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

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The central thesis of this paper is that if the publication of randomized controlled trials (RCTs) routinely included comprehensive information on 1) hazard ratios (HR), 2) median overall survival (OS), and 3) OS proportions at various time points (e.g., 6 months, 1 year, 3 years, 5 years), along with the associated relative risk (RR), absolute risk (AR), and number needed to treat (NNT) derived from the AR reduction, oncologists would be better equipped to answer patients' questions about the expected outcomes of cancer treatments. The two key patient questions highlighted by the authors are: "Doctor, can this treatment cure me, and what are the chances?" and "Doctor, can this treatment prolong my life, and by how much?"

To make their case, the authors selected the five most recent publications from the top medical journal, the New England Journal of Medicine (NEJM). They note that while “all five studies reported statistically significant reductions in the hazard ratio (HR) for progression-free survival (PFS), only three of the five studies showed reductions in both relative risk (RR) and absolute risk (AR). However, none of the five studies, including the tisotumab vedotin study - which showed a statistically significant reduction in HR for overall survival (OS) - achieved a reduction in both RR and AR.”

As a biostatistician who frequently reads NEJM papers, I find the authors' claims somewhat perplexing. The first patient question, "Doctor, can this treatment cure me, and what is the likelihood?" seems particularly difficult to answer based on the data typically presented in these trials. The NEJM papers in question, and clinical trials in general, are designed to answer broader population-level questions, such as Is drug X more effective than drug Y in treating disease Z in terms of health outcomes such as OS or PFS? These trials provide statistical evidence of efficacy (per pre-specified primary/secondary endpoints) and safety in a study population, but they are not designed to provide individualized predictions of cure or survival for specific patients.

For the second question "Doctor, can this treatment prolong my life, and by how much?", I do not see how including RR, AR, and NNT in published results helps in this regard. The complexity of cancer treatment outcomes and the diversity of patient responses make it difficult to distill these results into simple metrics that can directly answer such personal and specific patient questions.

While I appreciate the authors' desire to make clinical trial results more informative and accessible to oncologists and patients, I believe it is important to acknowledge the limitations of RCT data in answering deeply personalized questions about treatment outcomes. Enhancing the reporting of these trials with additional metrics may indeed be valuable, but it is

critical to recognize that the interpretation and application of these metrics will still require careful consideration by healthcare professionals or health authorities.

Overall, I am not convinced by the authors' claims.