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Palliative Care in Advanced Dementia: A Randomized Controlled Trial and Descriptive Analysis

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ABSTRACT

Background: **Few patients with end-stage dementia are enrolled in hospice care. A palliative care approach would nonetheless seem to be appropriate in various care settings, including the acute care hospital.**

Methods: **We conducted a randomized controlled trial of palliative care in patients with advanced dementia (Functional Assessment Staging Tool [FAST] stage 6d–7f) who were hospitalized with acute illness. Intervention patients received recommendations by a palliative care team with the goal of enhancing patient comfort; control patients received usual care without these recommendations.**

Results: **Among 99 patients enrolled over 3 years, groups were comparable at baseline in terms of gender, age, race, dementia stage, and advance directive status. Outcomes were similar in terms of mean number of hospitalizations, average length of stay, and mortality. Intervention patients were more likely than control patients to receive a palliative care plan (23% versus 4%; $p = 0.008$), usually on discharge, and more decisions were made to forgo certain medical treatments but the numbers were small. Fewer patients in the intervention group received intravenous therapy throughout the admission (66% vs. 81%, $p = 0.025$). Overall, additional interventions included daily phlebotomy for at least half of the admission (41%), systemic antibiotics (75%), and new feeding tubes (44%). Including tubes present at the time of randomization, a total of 69% received long-term enteral feeding.**

Conclusion: **It was difficult for a palliative care research team to influence the care of advanced dementia patients in the acute hospital setting. When patients have advanced dementia, there may be unique barriers, including perceived prognostic uncertainty, difficulty assessing comfort level, and perceptions about tube feeding. There must be a reexamination of treatment approaches for this severely impaired group of patients. Further study should attempt to identify patients prior to the need for acute hospitalization so goals can be established when there is less urgency to make life and death decisions.**

INTRODUCTION

PALLIATIVE CARE has gained considerable attention in recent years. Hospice, the traditional mode of palliative care in the United States, currently serves approximately 15% of patients who die.[1] However, only 2% of patients who receive hospice care have dementia as their primary diagnosis.[1] In addition, the majority of deaths continue to occur in the acute care setting[2] where

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abundant barriers to palliative care exist[3] and patients often undergo invasive, nonpalliative treatments.[4] With the increasing numbers of nursing homes offering hospice care, it is likely that more dementia patients will be served, but as one study suggests, the incentives may be fiscal in many cases and raise concerns about the quality of care that will be delivered.[5]

These problems may be due to the perception that the prognosis is less certain in advanced dementia than in other end-stage illnesses, or to a lack of recognition by physicians that irreversible dementias lead to inexorable decline and death. However, those individuals with dementia who survive until the end stage are totally dependent on others for all aspects of care, are mute, bedridden, and unable to eat when fed. Survival time of most patients with advanced dementia falls within traditional hospice guidelines of 6 months,[6] probably because of the comorbidities (medical complications and feeding disorders) that both lead to acute hospitalization and worsen prognosis.[7] Although subgroups of dementia patients may have prolonged life span, it is unclear if this is related to the disease alone or to the type of care rendered.[8] Furthermore, among hospitalized patients with advanced dementia, time spent in the hospital before death may be approximately the same as that of patients with advanced cancer,[4] and it is unclear that prognostic uncertainty is in fact greater for dementia than for other life-threatening illnesses.

In order to determine if a palliative care approach could be implemented for patients with advanced dementia, and if this approach could enhance patient comfort, we conducted a prospective, randomized controlled trial of palliative care versus usual care in a group of hospitalized acutely ill patients who had advanced, nonreversible dementia.

