Review of: "On the Need for Better Information from Randomized Clinical Trials in Oncology"

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This is an interesting paper that addresses long-standing issues in the randomized clinical trial (RCT) literature: the choice and interpretation of outcome measures. The paper's focus on recently-reported trials in an high quality journal is an appropriate source of data to investigate this question. I agree with the authors that both relative and absolute risk reduction should be reported, as well as number needed to treat (NNT), and that current reports are lacking.

However, there are also additional outcome assessments that are needed, particularly to address the patient questions that open the paper. The assessment of patient-reported outcomes, such as quality of life and symptom experience, is needed to understand the patient experience. Considerable research has shown that patient and provider ratings of these outcomes are not the same, and information obtained from the patients themselves is needed. A number of well-validated questionnaires are now available that are appropriate and feasible to implement in the clinical trials context (e.g., EORTC QLQ-C30, FACIT, PROMIS).

Another important consideration is the difference between clinical and statistical significance. With a sufficiently large sample, statistical significance can be found for small effects that are not meaningful for patient care. To some extent, this concern is is addressed by the NNT assessment, but it needs to be called out directly in the paper.

Finally, research on what clinicians (and patients) actually understand from clinical trial reports is needed. From a methodological perspective, researchers can incorporate and report more and better outcome measures and assessments. But the more important question may be what clinicians make of this research, as they are the ones who will use the RCT findings in clinical practice. I refer you to a number of excellent papers from Drs. Claire Snyder and Michael Brundage that have addressed these questions empirically.