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Development of regulatory biomarkers for identification of metallic allergens and non-allergens

Ying Mu[1] and **Chris Donahue**[2]
[1]U.S. Food and Drug Administration, USA
[2]National Institutes of Health, USA

The incidence of allergy/immunotoxicity-related post-market adverse events associated with medical devices is increasing. Biomarkers are commonly used in toxicology for risk assessment and clinically as diagnostic and monitoring tests. We developed a new *in vitro* model where human peripheral blood mononuclear cells (PBMC) isolated from four healthy donors were used to identify biomarkers that specifically respond to metallic allergens. Cells were exposed to well-known human metallic allergens and non-allergens for 24 hours. The cell surface markers were measured by employing flow cytometry. A primary goal was to determine whether the two cell types are transferable from the dendritic cell (DC) to the PBMC due to the clinical relevance of the PBMC. Of the 12 cell surface markers following the first tier selection, the expression of CD1X and CD86 on PBMC was confirmed and 3 other novel biomarkers were discovered (CD2X, CD3X and CD4X). The expression of CD1X on PBMCs was down-regulated significantly following exposure to three metallic allergens (cobalt (II) chloride, nickel (II) sulfate, potassium dichromate (VI)) while the expression remained the same when exposed to two metallic non-allergens (lead (IV) acetate, magnesium (II) chloride) compared to untreated PBMCs. Data from the all four donors showed the same pattern and the statistical value of CD1X alone yielded a p value<0.0001 and an accuracy greater than 95% based on receiver operating characteristic (ROC) analysis. We found the consistency of CD1X performance in PBMC even greater compared to that in DC. Data indicate that CD1X shows promise for use as a pre-clinical biomarker for screening potential allergenic responses to metal-containing devices. Further validation studies are planned.

ying.mu@fda.hhs.gov

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