METHODS

The study was conducted at Mount Sinai Hospital, a tertiary care referral center and teaching hospital for Mount Sinai School of Medicine. The study protocol was approved by the Institutional Review Board of the Mount Sinai School of Medicine, which included approval of the use of human subjects as well as an informed consent form that was signed by an appropriate surrogate. Informed consent was obtained from the appropriate surrogate using a hierarchy as outlined by the American College of Physicians guidelines on research in cognitively impaired subjects.[9]

Patients were eligible if they had advanced dementia and had been hospitalized for acute illness. Advanced dementia was defined as Functional Assessment Staging Tool (FAST)[10] of 6d or greater, with a stable baseline neurological deficit for at least 1 month. Thus, patients were not excluded if they had experienced a transient decline in mental status (i.e., due to delirium) in the month prior to randomization. Stage was determined based on best observable mental status during the period of observation and ascertained by history obtained from family or other caregivers, or from healthcare professionals who had been familiar with the patient prior to randomization. The FAST, which is based on observations of patients with Alzheimer's disease, was used because of its utility for describing functional status in the narrow group of patients with the most advanced stages of various types of dementia.

The patient's primary care physician in the hospital was asked permission to approach the family or other authorized decisionmaker for consent. Informed consent was obtained from a surrogate decisionmaker (duly appointed health care agent, legal guardian, or next of kin).

The palliative care team consisted of master's level clinical nurse specialist and one or more attending level, certified geriatrician who held academic appointments in the Departments of Medicine and Geriatrics. The nurse and physician(s) had extensive experience in assessing patients with advanced dementia and working with staff and family at the hospital. Eligible patients admitted to Mount Sinai Hospital over a 3-year period were identified through daily rounds by the palliative care team nurse.

Patients were assessed by the palliative care nurse as to appropriateness for inclusion; after informed consent was obtained, a physician member of the team obtained complete history and performed a physical examination. After this baseline evaluation, patients were randomly assigned to either the intervention or to the control group. The control group was treated by the primary care team without the input of the palliative care team. The intervention consisted of palliative care consultation by the team nurse and

physician investigator, who then visited the patient and discussed management with available members of the primary healthcare team in the hospital on a daily basis, excluding weekends. The palliative care team also met with family caregivers or other surrogates when they were available and attempted to arrange meetings after hours. If face-to-face meetings could not be arranged, discussions were held over the phone. During encounters with health professionals or family caregivers, the palliative care team discussed various care options (see below). In order to maintain blindness for the research assistant during data gathering from the chart, consultation did not include written notes on the chart.

The goal of the intervention was to enhance patient comfort. Recommendations included avoidance of nonpalliative procedures and mechanical restraints; administration of pain medication for painful maneuvers such as ulcer debridement or other medications for symptoms that were apparent; rehabilitation measures such as methods of positioning, massage therapy, or preventing contractures; counseling of surrogates and care providers regarding patient's rights and surrogate responsibilities as decision makers; and alternate care planning such as forgoing life-sustaining treatments, discharge to hospice, or discharge with palliative care plans and avoidance of rehospitalization. Palliative care was defined as a treatment plan guided by the goal of maximizing patient comfort and avoidance of painful or invasive treatments, including hospital admission, diagnostic tests, and invasive procedures, unless needed for symptom control.

A research assistant blinded to randomization status gathered information from the charts of patients in both arms of the study; data obtained included demographic characteristics, advance directives, comorbidities and physical findings, interventions, and care plans.

In addition to the general history and physical findings, patient characteristics recorded at baseline included age, gender, dementia stage, days to enrollment in the study, ethnic group, type of residence prior to hospital admission, and existence of an advance directive. Advance directives included living will, medical power of attorney (healthcare proxy), or oral directives (prior conversations held with the patient regarding his or her wishes for terminal care). Patients were also classified by acute medical illness defined as discharge (DRG) diagnosis. DRG diagnosis was determined by medical records personnel on discharge using standard criteria of the institution.

