Patient- and Physician-reported Satisfaction With Systemic Lupus Erythematosus Treatment in US Clinical Practice

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ABSTRACT

Purpose: This two-part study comprised two descriptive, cross-sectional surveys to evaluate treatment satisfaction among patients with systemic lupus erythematosus (SLE) and their physicians from US clinical practices. The Lupus Plus Project (LPP; part one) involved belimumab-containing regimens; the Disease Specific Program (DSP; part two) included all treatments and was designed to build on the body of evidence from part one.

Methods: The LPP recruited patients receiving belimumab, and comprised 2 paper questionnaires: a patient self-completion questionnaire (PSC) and a patient record form (PRF) completed by the physician. The DSP enrolled patients with SLE receiving any treatment and comprised four parts: a PSC, a PRF completed by the physician after patient consultation, face-to-face physician interviews, and a workload form completed by the physicians to indicate their total SLE patient workload. The key objective of this study was to assess physician and patient satisfaction with current treatment.

Findings: From the PSCs, data regarding patient-reported satisfaction with current treatment were available for 263 patients who were receiving belimumab combination therapy (LPP) and 250 patients who were receiving non-belimumab treatment (DSP). The majority of patients (belimumab, 86.3% [227/263]; non-belimumab, 78.4% [196/250]) responded positively (at least "somewhat satisfied") when asked about current treatment satisfaction, as did physicians (belimumab, 82.9% [311/375]; non-belimumab, 74.3% [326/439]). In multivariate analysis, factors most strongly associated with patient-reported satisfaction for patients receiving belimumab were patient-reported improvements in leisure activities since taking belimumab (odds ratio [OR] = 4.66), physician-reported improvements in fatigue (OR = 3.72), patient-reported improvements in general symptoms (OR = 3.02), and pain/achiness (OR = 2.71). Physician satisfaction was associated with clinical outcome such as improvements in pain/achiness (OR = 6.16), fatigue (OR = 3.76), and patient-reported satisfaction with treatment frequency (OR = 3.91). In patients receiving other SLE treatments, dosing frequency of current treatment (OR = 3.64) and a reduction in fatigue severity (OR = 3.61) were most strongly associated with patient-reported satisfaction; physician satisfaction was most strongly associated with a reduction in fatigue (OR = 6.22) and current remission status (OR = 6.05).

Implications: When considering SLE treatment satisfaction patients tend to consider impact on daily functioning, whereas physicians take into account a wider range of clinical outcomes; however, both strongly consider improvements in fatigue. These surveys provide insights into treatment satisfaction among prescribers and patients with SLE. GSK-ClinicalStudyRegister.com identifiers: GSK study 202146 [HO 15-15509] and 205086 [HO 15-16709]. (*Clin Ther*. 2017;39:1811–1826)

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INTRODUCTION

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease with diverse manifestations, characterized by periods of remission and flare.[1,2] There is no cure for SLE; however, several classes of drugs are used to manage the disease, including corticosteroid (CS), antimalarial (AM), and immunosuppressant (IS) agents and non-steroidal anti-inflammatory drugs (NSAIDs).[3]

Belimumab is a human IgG1λ monoclonal antibody approved for the treatment of adult patients with active, autoantibody-positive SLE who are receiving standard SLE therapy (referred to as standard of care [SoC]). The safety profile and efficacy of belimumab have been reported in two Phase III studies, Belimumab in Subjects with Systemic Lupus Erythematosus (BLISS)-52 and BLISS-76, in patients with autoantibody-positive, active SLE.[4,5]

An open-label, continuation study of the BLISS studies has reported an acceptable safety profile of belimumab for 5 years,[6] and a continuation study of a Phase II study reported that efficacy and tolerability outcomes were maintained up to 7 years.[7] Patient satisfaction has been shown to correlate with medication compliance and adherence,[8] both of which are challenging in chronic conditions such as SLE.[9] It is therefore worthwhile to investigate physician and patient satisfaction with belimumab, to further evaluate the real-world benefit of belimumab plus SoC.

This study reports data collected from the Adelphi Real World (ARW) Lupus Plus Project (LPP) and the Lupus Disease Specific Program (DSP) surveys. The LPP explored the use of belimumab from both the physician and patient perspective within US clinical practice. The DSP was a larger study that enrolled patients with SLE receiving any treatment. Thus, the DSP provided an opportunity to build on the body of evidence in patients receiving belimumab, generated by the LPP, and to contextualize the findings in relation to outcomes in patients receiving non-belimumab regimens.

METHODS

Study Design

This study reports data collected as part of the LPP and DSP. The LPP was a descriptive cross-sectional real-world survey of US rheumatologists and patients with SLE receiving belimumab alone or in combination with standard SLE therapy, which was conducted for the first time. After the LPP, a descriptive cross-sectional survey of US rheumatologists and their patients with SLE (the DSP) was performed. DSP surveys use validated methods to generate data from clinical practice regarding treatment practices, resource use, and quality of life.[10,11] The Lupus DSP is conducted at regular intervals (previously in 2010 and 2013), and it also collected data from nephrologists and their patients with lupus nephritis; here, we focus on rheumatologists and patients with SLE. The LPP used specific sections of the previous Lupus DSP survey, and both surveys were developed by ARW independent of GlaxoSmithKline (GSK), using the Adelphi Disease Specific Programme method.[11] The LPP survey comprised two paper questionnaires: a patient record form (PRF) completed by the physician and a patient self-completion questionnaire (PSC). The DSP survey consisted of four parts: physician interviews conducted face to face with participating physicians, a PRF completed by the physician after a patient consultation, and a PSC. A workload form was also completed in both surveys by the physicians to indicate their total SLE patient workload.

GSK sponsored an analysis of the anonymized data and prospectively added questions pertinent to the use of belimumab and/or current treatment and the management of SLE. The LPP survey was concluded 5 months before the DSP.

The number of physicians and patients who were satisfied with treatment was assessed. Satisfaction according to various factors was assessed, including demographic and disease characteristics and status and quality of life outcomes. Factors that were associated with satisfaction were identified. Tolerability was not assessed in this study; however, treatment-related adverse events recorded in the PRF and PSC were reported to GSK.

Study Population

For both arms of the study, eligible patients had a current, confirmed SLE diagnosis, were receiving marketed treatment for SLE (a small number of patients were also receiving rituximab), were ≥18 years of age, and were managed by a rheumatologist actively involved in the management of ≥4 (LPP) or ≥5 (DSP) patients with SLE per typical month. Board-certified rheumatologists who qualified as a