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Systemic lupus erythematosus (SLE)

New data show advantage of add-on therapy with belimumab in lupus nephritis

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ABSTRACT: If renal remission is achieved therapeutically in cases of lupus nephritis (LN), the 10-year survival rate increases significantly. Successful therapy is therefore of great importance. As a recent presentation at the ERA-EDTA Congress showed, this can be achieved by additional administration of belimumab.

Systemic lupus erythematosus (SLE) is a chronic, inflammatory, autoimmune disease, in which damage is caused to multiple organs and tissues by the formation and deposition of immune complexes (antigen-antibody complexes). The kidneys are also affected in about half of the patients when immune complexes accumulate in the glomeruli, resulting in a glomerulonephritis called lupus nephritis (LN). The severity of LN varies considerably, ranging from unnoticed, to acute and/or chronic terminal kidney failure despite intensive therapy.

LN is a determining factor for SLE outcomes. Patients with LN have a significantly higher mortality risk than patients with SLE without kidney involvement. If remission is achieved therapeutically in cases of LN, the 10-year survival rate increases significantly. Successful therapy is therefore of great importance.

Patients with LN are treated with immunosuppressive and anti-inflammatory therapies. The standard medications used include corticosteroids, cyclophosphamide, calcineurin inhibitors, azathioprine and mycophenolate acid. Another therapeutic approach is to neutralize "soluble human B lymphocyte stimulator protein" (BLyS), which is overexpressed in patients with SLE and which stimulates the growth of B lymphocytes. Belimumab is a human monoclonal antibody that binds to BLyS and blocks its activity on B cells.

Data from the BLISS-LN study [1] – a randomised, double-blind placebo-controlled trial that included 448 adult patients with active LN and presented today as a "Late Breaking Clinical Trial" at the ERA-EDTA Congress – showed that after 2 years of treatment the addition of belimumab to standard LN therapy resulted in a significantly better primary renal response at 104 weeks (43% vs 32% with placebo, p=0.0311; composite primary endpoint defined as urine protein creatinine ratio [uPCR] ≤0.7; estimated glomerular filtration rate [eGFR] no more than 20% below pre-flare value or ≥60 ml/min/1.73 m^2; no rescue therapy). The addition of belimumab to standard therapy also resulted in significantly more complete renal responses after 2 years: 30% vs 19.7% with placebo (p=0.0167). During the study, patients treated with belimumab had 50% less risk vs placebo of experiencing renal events that are associated with increased risk of poor renal prognosis (p=0.0014).

Two different standard LN therapy regimens were used – 118 patients received cyclophosphamide-based induction therapy followed by azathioprine maintenance of remission, and 328 patients received mycophenolate mofetil (MMF)-used for induction and maintenance of remission therapy. Benefits of belimumab were demonstrated on background of both standard therapies, although less treatment effect for improving renal response was shown in patients who were receiving induction with cyclophosphamide followed by maintenance of remission with azathioprine. Reduction of renal events associated with increased risk of poor renal prognosis was demonstrated on background of both standard therapies.

"MMF is already used in many patients. It has been shown to be equivalent to cyclophosphamide in the induction therapy of LN, and superior to azathioprine in the maintenance phase. Adding belimumab can further improve the treatment results", explains Dr Brad Rovin, from the Ohio State University, Division of Nephrology, Columbus, United States, who presented the study results at the ERA-EDTA congress.

The study showed no safety signals; the incidence of side effects was similar in both groups.

[1] Brad Rovin et al. EFFICACY AND SAFETY OF BELIMUMAB IN PATIENTS WITH ACTIVE LUPUS NEPHRITIS: A PHASE 3, RANDOMISED, PLACEBO-CONTROLLED TRIAL. LBCT 4544, presented at the ERA-EDTA Congress 2020.

About ERA-EDTA

With more than 7,000 active members, the ERA-EDTA is one of the biggest nephrology associations worldwide leading European nephrology and one of the most important European Medical Associations. It organizes annual congresses and other educational and scientific activities. ERA-EDTA also produces guidelines, collects data, and performs epidemiological studies through its Registry. The Society supports fellowships and educational/research projects through its committees and working groups. Its publications are NDT, CKJ (Open Access journal), and the online educational journal NDT-Educational.
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