Belimumab in Belfast

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Introduction

Belimumab, a fully humanised m-ab against B-LyS has been licensed and approved for the treatment of antibody positive SLE since 2015[1], with recent encouraging data from EULAR suggesting promise in the treatment of lupus nephritis[2].

Methods

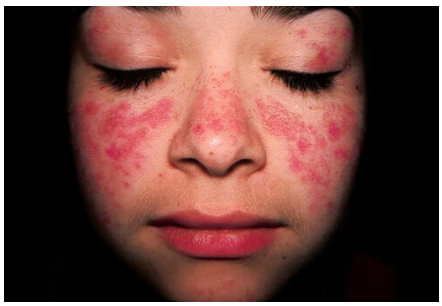
Six female patients were treated with belimumab in Musgrave Park Hospital from 2015-20 (mean age 52yrs old, range 47-56). Mean treatment duration was 13 months and 3 patients remain on treatment at the time of reporting.

Prior to treatment, mean SLEDAI-2K score was 10 (range 2-20). Two patients' dsDNA levels measured >300. There were multiple other antibody positivities. Complement levels were low in five patients.

Four patients had received previous mycophenolate, cyclophosphamide and rituximab. Hydroxychloroquine, azathioprine, methotrexate and ciclosporin were also used. One patient received no steroids throughout the period studied. One patient was taking 6mg deflazacort and the other four were on a mean dose of 24mg prednisolone (range 15-40mg) prior to starting belimumab.

	Steroid dose pre Belimumab	Steroid dose post Belimumab	SLEDAI-2k pre-Belimumab	SLEDAI-2k post-belimumab
Patient 1	nil	nil	2	2
Patient 2	Deflazacort 6mg	Deflazacort 12mg	20	7
Patient 3	Prednisolone 20mg	Prednisolone 20mg	7	7
Patient 4	Prednisolone 15mg	Prednisolone 10mg	10	6
Patient 5	Prednisolone 20mg	Prednisolone 10mg	10	2
Patient 6	Prednisolone 40mg	Prednisolone 10mg	11	4

References
1. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. Furie et al. *Arthritis Rheum* 2011; 63(12): 3918-30.
2. OP0164 BLISS-LN: A randomised, double-blind, placebo-controlled phase 2 trial of intravenous belimumab in patients with active lupus nephritis. Furie et al. *Annals of the Rheumatic Diseases* Jun 2020, 79 (Suppl 1): 10



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Results

Following treatment mean SLEDAI score was 4.7 (range 2-7). DsDNA remained unchanged in 4 patients, fell from >300iu/mL to 73iu/mL in 1 patient and increased from 7iu/mL to >300iu/mL in 1 patient. Both C4 and C3 increased in 4 patients and decreased in 2 patients. Only in two patients did previously low complement levels improve to the normal range.

All patients reported a subjective improvement in health on belimumab, though one later deteriorated on treatment. Skin and joints responded most significantly although one patient also had an improvement in urinary ACR.

Two patients had mental health side effects, including suicidal ideation in one patient which led to treatment cessation. The other also experienced recurrent chest infections and fatigue which led to treatment cessation. No other side effects were reported.

One patient's steroid dose reduced significantly from 40mg to 10mg prednisolone during treatment. Four patients were on a mean dose of 12.5mg (range 10-20mg) at the time of reporting.

Conclusion

In summary, belimumab treatment was associated with a definite improvement in skin and joints and resulted in a significantly reduced dose of prednisolone for our patients. One patient also had an improvement in urinary ACR during treatment. Biochemical values did not improve markedly during treatment. Mental health side effects were experienced by two out of six of our patients. The majority of our patients had required extensive previous treatment including cyclophosphamide and rituximab. In light of emerging evidence that belimumab is a viable option for SLE patients, we will explore increased prescription of this drug with ongoing caution regarding mental health side effects.