REAL WORLD EXPERIENCE WITH BELIMUMAB IN SYSTEMIC LUPUS ERYTHEMATOSUS IN A THIRD LEVEL HOSPITAL

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Introduction

- Belimumab (BLM), is a human monoclonal IgG1 antibody, which inhibits the activity of soluble BLyS (B cell survival factor), with specific indication for the treatment of patients with systemic lupus erythematosus (SLE) and inadequate response to conventional treatment.

- **Objectives :** To evaluate clinical effectiveness of belimumab for SLE in a third level Hospital setting in León, Spain.

Methods and patients

- **Study**: observational, descriptive and retrospective study with SLE who initiated belimumab at least 6 months before data analysis and had a minimum observation period of 12 months without discontinuing treatment

- **Patients:** diagnosed with SLE (SLICC criteria), treated with intravenous and subcutaneous BLM.

- **Outcomes:**
  - **Primary outcome:** overall clinical response to treatment.
  - **Secondary outcome:** improvement in disease activity, SLE manifestations and changes in corticosteroid dose

- **Variables:**
  - **General patient data:** age, sex.
  - **General SLE data:** evolution time of the disease; clinical, serological and immunological; SLEDAI-2k activity; previous treatments (DMARDs, immunosuppressants), corticosteroids and mean dose (mg/day).
  - **During BLM treatment**: SLEDAI-2k index during treatment, changes in immunological and hematological data; outbreaks, complications and mean corticosteroid dose (mg/day).

Results:

Nº patients	**33**
Female (n, %)	21 (63%)
Mean age in years (IQR)	38.1 (24.9-51.3)
Time since SLE diagnosis in years (IQR)	12.6 (5.75-19.45)
Mean time BLM in months (IQR)	16.8 (15-18.6)

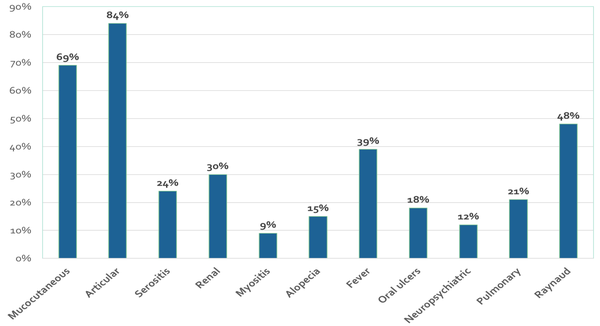
Table 1: General data

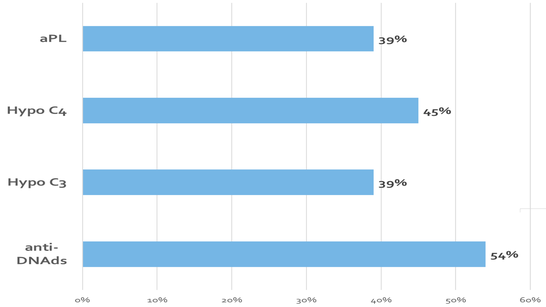
Discussion

- 33 patients (63% female) were included. At index, 6% had mild, 73% had moderate, and 21% had severe SLE.
- After 12 months, overall improvement in disease activity in patients was: ≥70% in 6%, ≥50% in 12%, ≥20% in 51%, <20% in 15%, and no improvement in 24%.
- Mean SLE Disease Activity Index score decreased from 10.0 at index to 7.9 at 6 months in the 33 patients assessed.
- A ≥30% improvement in arthritis, ≥40% in fatigue, ≥40% in mucocutaneous manifestations and ≥20% in low and anti-dsDNA antibody levels was experienced 12 months.
- 3 discontinued treatment before 12 months. At index, 87% received oral corticosteroids at a mean dose of 11.6 mg/day, which decreased to 7.6 mg/day at 12 months.
- Of the 12 patients receiving a high dose of corticosteroids (≥7.5 mg/day) at index, 42% were able to decrease dose and 2 discontinued corticosteroids after 12 months.

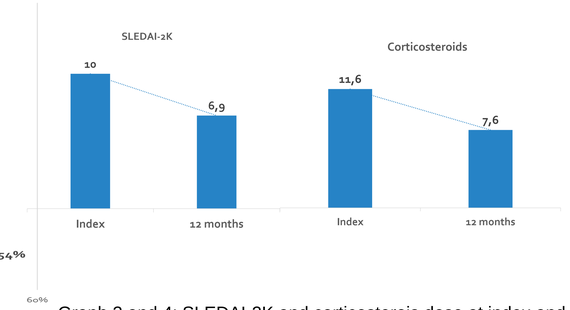
Conclusion:

Patients with SLE who received belimumab demonstrated clinical and serological improvement and a reduction in corticosteroid use after 12 months of treatment.





Graph 1 and 2: Clinical and serological data at index



Graph 3 and 4: SLEDAI-2K and corticosterois dose at index and after 12 months

Indication for BLM	
Cutaneous	9 (27%)
Renal	4 (12%)
Articular	17 (51%)
Serological	6 (18%)
Haematological	2 (6%)
Pulmonary	3 (9%)

Table 2: Indication for BLM

Time since SLE diagnosis in years	
<10 years	11 (33%)
10-20 years	15 (45%)
>20 years	7 (21%)

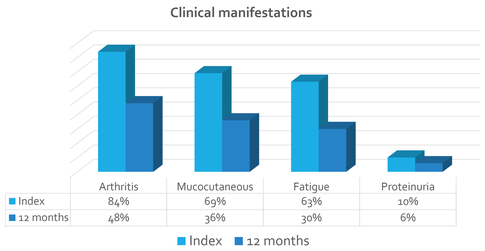
Table 3: Time since SLE diagnosis

Previous treatments	
Azathioprine	9 (27%)
Methotrexate	6 (18%)
Rituximab	5 (15%)
Mycophenolate	1 (3%)
Cyclosporine	1 (3%)
Concomitant treatments	
Hydroxychloroquine	33 (100%)
Azathioprine	1 (3%)
Methotrexate	11 (33%)
Mycophenolate	3 (10%)

Table 4: Concomitant and previous treatments

Security data with BLM	
Withdraw	3 (10%)
Infusion reactions	0 (0%)
Side effects	3 (10%) - 3 infection: 1 herpes zoster, 1 foliculitis, 1 UTI

Table 5: Security data with BLM



Graph 5: Clinical manifestations at index and after 12 months

References

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