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A Frailty Index Based on Routinely Collected Laboratory Safety Data Predicts Adverse Events in a Sex-Specific Manner in Clinical Trial Settings

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Abstract Text:

Background: Most clinical drug trials aim to exclude frail older adults, so whether they affect the results of such trials is unclear. Our group has shown that frailty can be quantified in outpatients with a frailty index (FI) based the accumulation of deficits in routine blood work and vital signs (FI_{LAB}). Our objectives were: 1. To explore sex differences in frailty using laboratory/safety data from the Coalition on Major Diseases (CAMD) database. 2. To evaluate the links between frailty and adverse events. **Methods:** Subjects (n=6351) were 74.0 ± 8.7 years old (56.4% female). The FI_{LAB} was constructed from results of between 22 and 48 standard laboratory tests (e.g. red cell, white cell & platelet counts, liver, kidney & thyroid function) including heart rate and blood pressure. Results within the trial reference normal range were scored as 0; values outside these ranges were scored as 1. Individual deficits were summed and divided by the number measured to yield an FI between 0-1. **Results:** Mean (±SD) FI_{LAB} scores were 0.104 ± 0.077 (n=6381; range=0-0.560) and increased with age. The mean FI for males was 0.107 ± 0.081 (n=3584; range=0-0.560), which was significantly higher than values in females (0.101 ± 0.075; n=2767; range=0-0.536; t=6.52, p<0.001). FI_{LAB} scores increased with age more steeply in males than in females. A cross-over was observed at age 65, after which age-specific mean FI scores were significantly higher in males. The number of adverse events had no association with age for either sex. The number of severe adverse events increased with increasing FI_{LAB} scores for both males (r=0.071, p<0.001) and females (r=0.072, p<0.001). **Conclusions:** In CAMD, males had significantly higher FI_{LAB} scores than did females. These findings contrast with the morbidity-mortality paradox seen with clinically-derived FI scores in community samples. There, females have higher mean FI scores, but lower FI lethality. Our data support the hypotheses that cellular and sub-cellular deficits scale up to promote frailty at the organ/organism levels and that males are more susceptible to their adverse effects, including disease risk and expression and death. Approaches to understanding of frailty, even in highly screened clinical trials, are needed.

Title:
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Theme:
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Topic:
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Sub Topic:
Novel outcomes measures

Learning Objectives:

- Investigate sex differences in frailty using laboratory/safety data.
- Evaluate the links between frailty and adverse events.

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Signed on 01/29/2018 by *Kenneth Rockwood*

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