

Form "EAST Multicenter Study Proposal"

Details #37 (submitted 01/30/2024)

Please indicate if this is a...

Revised MCT proposal submission

If a revised proposal summarize the changes made to this proposal based on the feedback received:

Further explained rationale for using invasive procedures as an outcome, added the option to include geriatrics consultation as a provider of specialty palliative care

Study Title

Palliative Care in the Trauma ICU (PiCIT) Trial

Primary Investigator:

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Institution that will be the primary site for the study:

R Adams Cowley Shock Trauma Center

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Are you a current member of EAST?

Yes

If you selected "No" above please identify a Sponsor that is an active EAST member:

Use this area to briefly outline the burden of the problem to be examined.

Specialized palliative care has demonstrated its profound ability to enhance the quality of patient care while reducing the exorbitant costs associated with end-of-life treatment, with one study of patients with severe TBI indicating that palliative care consultation was associated with an \$8,000 decrease in hospital costs. By effectively addressing symptoms and facilitating vital discussions concerning care goals, palliative care proves invaluable. However, medical patients continue to receive palliative care consultations during hospitalization more frequently than surgical patients do. A key reason behind this discrepancy lies in the deeply ingrained sense of personal responsibility that surgeons harbor toward their patients, reinforced by the concept of "surgical buy-in." This concept implies that surgeons and patients implicitly agree to navigate the initial operation and whatever consequences arise together. Consequently, surgeons are hesitant to incorporate palliative care into their surgical practice, fearing that they would fail to uphold their end of the implicit agreement.

Briefly review what major published studies exist on the topic of the proposed project.

A survey conducted among EAST members in 2014, specifically focusing on palliative care in the trauma ICU, revealed surgeons' reluctance to refer cases to palliative care for various reasons. Their concerns ranged from the fear of inaccurate communication of prognosis and diagnosis to apprehensions that the patient and their family would perceive the trauma team as giving up on the patient. Although the surgeons' determination to prolong the lives of critically ill patients is commendable, especially given that many trauma patients are young and otherwise healthy at the time of their traumatic event, this prevailing culture carries significant consequences. Estimates suggest that integrating palliative care consultation and advance care planning as a standard in ICUs would lead to earlier discontinuation of nonbeneficial life-sustaining therapy, resulting in an impressive 11% reduction in annual healthcare costs, equivalent to \$8.8 billion in the United States alone. As our population continues to age, the economic impact of implementing palliative care will only intensify.

While the benefits of palliative care in critically ill trauma patients have been evidenced in retrospective studies conducted at individual centers, comprehending the nationwide landscape where trauma and palliative care intersect would yield greater motivation to routinely involve palliative care specialists in our healthcare system. Such data would empower us to employ palliative care specialists in an evidence-based manner, ensuring optimal end-of-life care for our patients.

The underutilization of specialized palliative care services in trauma patients has resulted in a lack of data concerning palliative care in this specific population. Furthermore, existing palliative care literature tends to primarily focus on older adults, leaving a significant gap in knowledge regarding palliative care utilization and its implications for their younger counterparts (> 18 years of age). By including critically ill trauma patients of all ages, we aim to develop an understanding surrounding the impact specialized palliative care teams have on the care of patients aged 18-65, as well as the more commonly studied population of older adults.

Use this area to briefly outline how this idea is innovative and it's anticipated impact.

Critically ill trauma patients present a unique challenge as their condition arises suddenly, without warning, and often leaves them incapable of participating in decision-making. Consequently, the responsibility of making medical decisions falls upon family members who themselves are grappling with the emotional impact of the traumatic event. Many of these patients are young, lack advance directives, and have not engaged in conversations with their surrogate decision-makers regarding their preferences for life-sustaining therapy. Palliative care services can help patients and families to navigate this uncharted territory and have been proven to decrease rates of caregiver distress and depression. Additionally, palliative care teams can provide support to the surgical team taking care of the patient, many of whom may also be experiencing sadness or grief surrounding the status of their patient.

Describe what & how the proposed MCT will add to the existing body of knowledge & literature.

This study serves as an essential initial step in building a broader evidence base regarding critically ill trauma patients who benefit from the involvement of palliative care services in their care. By gaining a better understanding of the current landscape, we can identify areas that can be improved and implement interventions that will enhance our ability to provide care for our patients.

