Pooled Analysis of the Real-World Effectiveness of Belimumab in Treatment of Systemic Lupus Erythematosus Using Multi-Country Data from the OBSErve Studies

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Introduction

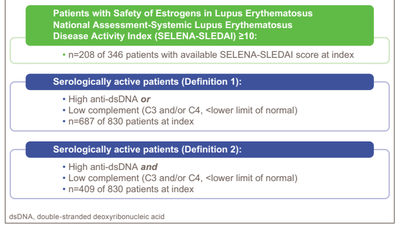
- Systemic lupus erythematosus (SLE) is a chronic autoimmune disease with various clinical presentations, making it a complex disease to manage[1]
- Belimumab is a B-cell-activating factor (BAFF)-specific inhibitor indicated for the treatment of patients with active, autoantibody-positive SLE[2–5]
- Utilisation patterns and the clinical benefit of belimumab in patients with SLE in real-world clinical practice have been studied separately in several countries[6–11] through the OBSErve (evaluation Of use of Belimumab in clinical practice SEttings) programme
- This study pools individual patient data from the OBSErve studies[6–11] to further evaluate the effectiveness of belimumab in a large sample of patients with SLE

Methods

Objectives

- Primary: to describe physician-assessed overall clinical response to belimumab at Month 6, i.e. the physicians' impression of change in overall clinical manifestations
- Secondary objectives included:
  - Belimumab treatment patterns and concomitant glucocorticosteroid (GC) use during 6 months of belimumab treatment
  - The physician-assessed overall clinical response at Month 6 amongst patient subgroups

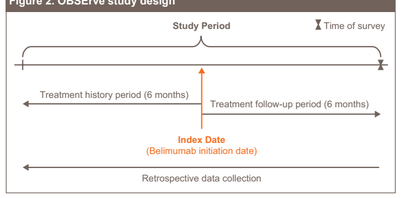
Figure 1. Patient subgroups



Study design

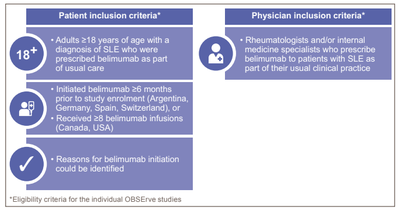
- This was a *post hoc* meta-analysis (GSK study 206351) of patient-level data pooled from six retrospective observational cohort studies (Argentina, Canada, Germany, Spain, Switzerland, United States of America [USA])[6–11] (**Figure 2**)

Figure 2. OBSErve study design



Study population

- The study population included all patients from the individual OBSErve studies



Statistical analyses

- Descriptive statistics were used to summarise continuous and categorical data
- A generalised linear ordinal regression model was fitted to estimate the clinical response to belimumab at Month 6, while accounting for countries, patients' characteristics and disease severity at index

Results

Baseline characteristics

- Data from 830 patients were pooled and analysed:

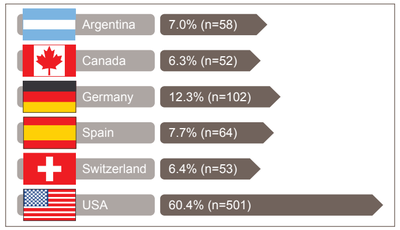
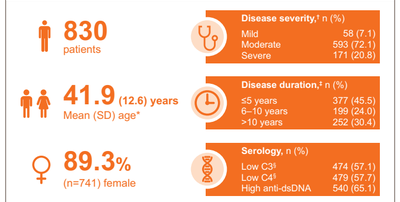


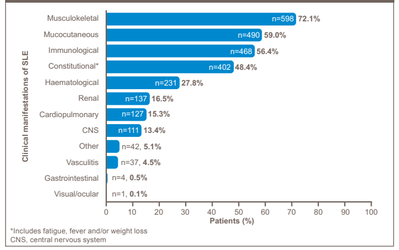
Figure 3. Baseline demographics and disease characteristics



Results (continued)

- At index, patients presented with a range of manifestations, with musculoskeletal, mucocutaneous and immunological being the most common (**Figure 4**)
- At index, the majority of patients had a SELENA-SLEDAI score ≥10 and/or were serologically active (**Figure 1**)

Figure 4. Clinical manifestations of SLE at index



Clinical improvements after 6 months of belimumab treatment

Figure 5. Physician-assessed overall clinical improvement at Month 6 in the overall population (A), and among serologically active patients and those with SELENA-SLEDAI ≥10 (B)

