

The (lack of) quality in assessing the quality of transplantation trials

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The conclusion [1] that 'overall quality of reporting of RCTs in organ transplantation is poor' is correct, but the legacy of a published article goes beyond its conclusion, and includes also the methods used to reach this conclusion. Hence, the methods themselves merit scrutiny. In this case, Pengel *et al.* [1] were aware of 'over 35 different scales to assess the methodological quality of RCTs'; yet, without any explanation whatsoever, they chose to use that which is arguably the worst among these. The Jadad score has been shown to be inadequate by virtue of its giving full marks, a perfect 5/5, even to fatally flawed trials [2,3]. The limitations of the Jadad score are self-evident, and do not require known examples to establish. For example, the Jadad score does not address the appropriateness of the data analysis, or allocation concealment, or of intent-to-treat, among other glaring deficiencies. Even though Pengel *et al.* [1] supplemented the Jadad score with an assessment of allocation concealment and intent-to-treat, this was done inadequately in that they considered only one of the two threats to allocation concealment. The one that was not considered is the ability of investigators to predict upcoming allocations based on knowledge of (i) previous allocations and (ii) the rules used to create the allocation sequence (i.e., permuted blocks of a given block size). This concern is most acute in unmasked trials, but even masked trials are often found to be masked in name only, and the intent to mask in no way ensures the success of the undertaking, and in no way precludes the possibility of prediction of future allocations. Allocation concealment is, in fact, not a binary phenomenon [4,5], and should not be treated as such.

Pengel *et al.* [1] did not tabulate the numbers of (ostensibly) masked and unmasked trials, but clearly the success of masking is questionable especially in transplantation trials, so allocation concealment is also questionable. Some methods of randomization are better than others at preventing prediction [5], but this aspect of trial quality does not seem to have been considered. Moreover, the trials considered were not tabulated, so we cannot go back and evaluate the methodological quality of the trials that have been rated as perfect.

The above concern is a real one. One can anticipate a time when any and every trial will meet the minimal

standards of the Jadad score, and will then be considered high quality (the article deals with the quality of reporting, but also uses the Jadad score as a means to evaluating the quality of the trial itself). But they will not be of high quality, and will instead continue to misrepresent the truth about safety and efficacy, with predictable adverse consequences to the patients who come to rely on these trials to inform their medical decisions. We need better trials, but just as much we need better methods of trial evaluation. The Jadad score, even supplemented, represents a choice to value the convenience of the researcher over the quality of the work, and as such represents a disservice to the scientific community and, especially, to the patients who rely on the quality of the research.

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