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Image assessment in immunotherapeutic trials: Use of novel combined RECIST 1.1 and immune-related response criteria (irRC)

S Agarwal¹, P Chokron², A Thabet¹, R S Arellano¹, X Ma², H Le², I Kazam², M Harisinghani¹ and R Walovitch²

¹Massachusetts General Hospital, USA

²World Care Clinical, LLC, USA

The objective of this study was to validate an image assessment method that combines RECIST 1.1 and irRC criteria. Regulatory agencies often request that immunotherapeutic tumor burden be assessed using validated methods (i.e., RECIST) and newer irRC paradigm. Two sets of image datasets (10 RECIST and 10 irRC/RECIST), consisting of pre/post-treatment CT images from melanoma subjects enrolled in a PD-1 immunotherapeutic trial, were read twice by five independent radiologists (IR). Inter- and intra- reader variability of the combined irRC/RECIST and RECIST methods were measured. In a separate analysis, overall read time for the combined method was compared to irRC and RECIST alone. The combined irRC review had the best inter-reader agreement (90-98%; kappa 0.74-0.94) and intra-reader agreement (80 -100%; kappa 0.38-1.0) with excellent intra-reader homogeneity for number of lesions assessed. No significant differences were observed between RECIST IR variability using the combined vs. independent method. Inter-reader agreement ranged from 85 to 95% with kappa 0.55-0.84. Combining the RECIST and irRC assessments resulted in an approximate 20% decrease in assessment time compared to individual RECIST and irRC assessments. In conclusion, in immunotherapeutic trials RECIST may lead to errors in tumor burden as lesions initially grow despite favorable treatment response. This study indicates that the Combined irRC/RECIST review method is robust, as it is reproducible and simplifies the process of simultaneously assessing the cytotoxic and immunotherapeutic responses of drugs, and may be an efficient time saving analytical tool.

Biography

S Agarwal is a practicing radiologist in the division of Abdominal Imaging and Intervention at Massachusetts General Hospital (MGH). She is Associate Director of Radiology Clinical Trials at MGH and an instructor in radiology at Harvard Medical School. She is board certified in diagnostic radiology.

jjirousek@wcclinical.com

Understanding and defining food allergy, intolerance, and sensitivity

Stephen Wangen

IBS Treatment Center, USA

Inflammation is probably the single most important health issue of our time. Food allergy and intolerance is one of the most underestimated and controllable causes of inflammation in modern day humans, with celiac disease being just the tip of the ice berg. Yet we continue to underestimate the impact of this profound problem, which affects millions of people. Why? Because we lack a common language to properly discuss it. The words allergy, intolerance, and sensitivity are used by healthcare practitioners and the public without any consistency in the science or the mechanism behind the reaction. Reactions are frequently labeled based on symptoms, standard of practice, or personal preference. Incorrect assumptions are commonly made and promoted as fact, and there is no consistency or foundation on which to build. This must change in order for us to move forward in this exciting and important field of immunology. A logical process for doing that is the focus of this presentation.

Biography

Stephen Wangen is one of the world's leading experts on IBS, food allergies and intolerances, and the ecosystem of the digestive tract. He is the Co-founder and Medical Director of the IBS Treatment Center, and the author of two popular books, "The Irritable Bowel Syndrome Solution" and the award winning "Healthier without Wheat: A New Understanding of Wheat Allergies, Celiac Disease, and Non-Celiac Gluten Intolerance." He is a licensed and board certified physician with a Doctoral degree in naturopathic medicine from the internationally renowned Bastyr University in Seattle, WA, where he also is a faculty member.

drwangen@comcast.net