Outcome measures included mortality, site of discharge, length of stay, number of readmissions, use of nonpalliative procedures, do-not-resuscitate (DNR) orders and cardiopulmonary resuscitation (CPR), and systemic antibiotics. Other outcome measures included whether a decision was made to forgo life-sustaining treatments, antibiotics, intravenous fluids, or blood drawing, and whether a decision was made to adopt an overall palliative care plan. Phlebotomy was determined as the number of days in which a patient received at least one venous blood draw; fingersticks for glucose determination were defined as the number of fingersticks performed per day in patients receiving insulin. Nonpalliative procedures included mechanical ventilation, enteral feeding, surgical procedures, intravenous lines, and injections other than those given for pain or anesthesia. Diagnostic tests included simple painful tests, such as phlebotomy or fingersticks, complex but noninvasive tests, and invasive tests. Invasive tests were those that produced potential risk or discomfort, such as computed tomography (CT) with contrast, endoscopy, arterial blood gas, or spinal tap; complex noninvasive tests included bone scan, CT without contrast, lung scan, echocardiography, or other ultrasound. Other interventions included indwelling nonsuprapubic bladder catheters and mechanical restraints. Indwelling bladder catheter was defined as the percentage of the total admission in days that an indwelling, nonsuprapubic catheter was present. Mechanical restraint use was determined by the number of days in which there was an order to administer wrist, mitten, or vest restraints.

Number of patients receiving an in-hospital DNR order, and number of days to the writing of a DNR order were determined. In order to account for any order that was revoked during the period of hospitalization, DNR status was determined at the time of discharge or death. Number of days to the writing of a DNR order was computed from the time of admission, excluding the first admission. Nonhospital DNR orders were determined separately, defined as the existence of such an order at the time of admission.

Terminal care plans were analyzed according to whether there was documentation of a surrogate decision to discontinue a particular treat-

ment, including enteral feeding, mechanical ventilation, intravenous lines, blood drawing (phlebotomy or arterial blood stick), antibiotics, or any life-sustaining treatment. In addition, the groups were analyzed as to whether there was an overall palliative care plan on discharge or at any time during the hospitalization.

Recommendations regarding palliative care interventions were made to the inpatient team at the hospital but contact between or after hospitalizations were generally with the family, because there was considerable variation among patients as to the nature, location, or existence of a consistent physician. On readmission, the patient was identified through a computerized system, usually less than 24 and no more than 48 hours after admission. Consent to continue in the study was obtained from the surrogate by phone, and the inpatient providers were contacted.

Outcomes were determined from the time of initial randomization until final discharge or in-hospital death. The entire period of observation and data gathering from time of the first randomization was 3 years. Specific data analyzed was gleaned only from the in-hospital experience, with the exception of the date of death for patients who survived the hospitalization, which was ascertained by telephone follow up.

χ^2 and Student's t test were used to compare intervention and control groups.

RESULTS

During 3 years, 100 patients were identified who met inclusion criteria and for whom informed consent could be obtained. One patient was discharged in the first 24 hours after randomization and was not readmitted, and was excluded from analysis. Of the remaining 99 patients, 48 were randomly assigned to the intervention group and 51 to the control group.

Baseline characteristics are summarized in Table 1. The groups were comparable in terms of age, gender, dementia stage, race or ethnic group, existence of advance directives, whether the patient had been admitted from home or a nursing home, DRG diagnosis for the first admission, and

TABLE 1. CHARACTERISTICS AT RANDOMIZATION

	Intervention	*Control*	*Totals*
Number	48 (48.5)	51 (51.5)	99
Days in hospital	9.0 ± 11.7	6.7 ± 7.6	
Female	37 (77.1)	44 (86.3)	81 (81.8)
Mean age in years (range)	83.9 (63–99)	85.6 (72–100)	84.8 (63–100)
Race/ethnic group			
Black	20 (41.7)	19 (37.3)	39 (39.4)
White	18 (37.5)	18 (35.3)	36 (36.4)
Latino	9 (18.8)	13 (25.5)	22 (22.2)
Asian	1 (2.1)	1 (2.0)	2 (2.0)
Dementia stage			
6d-7b	26 (54.2)	21 (41.2)	47 (47.5)
7c-7f	22 (45.8)	30 (58.8)	52 (52.5)
Residence prior to admission			
Home	16 (33.3)	13 (25.5)	29 (29.3)
Nursing home	32 (66.7)	38 (74.5)	70 (70.7)
Advance directives			
Any advance directive	8 (16.7)	7 (13.7)	15 (15.2)
Living will[a]	5 (10.4)	0 (0)	5 (5.1)
Healthcare proxy	4 (8.3)	5 (9.8)	9 (9.1)
Oral	3 (6.3)	3 (5.9)	6 (6.1)
Feeding tube present	12 (25)	12 (23.5)	24 (24.2)
Discharge (DRG) diagnosis			
Pulmonary/pneumonia	40 (44)	43 (44)	83 (43.7)
Other infection	11 (15)	15 (15)	26 (13.7)
GI	13 (14)	10 (10)	23 (12.1)
Cerebrovascular	2 (2)	4 (4)	6 (3.2)
Cardiac	5 (5.4)	2 (2.0)	7 (3.7)
Other	21 (23)	24 (15)	45 (23.7)

