The Value of CMR Over Other Modalities in Clinical Trials Chun Yuan, PhD, FAHA

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According to clinicaltrials.gov, a clinical trial can be constructed to assess the effects of specific interventions. These interventions may be (a) medical products such as drugs or devices; (b) procedures; or (c) changes to participants' behavior, for example, diet. Clinical trials may test a new medical approach by comparing its results with those of (a) a standard approach already available; or (b) a placebo containing no active ingredients; or (c) a placebo involving no intervention.

Imaging may play a key role in clinical trials due to desirable features including the ability to extract reliable quantitative information in serial studies. As a non-invasive technique, MRI has many unique advantages because it allows simultaneous quantitative assessment of 3D anatomic, functional, and metabolic information.

This lecture will focus on clinical trials using CV MR in vessel wall imaging compared with other imaging modalities to evaluate atherosclerotic lesion progression and regression. Atherosclerosis imaging, especially MRI based techniques, has been on the forefront of gaining an understanding of atherosclerosis progression and identifying vulnerable plaques that pose increased risk of causing heart attack, stroke, and other CV-related clinical events. Clinical trials are critical to achieving many goals of atherosclerosis imaging.

Atherosclerosis is widely recognized as a multifactorial disease with outcomes arising from complex factors such as plaque components, blood flow, luminal stenosis, and inflammation. Due to compensatory remodeling, atherosclerotic lesions may grow outward without impacting lumen size. Thus, MR based vessel wall imaging is focused on the visualization of vessel wall and the identification and quantification of atherosclerotic plaque tissue components. Over the years, with continuous technical advancement, a series of

parameters associated with *in vivo* plaque morphology and composition were evaluated and validated against histology and other imaging-based gold standard. From a technical point of view, MRI of atherosclerosis relies on the use of (a) combined black and bright blood techniques to distinguish vessel lumen and wall tissues, (b) specific multi-sequence approach to identify main plaque tissue components, (c) novel coil designs to improve image SNR and spatial resolution, and(d) contrast-agent applications that highlight vessel neovasculature and improve tissue contrast.

This lecture will introduce the use of vessel wall MRI in clinical trials, using imaging based biomarkers (a) to evaluate the effects of treatment using various pharmaceutical compounds in different vascular beds and (b) to monitor atherosclerotic lesion progression. Comparing MRI based techniques with other imaging modalities in such trials will also be discussed. In general, MRI based vessel wall imaging provides a non-invasive means to evaluate plaque burden and tissue composition and this technique is now ready for large scale multi-center studies.