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Medicine Based Evidence for Individualized Decision Making: Case Study of Systemic Lupus Erythematosis

Running Head: Medicine Based Evidence In Systemic Lupus

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Clinical Significance

- Evidence to guide treatment decisions for a given patient is a multi-dimensional longitudinal profile incorporating biological, clinical, psychological and social environmental information idiosyncratic to the particular patient.
- We developed a taxonomy of lupus patient histories in the context of response to a new therapy that provides an example of how far more nuanced information than that customarily made available from RCTs can be tuned to the needs of clinical practice.

ABSTRACT

To guide management decisions of an index patient evidence is required from comparisons between approximate matches to the profile of the index case, where some matches contain responses to treatment and others act as controls. We describe a method for constructing clinically relevant histories/profiles using data collected but unreported from two recent phase 3 RCTs assessing belimumab in subjects with clinically active and serologically positive SLE. Outcomes were the SRI (SLE Responder Index) measured at 52 weeks. Among 1175 subjects we constructed an algorithm utilizing 11 trajectory variables including 4 biological, 2 clinical and 5 social/behavioral. Across all biological and social/behavioral variables, the proportion of responders based on the SRI whose value indicated clinical worsening or no improvement ranged from 27.5% to 42.3%. Kappa values suggested poor agreement indicating that each biological and patient reported outcome provides different information than gleaned from the SRI. The richly detailed patient profiles

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