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P376 -Clinical evaluation of biosimilar anti-CD20 monoclonal antibody with Rituximab in the treatment of ANCA-Associated Vasculitis

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Background:

Rituximab (RTX) an anti-CD20 monoclonal antibody has proven effective both for the induction and maintenance of remission in ANCA-associated vasculitis (AAV), refractory SLE and other glomerulonephritides. In April 2017, Truxima®, the first biosimilar version of rituximab launched in the UK. We performed a clinical evaluation of MabThera® compared to the newly licensed Truxima® in our centre.

Method

We conducted a retrospective review of 242 patients with AAV, SLE and other forms of glomerulonephritis. Each patient received at least one form of RTX (either MabThera© or Truxima©) between 2010 and 2018. The median (IQR) period of follow up was 2.9 (1.5-4.8) years. We collected data on patient demographics, cumulative doses, and clinical and biochemical outcomes after treatment. Outcomes were measured using CD19 depletion (defined as CD19+ cell count of <0.005x109 cells/L in peripheral blood at 6 months), with a combination of eGFR, uPCR and immunoglobulin titres throughout treatment and at last follow-up (LTFU). We included rates of adverse events (including anaphylaxis, fever and rash) and relapses in each group. Relapses were defined as either clinical or biochemical evidence in the form of eGFR and/or uPCR. Rates of CD19 depletion, relapse and adverse events were compared between patients in the MabThera© and Truxima© groups.

Result

Of the 242 patients receiving anti-CD20 therapy, 192 (79.3%) patients received MabThera© and 45 (20.7%) Truxima© as the initial preparation of RTX treatment. There was a significant improvement in eGFR and reduction in proteinuria in both preparations at LTFU (both $p<0.05$). The percentage of patients who became CD19 B cell deplete at six months was 70.7% (116/164) in the MabThera© group and 94.3% (33/35) with Truxima© ($p=0.002$). There was one episode of reported anaphylaxis in the MabThera© group. There was no significant difference between the two preparations in AAV patients with regards to the proportion of B cell depleted patients at 6 months (Fischer's exact test; $p=0.5207$). There was a reduction in proteinuria in MabThera© ($p<0.001$) and in Truxima© ($p=0.05$) in AAV patients at LTFU. A subpopulation comparison of the two preparations received by patients with AAV is shown in Table 1.

Conclusions

We report equivalence in clinical efficacy and safety of the biosimilar anti-CD20 monoclonal antibodies MabThera© and Truxima©, especially in the treatment of AAV. With biosimilars being used increasingly in clinical practice, this comparable profile can provide reassurance for the use of Truxima©, and improve cost-effective access to Rituximab.