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# clinical trials methodology

## 316P Comparison of assessments by blinded independent central reviewers and local investigators: An analysis of phase III randomized control trials on solid cancers (2010-2015)

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**Background:** Accurate and unbiased assessment of tumor response or progression is crucial in randomized control trials. Blind independent central reviews are usually used as a supplemental or monitor to local investigator assessment but are costly. It is worth determining the value of central assessment.

**Methods:** We compared central and local assessments by study-level pooling analysis and correlation analysis, primarily through investigating treatment effects of objective response rate (ORR), disease control rate (DCR), progression-free survival (PFS) and time-to-progression (TTP). Evaluation for response between two assessments was also compared. Eligible trials were phase III RCTs of anti-cancer drugs for non-hematologic solid tumors, searched in PubMed between the dates of Jan 1, 2010 to Jun 24, 2015.

**Results:** Of 61 included trials involving 37,396 patients, 10 (16%) trials were with different statistical conclusion regarding primary or secondary endpoints between two assessments. However, pooling analysis found no significant difference when comparing estimates of treatment effects between two assessments, pooled odds ratios (OR) of ORR, DCR, PFS and TTP was 1.03 [95% CI 0.98-1.09], 0.96 [0.90-1.03], 1.01 [0.99-1.03] and 1.04 [0.95-1.14], respectively. This concordant outcome could be found regardless of mask (open/blind), region (global/intercontinental), tumor type, study design (superiority/non-inferiority), criteria of tumor assessment (RECIST/WHO). Correlation analysis also indicated their concordance on treatment effects (ORR, DCR, PFS: $r > 0.80$, $p < 0.01$; TTP: $r = 0.896$, $p = 0.293$). Synthesis for response evaluation indicated central ORR and DCR were numerically higher than those of the local in both experimental arms and control arms, without evaluation bias (ORR: OR = 1.02 [0.97-1.08]; DCR: OR = 0.96 [0.90-1.03]).

**Conclusions:** Central assessment remains an irreplaceable method but the necessity to apply it in a complete-case fashion should be questioned regarding efficiency, especially in trials with double-blind design. A modified strategy, such as sampling central assessment, warrants further evaluation.

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