



Poster # 43

Title of poster: Consent rates by age for an early in-bed cycling trial for critically ill patients: Preliminary results.

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Abstract

Background:

Well-conducted clinical trials are essential for improving current standards of care and introducing new methods of therapy for critically ill patients. Previous research documented that older patients were less likely to be enrolled in critical care clinical trials (1). The primary objective of this substudy was to determine if the consent rate for older adults (>60 years) was different than younger adults in the TryCYCLE study (a prospective pilot study of the safety and feasibility of early cycle ergometry in mechanically ventilated (MV) adult patients). Our secondary objective was to determine if the consent rate was different for consent given by a patient versus a substitute decision maker (SDM).

Methods:

We analyzed data for the first 35 consent encounters in TryCYCLE at St. Joseph's Healthcare, Hamilton. Patients were eligible for TryCYCLE if they were invasively MV for ≤ 4 days, within their first week of ICU admission and able to ambulate independently pre-hospital. Research personnel approached eligible critically ill patients or their SDM for informed consent. We collected demographic data on all eligible patients approached for consent, reasons for declining consent, and hypothesized there would be no difference in consent rates between older and younger adults. Additionally, we hypothesized that there would no difference in consent rates between consent given by patients and SDMs. We used Fisher's exact test to determine if there was a significant difference in consent rates.

Results:

Between October 28, 2013 and July 25, 2014, we approached 35 eligible patients or their SDMs for informed consent. The mean (standard deviation) age of eligible patients was 66.9(11.9) years, and 17(48.6%) were female. Our overall consent rate was 31(88.6%). The consent rate for older versus younger patients was 20(83.3%) and 11(100%), respectively ($p=0.285$ for the difference). The consent rate for patients versus SDMs was 7(100%) and 24(85.7%), respectively ($p=0.562$ for the difference). Reasons for declining consent included: concern for Achilles tendon rupture ($n=1$), lack of interest by SDM ($n=1$), impression that the patient would not enjoy cycling ($n=1$), and unknown ($n=1$).

Conclusions:

Based on preliminary data, we found no difference in the consent rates between older and younger critically ill adults for this early rehabilitation trial. Twenty percent of patients provided

first person informed consent. We also found no difference in consent rates between patients and SDMs approached for this study. Our results demonstrate that older adults are equally as likely as younger adults to consent to an early in-bed cycling study for critically ill, mechanically ventilated adults. As this research program expands to a multi-centre randomized pilot study, our preliminary results underscore the feasibility of recruiting both older and younger critically ill patients to an early rehabilitation study.

1. Cooke CR, Erickson SE, Watkins TR, et al. Age-, sex-, and race-based differences among patients enrolled versus not enrolled in acute lung injury clinical trials. *Crit Care Med*. 2010;38(6):1450-57

