

Treatment of polyarteritis nodosa and microscopic polyangiitis with poor prognosis factors: a prospective trial comparing glucocorticoids and six or twelve cyclophosphamide pulses in sixty-five patients.

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OBJECTIVE:

Because the optimal cyclophosphamide (CY) treatment duration for severe polyarteritis nodosa (PAN) without virus infection and microscopic polyangiitis (MPA) has not been established, we conducted a trial to compare the effectiveness of 6 versus 12 CY pulses given in combination with corticosteroids (CS).

METHODS:

Sixty-five (18 PAN, 47 MPA) previously untreated patients were randomized to receive 12 (n = 34) or 6 (n = 31) CY pulses combined with CS. PAN and MPA were histologically proven or met ACR criteria. All patients presented ≥ 1 factor of severity according to the five factor score (FFS). CY pulses were administered every 2 weeks for 1 month, then every 4 weeks. The end point of the study was the number of events (relapses and/or deaths) occurring in each group, analyzed according to an intention-to-treat strategy. The outcome was evaluated by Cox proportional hazards analysis.

RESULTS:

The baseline characteristics were similar for both groups. The mean (+/- SD) followup was 32 +/- 21 months. Survival analysis showed a significantly lower relapse probability (P = 0.02; hazards ratio [HR] = 0.34) and higher event-free survival (P = 0.02, HR = 0.44) for the 12 CY-pulse group while the mortality rates were not significantly different (P = 0.47).

CONCLUSION:

These results suggest that 6 CY pulses are less effective than 12 CY pulses to treat severe PAN and MPA, particularly with respect to the risk of relapses.