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Improving power in PSA response analyses of metastatic castration-resistant prostate cancer trials

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Abstract (600 word limit)

To determine how much an augmented analysis approach could improve the efficiency of prostate-specific antigen (PSA) response analyses in clinical practice. PSA response rates are commonly used outcome measures in metastatic castration-resistant prostate cancer (mCRPC) trial reports. PSA response is evaluated by comparing continuous PSA data (e.g., change from baseline) to a threshold (e.g., 50% reduction). A literature review identified published prostate cancer trials that included a waterfall plot of continuous PSA data. This continuous data was extracted to enable the conventional and augmented approaches to be compared. The authors applied a model unvalidated for non-clear fluids as enteral feeding, the scanning protocol was not clearly described and essential anatomical landmarks required for correct interpretation are not visible in the presented images.

Important of Research (200 word limit)

In conclusion, the augmented analysis can provide substantial statistical advantages. Given its ease of use, it offers an effective means of improving the efficiency of clinical trials that utilise responder endpoints, such as PC trials that analyse PSA response or time to PSA progression. Embracing the use of this method could help make clinical trials far more efficient, reducing the sample size required by clinical trials, which will in turn speed up research and reduce costs. For fields in which the clinical landscape evolves rapidly, this may be invaluable to maximizing the value of a given clinical trial. (200 word limit)

Biography (200 word limit)

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Michael J. Grayling is a Newcastle University Research Fellow in Biostatistics, interested in methodology for improving the design and analysis of clinical trials. As well as working on developing methodology, He is also interested in collaborating on real trials. He is in Newcastle since November 2018. Prior to this I was a Statistician at the MRC Biostatistics

Unit, University of Cambridge. (200 word limit)

Information of Institute and Laboratory (200 word limit

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