comes did not differ significantly; serious adverse events MMF 32/70 (46%) vs. CYC 27/70 (39%) (RD 7%, 95% CI –9 to 23%), serious infections MMF 18/70 (26%) vs. CYC 11/70 (16%) (RD 10%, 95% CI –3 to 23%), dialysis MMF 2/70 (3%) vs. CYC 3/70 (4%) (RD –1%, 95% CI –8 to 5%), death MMF 5/70 (7%) vs. CYC 4/70 (6%) (RD 1%, 95% CI –7 to 10%).

Conclusion.– In the primary analysis we were unable to demonstrate that MMF is non-inferior to IV CYC for remission induction at six months in newly diagnosed AAV. How, glucocorticoid treatment affects remission induction with MMF requires further study. Longer term safety outcomes and relapse data are required to fully understand the role of MMF as induction therapy for severe AAV.

http://dx.doi.org/10.1016/j.jlpm.2013.02.067

A66 Rituximab versus azathioprine for maintenance in ANCA-associated vasculitis. A prospective study in 117 patients


Introduction.– Once ANCA-associated vasculitis (AAV) remission has been achieved with CS and cyclophosphamide (CYC), maintenance therapy usually relies on azathioprine (AZA) or methotrexate. However, 28-month relapse rate remains of 28%. Although rituximab (RTX) has been demonstrated to be as effective as CYC for induction of complete remission by 6 months, some studies showed that half of the patients without maintenance relapsed within 2 years. The results of a prospective, randomized TRIL trial of RTX vs. AZA to maintain AAV remission are reported.

Patients.– Once remission was obtained with a conventional regimen, patients with newly diagnosed or relapsing AAV were randomly assigned to receive a 500-mg RTX infusion on D1, D15, 5.5 months later, then every 6 months for a total of five infusions over 18 months, or AZA for 22 months (2 mg/kg/d). The primary endpoint was the major relapse rate at 28 months. Other outcome measures were the severe adverse event (SAE) rate associated with maintenance regimen.

Results.– Among the 117 patients (66 men/51 women; mean age, 55 ± 13 years; 93 newly diagnosed and 24 relapsers) participating in the study (59 in the AZA arm, 58 in the RTX arm): 89 had GPA, 23 MPA and five kidney-limited diseases. The main clinical manifestations at diagnosis or relapse included ENT involvement in 88 (77.2%), lung in 69 (60.5%) and kidney in 82 (71.9%). Creatininemia was 185 ± 184 μmol/L. All patients have completed their follow-up. Major relapses have occurred in 18 (15.7%) patients: three (5.4%) in the RTX arm and 15 (25.4%) in the AZA arm, with two AZA-arm deaths (one sepsis, one pancreatic cancer). Thirty-three experienced SAE: 18 related to AZA, 15 to RTX. In the AZA arm, 12 infections (one fatal) and one skin cancer were observed vs. 11 infections (none fatal) in the RTX arm.

Conclusion.– This study demonstrated that 500 mg of RTX every 6 months was superior to AZA to maintain AAV remission. The infection frequencies were comparable in the two arms, and other SAE were infrequent and resolved in most patients.

http://dx.doi.org/10.1016/j.jlpm.2013.02.068

A67 Treatment of systemic necrotizing vasculitides in patients ≧ 65 years old: Results of the multicenter randomized CORTAGE trial


Introduction.– Trial aim was to optimize the therapeutic strategy for patients ≧ 65 yo with SNV (PAN, GPA, MPA or EGPA).

Patients.– Multicenter RCT on patients ≧ 65 yo with newly diagnosed SNV to compare conventional therapy (based on FMS: for all, ~28 mo of CS alone, combined with 500-mg/m2 CYC IV pulses every 2–3 wk