

Comparison of biosimilar rituximab (Truxima®) to the originator (Mabthera®) in patients with lupus nephritis

Dr. Jennifer O'Brien¹, Dr. Pek Ghe Tan¹, Dr. Tom Cairns^{1,2}, Professor Liz Lightstone^{1,2}

¹Imperial Lupus Centre, Imperial College Healthcare NHS Trust, London, United Kingdom, ²Centre for Inflammatory Disease, Dept of Immunology & Inflammation, Imperial College London, London, UK

Background and aims:

Rituximab, an anti CD20 monoclonal antibody (mAb) is increasingly used for the treatment of lupus nephritis (LN). A biosimilar version of rituximab, 'Truxima' has been available since 2017. Biosimilar medications offer the advantage of lower financial cost to the originator drug whilst maintaining quality and efficacy. Currently, Truxima costs less than half the price (44%) of the reference drug, Mabthera. We aimed to examine the efficacy of Truxima when compared to Mabthera in the treatment of patients LN.

Method:

All patients with biopsy proven LN treated with rituximab from 1st January 2016 to 1st September 2019 were identified using a local histopathology database and a pharmacy dispensary database. They were stratified into "Truxima" or "Mabthera" groups depending on which form of rituximab was administered. Patients who had previously received rituximab or cyclophosphamide, those who received rituximab concurrently with plasma exchange or cyclophosphamide and those with <3 months follow-up were excluded.

Primary outcomes assessed included time to B-cell depletion (defined as an absolute B-cell count (ABC) of <10) and time to B-cell repletion (ABC ≥ 10). Secondary outcomes assessed included time to complete and partial remission (defined as urine protein creatinine ratio (uPCR) <50mg/mmol plus estimated glomerular filtration rate (eGFR) ≥ 60ml/min/1.73m² or not >20% below baseline, and uPCR >50% improvement from baseline and <300mg/mmol if >300mg/mmol at baseline, plus eGFR not >20% below baseline respectively); infection rates (defined as infections requiring admission or administration of antibiotics) and infusion reactions.

Results:

21 and 15 patient received Truxima and Mabthera respectively as part of our standard steroid minimising protocol 'Rituxilup' for biopsy proven lupus nephritis. 32 (89%) were female. There were no differences between the two groups in terms of follow-up time; baseline demographics (age, gender); serum creatinine (sCr); serology at time of treatment; extra-renal involvement or lupus nephritis class (27 were Class III or Class IV +/- Class V, according to ISN/RPS classification system).

There was no difference in days to B-cell depletion (p=0.78) or B-cell repletion (p=0.33). The median number of days to depletion overall was 27 (IQR 18-49) and days to repletion was 160 (IQR 111-237).

16 (76%) patients and 9 (60%) patients in the Truxima and Mabthera groups respectively achieved complete or partial remission (p=0.45), with a median time overall of 125 days (IQR 79-239).

Rate of infections requiring admission (Truxima: 4, Mabthera: 2, p=1) or rates of major infusion reaction (Truxima: 2, Mabthera: 1, p=0.76) were comparable.

Conclusion:

Reassuringly, the biosimilar anti CD20 mAb Truxima appears equivalent in terms of efficacy and safety when compared to the originator, Mabthera, in our group of patients. Its use may improve cost-effectiveness of treatment of lupus nephritis and in this cohort meant a saving of approximately £22,000.