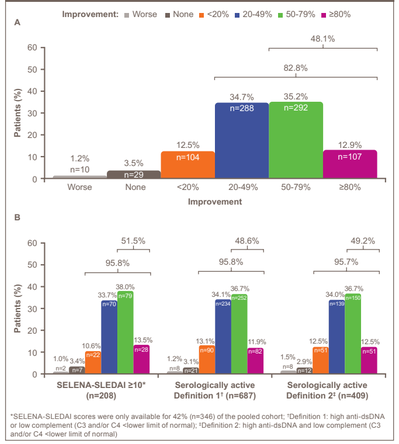


Figure 6. Predictors of a large (≥50%) physician-assessed overall clinical improvement following 6 months of belimumab treatment based on different baseline characteristics

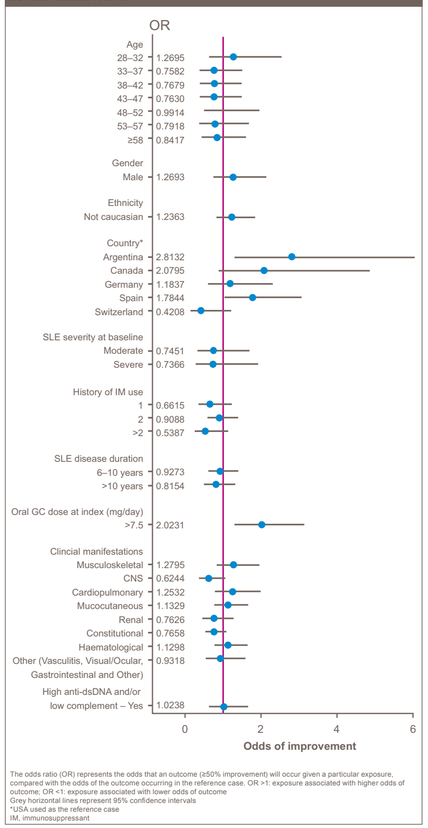
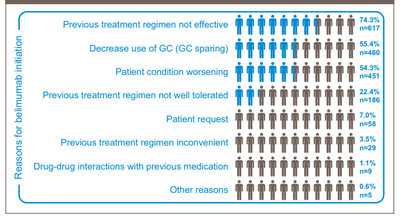
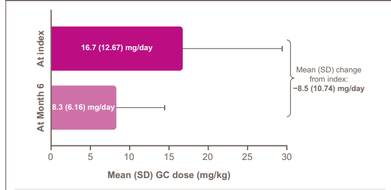


Figure 7. Reasons for belimumab initiation



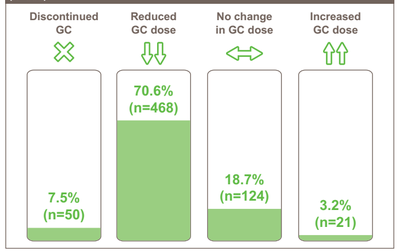
- Data on belimumab discontinuation were available for patients from Argentina, Germany, Spain and Switzerland only (n=277). Overall, 4.3% (n=12) of patients discontinued belimumab during 6 months of treatment
  - The most common reasons for belimumab discontinuation were patient request and ineffective treatment (both n=4, 33.3%), and adverse event and disease progression (both n=3, 25.0%)

Figure 8. Change in mean oral GC dose at Month 6



Among those with >7.5 mg/day dose of oral prednisone-equivalent GC at index (n=526, 79.3%), 52.6% (n=258/491) reduced their GC dose to ≤7.5 mg/day

Figure 9. Change in oral GC use during 6 months of belimumab treatment (n=663)



Conclusions

- This study provides important real-world insights into outcomes in a large multinational sample of patients with SLE treated with belimumab
  - Study limitations: the primary endpoint was based on the subjective clinical judgement of the treating physician, and the study did not include a control group to compare belimumab treatment with other standard SLE therapies
- After 6 months of treatment with belimumab, the majority of patients demonstrated clinical improvements in SLE; results were consistent between the pooled population and patients with SELENA-SLEDAI ≥10 or serologically active
- High prednisone-equivalent GC dose (>7.5 mg/day) at belimumab initiation was significantly associated with ≥50% overall clinical improvement at Month 6
- Belimumab was GC sparing; 78.1% of patients receiving oral GC at belimumab initiation decreased their dose or discontinued GC after 6 months of belimumab treatment

References

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