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Title: Unique Cytokine Signature in the Serum of Women with Fibromyalgia

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Objectives: The objective of this study was to examine serum cytokine levels of women who participated in a cross-sectional, observational study conducted to characterize the relationships among perceived stress, pain, fatigue, depression, sleep quality, biomarkers, and functional status in women with FMS.

Background: Fibromyalgia (FMS) is a chronic pain syndrome with a complex but poorly understood pathogenesis affecting approximately 10 million adults in the United States. It is estimated that 90% of diagnoses are reported in women. The lack of a clear etiology of FMS has limited the effective diagnosis and treatment of this debilitating condition.

Methods: The protocol was approved by the Institutional Review Board (IRB) of Virginia Commonwealth University. Study participants were administered a set of questionnaires, followed by venipuncture and collection of a 3 cc blood sample for biomarker analysis. Blood samples were collected into heparinized Vacutainer tubes. All samples were analyzed for cytokine levels using the 17-plex Human Bio-Rad cytokine, chemokine, and growth factor assay kit (Bio-Rad; Hercules, CA).

Results: Post hoc analysis of serum cytokine levels was performed to determine if patterns appeared that were not specified a priori. Upon examination of the 17 cytokines/chemokines detected, patients with FMS exhibited increases in key patterns of cytokines that are consistent with a T helper cell type one signature. This TH1 skewed cytokine pattern was characterized by an elevated average serum IFN-gamma of 31.1 pg/mL (normal range 2-5 pg/mL) and decreased average serum IL-4. Furthermore there was a clear elevation in hematopoietic cytokines such as IL-7 (FMS 9.27 pg/mL, normal less than 1pg/mL) and GM-CSF (FMS 25.90 pg/mL, normal 2.5pg/mL).

Conclusion: The finding of a well-known inflammatory pattern of cytokine elevations not only supports the role of inflammation in FMS but may lead to more definitive diagnostic tools for clinicians treating FMS. The elevation of the hematopoietic cytokines provide strong evidence of immune dysregulation in patients with FMS.