[a] $p = 0.02$; Pearson χ^2.

presence of a feeding tube at the time of randomization.

Ninety-nine subjects had a total of 190 hospital admissions; 48 intervention patients had a total of 92 admissions, and 51 control patients had 98 admissions. There was no significant difference between groups in terms of number of rehospitalizations, mean length of stay postrandomization, and percent who died during hospitalization.

With a few exceptions, the groups were comparable in terms of procedures and outcomes (Tables 2 and 3). Few patients received invasive or complex diagnostic tests, but 41% received daily phlebotomy for at least half of the admission. Overall, 74% of patients received intravenous therapy throughout the admission, 75% received systemic antibiotics, and 44% received new feeding tubes. Including tubes present at the time of randomization, a total of 69% received long term tube feeding. Intervention patients were significantly more likely to have an overall palliative care plan ($p = 0.008$), but in 9 of 11 cases, this was not adopted until discharge (Table 3).

DISCUSSION

This study failed to demonstrate that a palliative care intervention by a research team could have an impact on specific treatment plans in hospitalized patients with advanced dementia. Patients in the intervention group were discharged significantly more often with the intention to institute a palliative care plan; however, interventions during time spent outside of the hospital could not be measured. In one patient who was readmitted, the palliative care plan was abandoned in the hospital.

There are several possible reasons for the apparent lack of impact on specific treatments. First, the numbers were small, and we cannot rule out

TABLE 2. OUTCOMES IN 99 PATIENTS

	Intervention	*Control*	p *value*	*Pooled*
Outcome				
Total admissions for group	92	98		190
Mean	1.94	1.90	0.92[a]	1.92
Range	1–7	1–13		1–13
Length of stay after randomization (days)	8.8	9.7	0.46[a]	9.3
Range	1–93	1–63		1–93
Died during hospitalization	12 (25)	12 (24.5)	0.96[b]	24 (24.2)
Procedures: number of patients				
New feeding tube[c]	22 (45.8)	22 (43.1)	0.79[b]	44 (44.4)
Total feeding tube	34 (70.8)	34 (66.7)	0.66	68 (68.7)
Mechanical ventilation[c]	2 (4.2)	4 (7.8)	0.44[b]	6 (6.1)
Tracheostomy[c]	0	1	[d]	1 (1)
CPR[c]	0 (0)	3 (5.9)	[d]	3 (2)
Systemic antibiotics	73 (79.3)	69 (70.4)	0.16[b]	142 (74.7)
Interventions during 190 admissions				
IV for entire admission	61 (66)	79 (81)	0.025[b]	140 (73.7)
Indwelling urinary catheter	41 (44.6)	51 (52.0)	0.30[b]	92 (48)
Mechanical restraints	13 (54.2)	11 (45.8)	0.33[b]	24 (12.6)
Days with restraints (mean)	5.18	6.56	0.14[a]	5.79
Daily phlebotomy for at least 50% of admission	32 (34.8)	46 (46.9)	0.089	78 (41)
Daily sc/im injection for at least 50% of admission	16 (17.4)	21 (21.6)	0.461	37 (19)
≥1 complex noninvasive test	10 (11)	4 (4)	0.12	14 (7.4)
≥1 invasive test	5 (4.3)	2 (2.0)	0.215	7 (3.7)
# fingersticks per day in patients receiving insulin	1.56	2.01	0.15	1.83

[a] t test.
[b] Pearson χ^2.
[c] Received only once per patient.
[d] Expected frequencies <5 in at least 2 cells.

