NLM AIDSLINE

Combination foscarnet and ganciclovir therapy vs monotherapy for the treatment of relapsed cytomegalovirus retinitis in patients with AIDS: The cytomegalovirus retinitis. retreatment trial

Jabs DA

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Purpose: In order to determine the best therapeutic regimen for treatment of cytomegalovirus (CMV) retinitis which has relapsed, 279 patients with the acquired immune deficiency syndrome (AIDS) and either persistently active or relapsed CMV retinitis were enrolled in a multicenter, randomized, controlled, clinical trial. Patients were randomized to one of 3 regimens: induction with foscarnet at 90 mg/kg intravenously (IV) every 12 hours for 2 weeks, followed by maintenance at 120 mg/kg/day (Fos); induction with ganciclovir at 5 mg/kg IV every 12 hours for 2 weeks followed by maintenance at 10 mg/kg/day (Gcv); continuation of previous maintenance therapy plus induction with the other drug (either or ganciclovir or foscarnet) for 2 weeks followed by maintenance with both drugs, ganciclovir at 5 mg/kg/day and foscarnet at 90 mg/kg/day (Cmb). Results: Mortality was similar among the 3 groups; median survivals were: Fos, 8.4 months; Gcv, 9.0 months; Cmb, 8.6 months(p=0.894). Analysis of retinitis progression, as evaluated in a masked fashion by a centralized Fundus Photograph Reading Center, revealed that Cmb was the most effective regimen for controlling the retinitis. Median times to progression were: Fos, 1.3 months; Gcv, 2.0 months; Cmb, 4.3 months (p=0.000008). Switching from one monotherapy to another was no more effective than remaining on the same drug (adjusted relative risk for progression=1.00, p=0.983). Although no difference could be detected in visual acuity outcomes, visual field loss and retinal area involvement both paralleled the progression results with the most favorable results in the Cmb group. Rates of visual field loss were: Fos, 28%/month; Gcv, 18%/month; Cmb, 16%/month (p=0.009); and rates of increase of retinal area involved by CMV were: Fos, 2.47%/month; Gcv, 1.40%/month; Cmb, 1.19%/month (p=0.041). Although side effects were similar among the three treatment groups, combination therapy was associated with the greatest negative impact of treatment on guality of life measures. Conclusions: For patients with AIDS and relapsed CMV retinitis who can tolerate both drugs, combination therapy appeared to be the most effective therapy for controlling CMV retinitis.

Acquired Immunodeficiency Syndrome/*COMPLICATIONS Antiviral Agents/ADMINISTRATION & DOSAGE/*THERAPEUTIC USE Cytomegalovirus Retinitis/COMPLICATIONS/*DRUG THERAPY Drug Therapy, Combination Foscarnet/ADMINISTRATION & DOSAGE/*THERAPEUTIC USE Ganciclovir/ADMINISTRATION & DOSAGE/*THERAPEUTIC USE Quality of Life Recurrence Treatment Outcome ABSTRACT

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