Primary aim

to determine impact of timing of palliative care evaluation on rate of invasive procedures performed in critically ill trauma patients

Secondary aims	To determine association of timing of palliative care evaluation with hospital and intensive care unit (ICU) length of stay, ventilator days, discharge disposition, in-hospital mortality and 30-day mortality
Tertiary aim	
Design	Prospective (observational with or without consent requirement) -Trauma patient requiring ICU stay for any reason during their index admission -18 years or older
Inclusion Criteria	-Admitted to designated trauma center -Evaluated by palliative care service, or by geriatrics service based on institutional standard practice
Exclusion Criteria	death within 72 hours of admission, inability to contact next of kin/surrogate decision-maker/caregiver within 72 hours of admission, pregnant patients, inmates
Please describe, completely but succinctly, how the project will be conducted.	An investigator at each site will be responsible for identifying and enrolling appropriate patients based on the above criteria. They will enter deidentified data into a REDCap database. Additionally, they will fill out a questionnaire regarding their site and it's characteristics. Once the data collection phase is complete, the primary investigator will download the data and the statistician will perform the appropriate data analysis.
Primary Outcome	Number of invasive procedures performed Hospital and intensive care unit (ICU) length of stay Ventilator days Discharge disposition
Secondary Outcome(s)	In-hospital mortality 30-day mortality
Select the variables to be collected & analyzed:	Baseline Participating Institution Information, Demographics, Baseline Clinical Characteristics, Hospital Course, Treatments & Interventions, Outcomes of Interest
Additional variables:	Discharge disposition, presence of advanced directives on admission, changes in code status

The data collected will include patient demographics, clinical and injury characteristics, hospital course, and outcomes (invasive procedures performed, hospital and ICU length of stay, ventilator days, in-hospital and 30-day mortality, discharge disposition [home, acute inpatient rehabilitation, subacute rehab, hospice]), complications, and changes in code status. The early palliative care group is defined as those who receive a palliative care evaluation within 72 hours of admission. The late palliative care group is defined as those who receive palliative care evaluation after 72 hours of admission. This delineation was chosen based on the TQIP Palliative Care Best Practices Guidelines, which suggest that patients with positive palliative care needs screening have a family meeting with goals of care discussion within 72 hours of admission. Invasive procedures are defined as non-operative procedural interventions (continuous renal replacement therapy, extracorporeal membrane oxygenation, and placement of an intracranial pressure monitor, central venous access, chest tube placement, and/or intubation, all of which are not as a part of the initial resuscitation phase) and operative interventions which include tracheostomy, percutaneous endoscopic gastrostomy tube placement, and any other operation that the patient requires.

Outline the data collection plan/tool succinctly

Additionally, each participating center will be asked to fill out a survey describing a number of characteristics about their institution. These will include geographic region, location (i.e. urban, suburban, rural or military), trauma center designated level, number of trauma evaluations and admissions annually, characteristics and availability of their specialized palliative care services, ICU characteristics, presence of trainees, and demographics of their trauma population.

Institutional Review Board (IRB) exemption and waiver of consent have been obtained at the University of Maryland, which is the coordinating center. Each participating institution will be responsible for submitting to their institutional IRB. Each center will be responsible for screening and enrolling patients based on the above criteria. Variables to be collected are outlined in the data collection form and will be input into REDCap by each center after a data use agreement (DUA) is obtained. Once the IRB has been approved an DUA has been executed, each center will be given access to the study's REDCap database. Data will be de-identified at time of entry into REDCap to minimize risk of breach of confidentiality. Upon completion of the database, the data will be downloaded by the primary investigators and shared with the institution's statistician, who has assisted in the design of this study and will be performing the analyses.

Has IRB approval been obtained at the primary site?

Yes

Is DUA required for participation in the study?

Yes

If applicable, list the primary contact (name/email) to contact to initiate & execute DUA:

Identify the individuals that will primarily be responsible for data collection process:

Will vary based on institution

Is there a primary statistician assigned to assist the PI w/design & data analysis?

Yes

If no, how was study design/power analysis determined/who will handle analysis once complete?

