almost half of the eligible patients we approached for our study. The barriers we describe to enrollment mirror those commonly seen in palliative care studies in other settings. Adaptive approaches and protocols for recruitment have been suggested to increase participation in palliative care studies. These include integrating screening questions into clinical service; tailoring research information to each patient; and increased collaboration between research and clinical teams.[29,32,33]

Limitations

It is important to highlight the limitations of our study. First, while the findings we describe are important and have implications for ED and palliative care research, they are descriptive and do not test predetermined hypotheses. Given the chief aim of our randomized controlled trial is to compare early palliative care consultation to care as usual, our power calculations and sample size estimates were based on testing outcomes between these 2 groups. In addition to tracking reasons for declining participation, it would have been interesting to describe differences among those who do and do not participate as well as audio-record interactions between research staff during the recruitment process. Furthermore, these and other qualitative data collection techniques could be applied to future studies.

Conclusions

The ED itself represents a new setting for recruitment of patients with advanced cancer for palliative care research. Developing specific strategies to overcome physician and family barriers, training research coordinators and staff on how to overcome obstacles specific to the ED setting, and broadening inclusion criteria may help increase recruitment of ED patients with life-limiting disease. In addition, future studies can use this data to better predict the amount of time needed to enroll enough patients to have statistically significant data. Our study suggests that recruitment in the ED for patients with advanced cancer is an exciting and real possibility – and it demonstrates well-known barriers that may be anticipated in future studies to predict enrollment time needed, expand recruitment, and intercept more eligible patients to reach the sample size needed.

Acknowledgments

A version of this paper was accepted for poster presentation at the 2012 annual meetings of the American Geriatrics Society (May 2-5, Seattle, WA) and the Society for Academic Emergency Medicine (May 9-12, Chicago, IL).

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