TABLE 3. TERMINAL CARE PLANS IN 99 PATIENTS

	Intervention	*Control*	p *value*	*Pooled*
Decisions to forgo treatments				
Enteral feeds	3 (6.3)	4 (7.8)	[a]	7 (7.1)
Mechanical ventilation	3 (6.3)	0 (0)	[a]	3 (3.0)
Intravenous lines	5 (10.4)	1 (2.0)	[a]	6 (6.1)
Blood draws	4 (8.3)	0 (0)	[a]	4 (4.0)
Antibiotics	3 (6.3)	0 (0)	[a]	3 (3.0)
CPR in-hospital	62 (67.4)	63 (64.3)	0.65[b]	125 (65.8)
CPR nonhospital	47 (51.1)	38 (38.8)	0.10[b]	85 (44.7)
Palliative care plan	11 (22.9)	2 (3.9)	0.008[b]	13 (13.1)
During hospitalization	2	0	[a]	2 (2.0)
Upon discharge	9	2	[a]	11 (11.1)

[a]Expected frequencies <5 in at least 2 cells.
[b]Pearson χ^2.

a type II error, particularly in light of the fact that there was a trend toward more decisions to forgo certain treatments among the intervention groups. It is possible that larger numbers might have revealed differences in certain categories. However, a key factor may well have been the nature of the intervention team rather than the recommendations. In a multicenter study of seriously ill hospitalized patients, a consultation model did not appear to change physician practice, despite knowledge of patient and family wishes.[11] As in that study, our team was not invited to consult, but rather offered the intervention in the context of research. Moreover, the outcome data reflect only the time since randomization when, on the average, the patient had already spent a week or more in the hospital (Table 1). Thus, it may have been especially difficult to influence a care plan that was well established. More than half of the 48 intervention patients had only one hospitalization, in most cases because they died during that admission or shortly afterwards, so any impact that carried over into subsequent hospitalizations of survivors might be too small to measure. This would be magnified by the underlying problem of introducing the idea of palliative care for the first time in the acute care setting.

Another possible reason for a lack of measurable impact might be selection bias. Theoretically, a family that agreed to hospitalize a relative with advanced dementia might also be less likely to opt for a palliative care plan. Still, the fact that surrogates of 99 hospitalized patients consented to enrollment in this study, suggests they might have been open to adopting palliative care measures. As previously reported, very few surrogates approached for consent refused to enroll the patient in the study (12).

Another contributing factor might be that it was often difficult to contact surrogates to discuss care options on an ongoing basis. In five cases surrogates lived in distant locations (Texas, Utah, Georgia, Florida, and Mexico); others were difficult to reach by phone, and very few made visits during the day. Although phone contact occurred, efforts to meet with surrogates face to face after hours were often unsuccessful. This limited ability to interact with surrogates in the intervention group likely served as an obstacle to developing an alternative plan of care.

Another factor might be a failure of providers to consider advanced dementia a terminal illness. This is reflected in the small number of dementia patients referred to hospice,[1] which in turn could be related to prognostic uncertainty, despite the limited prognosis for patients with end-stage dementia.[13] However, it currently is possible to define a terminal stage of dementia, i.e., end-stage dementia is frequently accompanied by severe, irreversible incoordination of the oropharyngeal phase of eating, leading to death in the absence of artificial nutrition and hydration.[14] Sixty-nine percent of the patients in the current study were receiving long-term enteral feeding at the conclusion of the study, and although the medical rationale for tube feeding was rarely precisely documented, most instances appeared to be related to weight loss or feeding difficulties.

Another possible limiting factor was the ab-

sence of continuity of care by physicians for patients in both groups. In few cases did the same physician know the patient prior to or follow the patient after hospitalization. A temporary care provider during hospitalization would have less time and commitment to accede to recommendations made by a research team.

