Amanda Westlake
CRC IRB Protocol
March 13, 2013

Efficacy of Protocol-Driven Hospice Referral in Older ICU Survivors

A. Study Purpose and Rationale

Older ICU survivors are a large and growing population; nearly half of all patients admitted to intensive care units (ICUs) are now age 65 or older. Moreover, older adults who survive critical illness have high short-term mortality: in one study of over 7,000 medical and surgical ICUs patients over age 65, mortality at 28 days post hospital discharge was 26%.[1] Another study found that among the subset of patients who required mechanical ventilation during their ICU stay, 6-month mortality was as high as 30%.[2] Despite the heavy chronic symptom burden and poor prognosis of these patients, hospice is underutilized in this population. In our institution as few as 3.6% of older ICU survivors are discharged to hospice.[3] The goal of this study is to introduce a systematic change in the way that older ICU survivors are assessed order to increase hospice utilization in this population.

B. Study Design and Statistical Analysis

Study Design: Single-center prospective cohort study, utilizing a historical control, assessing the efficacy of a protocol-driven hospice referral in older ICU survivors.
Primary outcome: enrollment in hospice at hospital discharged (defined by designation of hospice benefit in the discharge social work note).
Setting: tertiary-care academic medical center.
Participants: consecutive patients discharged from the medical ICU.
Subject Selection: Inclusion criteria include patients ≥ 65 years old who received mechanical ventilation for ≥ 1 day during ICU stay. Exclusion criterion: status post solid organ transplant.
Statistical analysis: chi-square test of proportions. Statistical significance set at a 2-tailed p-value of <0.05.
Power analysis: sample size calculated to provide at least 80% power to detect a 5.5% absolute difference in hospice referral.

C. Study Procedure

Consecutive medical ICU survivors will be screened for hospice appropriateness with a short questionnaire addressing 3 domains: palliative care needs, treatment goals, and resuscitation status. If the participant screens in for hospice over all 3 domains, the research assistant will ask the patient's primary medical team to make a determination about likely prognosis (≤6 months or >6 months). For those patients with prognosis ≤6 months, hospice referral will be initiated by the social worker. Referral will consist of educating the patient about hospice benefits (including inpatient hospice, home hospice and hospice services delivered at a skilled nursing facility). For patients who elect to receive hospice services, the social worker will facilitate enrollment. All questionnaires will be shared with the patient's primary medical team, regardless of whether or not the patient screen in for hospice appropriateness.

D. Study Questionnaires

Please see attached Appendix.

E. Study Subjects

Participants: consecutive patients discharged from medical ICU; inclusion and exclusion criteria as above.

F. Recruitment of Subjects

Recruitment will begin on the day the potential participants are discharged from the ICU to the general medical floor. Potential participants will be identified by screening the demographic and clinical characteristics of ICU discharges. Once a patient is identified as meeting inclusion criteria, researchers will contact the patient's primary medical team to ascertain the patient's willingness to be approached about study enrollment. For those patients unable to consent to study enrollment, the patient's proxy or surrogate will be approached.

G. Confidentiality of Study Data

Study data with PHI will be stored in password-protected databases and will be accessible only by the research assistant and the PI. Once data collection is complete, all data will be de-identified. Any paper records will be stored in a locked filing cabinet.

H. Potential Conflict of Interest

None.

I. Location of the Study

Columbia University Medical Center, New York, NY.

J. Potential Risks

For some patients, the psychological impact of being screened for hospice eligibility may constitute a risk of participating in the study. Barring this, the study poses no risks beyond that of usual care.

K. Potential Benefits

For those found to be eligible for hospice, participation in the study is likely to facilitate their enrollment in hospice, which has been shown to provide a wide range of benefits for patients at the end of life. All participants will be screened for common symptoms. Their medical providers will be provided with their responses to this screen, which will presumably a) increase clinician's awareness of the patient's symptom burden and b) incite actions on behalf of the healthcare team to alleviate those symptoms.

L. Alternative Therapies

Standard of care, including any curative treatments that may be available to the patient.

M. Compensation to Subjects

None

N. Costs to Subjects

No direct costs; financial costs may be incurred if referral is made to hospice.

---

[1] Fuchs L et al. ICU Admission characteristics and mortality rates among elderly and very elderly patients. Intensive Care Med. 2012 Oct;38(10):1654-61.

[2] Wunsch H, Guerra C, Barnato AE, Angus DC, Li G, Linde-Zwirble WT. Three- year outcomes for Medicare beneficiaries who survive intensive care. JAMA 2010;303:849-856.

[3] Baldwin M, Wunsch H, Reyfman P, Narain W, Blinderman C, Schluger N. Older intensive care survivors have unmet palliatve care needs independent of chronic critical illness. Submitted for publication. 2013.