

LETTER

Underpowered trials in critical care medicine: how to deal with them?

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on behalf of the IMPACT Study Group

See related research by Aberegg et al., <http://ccforum.com/content/14/2/R77>

In their recently published article, Dr Aberegg and colleagues described interesting results of a literature search for randomized controlled trials comparing mortality of therapies for critically ill adults in five high impact journals over a 10 year period [1]. The authors show that the predicted delta (the effect size of a therapy compared to control) used for power calculations was substantially larger than the observed delta in the majority of the included studies. They conclude that this finding, referred to as 'delta inflation,' led to underpowered trials in the field of critical care medicine.

We agree that treatment effects are small in this field of medicine and that many critical care trials have been underpowered. This problem is particularly relevant to the field of neurocritical care after traumatic brain injury [2]. The IMPACT (International Mission on Prognosis and Clinical Trial Design in Traumatic Brain Injury) Study Group extensively investigated possible causes and solutions and recently reported recommendations for improving the design and analysis of future clinical trials in traumatic brain injury to increase statistical power [3]. These include the use of relatively broad enrolment criteria instead of strict patient selection [4], covariate adjustment for baseline patient characteristics [5], and ordinal rather than dichotomous outcome analysis [6]. In our opinion these recommendations are also applicable to other fields of critical care research characterized by heterogeneous patient populations. We submit that adopting these recommendations in future trials will increase the chance of detecting small but clinically relevant treatment effects in critical care medicine.

Competing interests

All authors are members of the IMPACT Study Group. The work of the IMPACT Study Group is funded by a grant of the US National Institutes of Health (NS-042691).

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Published: 8 June 2010

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doi:10.1186/cc9021

Cite this article as: Roozenbeek B, et al.: Underpowered trials in critical care medicine: how to deal with it?. *Critical Care* 2010, **14**:423.

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