A possible factor in decisions to forgo life-sustaining treatments is stringent law in New York State, where a high evidentiary standard must be met for patients without decisional capacity.[15] It has been our experience in our hospital that physicians were reluctant to avoid life-sustaining treatments or other aggressive maneuvers for such patients in the absence of formal, written advance directives, even when providers acknowledge the gravity of the patient's illness. There may be a greater reluctance in the case of artificial nutrition and hydration, for which there is a separate legal standard in New York State as compared to other life-sustaining treatments.[16] In this study, there appeared to be greater reluctance to forgo tube feeding than other treatments, which is consistent with findings in other studies.[17,18]

An important caveat in devising palliative care recommendations[19] for patients with advanced dementia is that it is not possible to know with any certainty what the patients themselves experience. Observational scales have been developed[20] in which nonverbal behaviors are assumed to reflect pain experienced by such patients. It was our experience during a preliminary observation that certain behaviors were more likely to be seen during specific interventions, such as turning, dressing changes, or blood draws, but it was beyond the capability of our study to measure these effectively. Although more enduring symptoms such as dyspnea can be surmised by observation, there is no method of assessing symptoms such as nausea in such patients and no directed palliative care intervention can thus be recommended; vomiting, which is observable, might actually bring relief, but persistent vomiting was not observed in our cohort and it is not a common feature in advanced dementia. Although pharmacotherapy is sometimes an appropriate treatment for restlessness and agitation, we often recommended nonpharmacologic approaches, such as attention to the underlying cause, restraint removal, or repositioning and massage. These approaches are particularly important in neurologically impaired patients, and although our study design did not include ongoing observation of nonverbal behaviors, such approaches and their impact would be difficult to measure, although intuitively appropriate.

Given the inabilility to assess physical and psychological comfort in this unique group of patients objectively, a key element of palliative care is avoidance of painful interventions. Therefore, we used indirect measures such as the use of procedures and devices reported by cognitively intact elderly hospitalized patients to produce various degrees of pain or discomfort.[21] Although there is controversy as to whether pain perception differs in elderly individuals and specifically those with neurological impairments,[22] there is no reason to assume that such interventions do anything but increase the likelihood of discomfort. By explaining that dementia was not inherently a painful disease and that painful treatments could be avoided, we made efforts to ensure that family members didn't feel that forgoing treatments constituted "giving up" on their relative. More treatments were, in fact, forgone in the intervention group, although the numbers were small, even though that group of patients did not, overall, have more written and oral advance directives. Five intervention patients and no control patients had living wills, but this could have been related to the persistence of the intervention team in learning about the patient's wishes.

There was inconsistent information available to determine whether a decision to provide a specific treatment was made in accordance with a patient's specific wishes. However, there was no case in which a written or oral advance directive instructed caregivers to provide invasive treatments or prolong life despite hopeless illness. Likewise, there was no situation in which the stated indication for a life-sustaining treatment was for palliation. In some situations, when surrogate decisionmakers desired interventions such as tube feeding, there was no evidence that these requests were derived from a patient's specific, previously stated wish; rather, the decisions were derived from the stated reluctance of the family member to forgo the treatment.

Patients in our study were those hospitalized with acute illness in a tertiary care referral center and the findings might not be generalizable to other populations. However, frail nursing home patients are commonly transferred to hospitals

for acute care. Although the diagnosis of dementia per se may be associated with a lower risk of hospitalization for some nursing home patients, severe functional impairment, and particularly the presence of a feeding tube are important predictors of hospitalization.[23]

CONCLUSIONS

It was difficult for a palliative care research team to influence care of advanced dementia patients in the acute hospital setting. There may be unique barriers when patients have advanced dementia, despite the profound impairments that exist, including perceived prognostic uncertainty, difficulty assessing pain and discomfort, and perceptions about tube feeding. There must be a reexamination of treatment approaches for this severely impaired group of patients and a need to approach advanced dementia as one would approach other end-stage illnesses. Further study should attempt to identify patients prior to the need for acute hospitalization so goals can be established when there is less urgency to make life and death decisions.

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