2013 ASCO Annual Meeting
May 31 – June 4, 2013
McCormick Place • Chicago, Illinois
Building Bridges to Conquer Cancer

Accuracy and clinical utility of in vitro cytometric profiling to personalize chemotherapy: Preliminary findings of a systematic review and meta-analysis.

Sub-category:
Molecular Diagnostics and Imaging

Category:
Tumor Biology

Meeting:
2013 ASCO Annual Meeting

Abstract No:
E22188

Citation:
J Clin Oncol 31, 2013 (suppl; abst e22188)

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Abstract:
Background: Cytometric analysis, or in-vitro functional profiling, has been developed as a method to predict tumor response to different drugs with the premise to personalize chemotherapy and improve patient outcomes. **Methods:** We performed a systematic review and a meta-analysis a) of correlative studies using cytometric profiling that reported diagnostic accuracy (sensitivity and specificity) and b) of effectiveness studies comparing patient outcomes when allocated to treatment guided by a cytometric assay versus population-based standard of care. We used Meta-DiSc software to find pooled sensitivity and specificity and analyze the summary receiver operating characteristic (sROC) curve and used Review Manager 5.1 to generate forest plots on overall tumor response (50% or greater decrease in tumor diameter) and on 1-year overall survival. **Results:** We included 28 mostly retrospective trials (n=664) reporting accuracy data and 15 prospective trials (n=1917) reporting therapeutic efficacy data. The accuracy of correlative study revealed an overall sensitivity of 0.922 (95% confidence interval 0.888 to 0.948), specificity of 0.724 (95% CI 0.669 to 0.774) and an area under the sROC curve of 0.893 (SE=0.023, $p<0.001$). Studies comparing the clinical utility revealed a two-fold overall tumor response for an assay-guided therapy versus standard of care therapy (odds ratio 2.04, 95% CI 1.62 to 2.57, $p<0.001$). Similarly, patients who received assay-guided therapy compared to those who received standard of care or physician's choice had a significantly higher 1-year survival rate (OR 1.44, 95% CI 1.06 to 1.95, $p=0.02$). **Conclusions:** Despite various limitations of individual studies, the aggregate and fairly consistent evidence of these data suggests cytometric profiling to be accurate, to improve overall tumor response, and to increase 1-year patient survival. Given the enormous potential for our society, a well-designed and sufficiently-powered randomized controlled trial is urgently needed to validate these results.

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Receiver Operator Curve (sROC) for Assay Correlation with Clinical Response by Disease Type