



Serum Free Light Chain Analysis for the Diagnosis, Management, and Prognosis of Plasma Cell Dyscrasias: Future Research Needs: Future Research Needs Paper Number 23

U. S. Department of Health and Human Services, Agency for Healthcare Research and Quality

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Plasma cell dyscrasias (PCDs) are a group of clonal disorders characterized by the uninhibited expansion of a monoclonal population of malignant plasma cells. Plasma cells arise from B cells in the bone marrow and produce immunoglobulins that constitute the body's normal humoral immune response. The immunoglobulin molecule is composed of a heavy chain and a light chain. Plasma cells normally produce light chains in excess that do not bind to heavy chains to form a complete immunoglobulin molecule and instead enter the bloodstream as free light chains (FLCs). In PCDs, each abnormally expanded clone of malignant plasma cells produce an excess of either intact immunoglobulin or FLCs of a single type called a monoclonal protein (Mprotein) or paraprotein. The serum FLC (SFLC assay (the Freelite™ Assay, The Binding Site Ltd., Birmingham, United Kingdom) was introduced in 2001 to measure the FLC component in particular. The SFLC assay works by recognizing an epitope that is detectable only on light chains that are not bound to the heavy chain of the immunoglobulin molecule (i.e., FLCs) in the serum. It has been suggested that the SFLC assay could play an adjunctive role in screening, diagnosis, monitoring, and prognosis of PCDs in high-risk populations. The assay could allow for quantitative monitoring of response and remission after treatment and provide prognostic information, potentially reducing the need for frequent bone marrow biopsy for purposes of quantifying plasma cells, which is required as part of stringent monitoring for monoclonal gammopathy of undetermined significance (MGUS) progression to multiple myeloma (MM) or defining disease remission, and potentially could be used in conjunction with serum protein electrophoresis (SPEP) and serum immunofixation electrophoresis (SIFE) to replace urine tests that require 24-hour collection (urine protein electrophoresis [UPEP] and urine immunofixation electrophoresis [UIFE]), which could simplify diagnosis and disease monitoring. The SFLC assay may also be the only means of detecting a disease marker in some disease settings: nonsecretory MM, where SFLCs are often the only marker of the disease; AL amyloidosis (systemic amyloidosis in which amyloid [A] proteins derived from immunoglobulin light chains [L] are deposited in tissue), where low monoclonal protein (M-protein) concentrations may not be detected by means of conventional techniques; and light chain MM, where the M-protein consists only of FLCs. The following Key Questions are reviewed. KQ 1: Does adding the SFLC assay and the kappa/lambda ratio to traditional testing (SPEP, UPEP, SIFE, or UIFE), compared with traditional testing alone, improve the diagnostic accuracy for PCDs (MGUS, MM, nonsecretory MM, or AL amyloidosis) in undiagnosed patients suspected of having a PCD? KQ 2: As compared with traditional tests, how well does the SFLC assay independently predict progression to MM in patients with MGUS? KQ 3: In patients with an existing diagnosis of PCD (MM, nonsecretory MM, or AL amyloidosis), does the use of the SFLC assay result in different treatment decisions as compared with traditional tests? Does the use of the SFLC assay affect the management of patients by allowing for earlier institution of specific therapies? Does the use of the SFLC assay influence the duration of treatment? Does the use of the SFLC assay influence the type of treatment (e.g., radiation therapy)? KQ4: In patients with an existing diagnosis of PCD (MM, nonsecretory MM, or AL amyloidosis), is the SFLC assay better than traditional tests in indicating how the patient responds to treatment and of outcomes (overall survival, disease-free survival, remission, light chain escape, and quality

of life)? KQ 5: In patients with an existing diagnosis of PCD (MM, nonsecretory MM, or AL amyloidosis), does the use of the SFLC assay reduce the need for other interventions (e.g., bone marrow biopsy)?

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