We will use Chi-square test and Fisher's exact test for categorical data and difference in proportions. Analysis of Variance (ANOVA) will be used for test of difference in means and non-parametric tests (e.g. Kruskal-Wallis test) upon violations of the ANOVA assumptions.

Include detailed description of the data analysis plan:

The main outcome for the study is a count variable: the number of invasive procedures performed and for the multivariable model a Poisson or Negative binomial regression model will be appropriate. For continuous outcomes, regression models will be used. For binary outcomes, logistic regression models will be used. To alleviate the potential heterogeneity among different centers we will use mixed effect models with random intercepts for the centers.

Include Power Analysis:

Given that very few studies in the literature have assessed the association of palliative care consultation with invasive procedures, this analysis is based on effect sizes (means and proportions) presented in Spencer et al., 20235. Spencer et al. identified differences in rates of invasive procedures (1.7% vs. 11.7%), length of stay (7.0 vs. 17.5 days), ventilator days (2.4 vs. 7.0 days), and hospital cost (\$17,654 vs \$53,165) between patients who had early palliative care consultation (72 hours) respectively. The smallest difference in proportions is 10%. Under this assumption, at least 90% statistical power and 5% Type I error (Alpha=0.05) we will need at least 130 patients in each group (early and late palliative care) to test for statistical significance of the smallest difference in proportions. For larger differences the statistical power will be greater than 90%. The smallest difference in means is for ventilator days (2.4 vs 7.0) and we assume standard deviation of at most 15 days. Under these conditions with at least 90% statistical power with Type I error (Alpha=0.05) we will need at least 225 patients in each group to test for statistical significance of the smallest difference in means. For larger differences the statistical power will be greater than 90%. Overall, assuming no critical missing values, we will need a sample of at least 450 patients (225 per group). If we assume a certain amount of critical missing values or ineligible patients, we have to increase the sample size accordingly. For example, assuming 30% missing/ineligible data, the sample size should increase to at least 585 patients (292 per group).

Please note what your enrollment procedure for this study entails:

The investigator at each institution will be responsible for identifying and enrolling appropriate patients based on the inclusion and exclusion criteria.

Outline consent procedures here, if applicable:

N/A

Please indicate what resources are available at the primary study institution:

Presence of a dedicated statistician

Include a brief listing of key references:

1. Williamson TL, Adil SM, Shalita C, et al. Palliative Care Consultations in Patients with Severe Traumatic Brain Injury: Who Receives Palliative Care Consultations and What Does that Mean for Utilization? *Neurocrit Care*. 2022;36(3):781-790. doi:10.1007/s12028-021-01366-2

2. O'Connell K, Maier R. Palliative care in the trauma ICU: *Curr Opin Crit Care*. 2016;22(6):584-590. doi:10.1097/MCC.0000000000000357

3. Schwarze ML, Bradley CT, Brasel KJ. Surgical "buy-in": The contractual relationship between surgeons and patients that influences decisions regarding life-supporting therapy*. *Crit Care Med*. 2010;38(3):843-848. doi:10.1097/CCM.0b013e3181cc466b

4. Karlekar M, Collier B, Parish A, Olson L, Elasy T. Utilization and determinants of palliative care in the trauma intensive care unit: Results of a national survey. *Palliat Med*. 2014;28(8):1062-1068. doi:10.1177/0269216314534514

5. Spencer AL, Miller PR, Russell GB, Cornea I, Marterre B. Timing is everything: Early versus late palliative care consults in trauma. *J Trauma Acute Care Surg*. 2023;94(5):652-658. doi:10.1097/TA.0000000000003881

6. Rotundo E, Braunreuther E, Dale M, et al. Retrospective Review of Trauma ICU Patients With and Without Palliative Care Intervention. *J Am Coll Surg*. 2022;235(2):278-284. doi:10.1097/XCS.0000000000000220

7. El-Jawahri A, Greer JA, Pirl WF, et al. Effects of Early Integrated Palliative Care on Caregivers of Patients with Lung and Gastrointestinal Cancer: A Randomized Clinical Trial. *The Oncologist*. 2017;22(12):1528-1534. doi:10.1634/theoncologist.2017-0227

8. ACS TQIP Palliative Care Best Practice Guidelines. Published online October 2017. https://www.facs.org/media/g3rfegcn/palliative_guidelines.pdf