

Mycophenolate mofetil and tacrolimus versus tacrolimus alone for the treatment of idiopathic membranous glomerulonephritis – A randomised controlled trial.

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Background:

Tacrolimus (TAC) is effective in treating membranous nephropathy (MN); however relapses are frequent after treatment cessation. We conducted a randomised controlled trial to examine whether the addition of mycophenolate mofetil (MMF) to TAC would reduce relapse rate.

Methods:

40 patients with biopsy proven idiopathic MN and nephrotic syndrome were randomly assigned to receive either TAC monotherapy (n=20) or TAC combined with MMF (n=20) for 12 months. When patients had been in remission for 1 year on treatment the MMF was stopped and the TAC gradually withdrawn in both groups over 6 months. Patients also received supportive treatment with angiotensin blockade, statins, diuretics and anticoagulation as needed. Primary endpoint was relapse rate following treatment withdrawal. Secondary outcomes were remission rate, time to remission and change in renal function.

Results:

16/20 (80%) of patients in the TAC group achieved remission compared to 19/20 (95%) in the TAC/MMF group (p=0.34). The median time to remission in the TAC group was 54 weeks compared to 40 weeks in the TAC/MMF group (p=0.46). There was no difference in the relapse rate between the groups: 8/16 (50%) patients in the TAC group relapsed compared to 8/19 (42%) in the TAC/MMF group (p=0.7). The addition of MMF to TAC did not adversely affect the safety of the treatment.

Conclusions:

Addition of MMF to TAC does not alter the relapse rate of nephrotic syndrome in patients with MN.