Drug Monitor

Treating Trichomoniasis

Trichomoniasis, a sexually transmitted disease that is caused by *Trichomonas vaginalis* and affects 3% of American women, is commonly treated with one of two FDA-approved nitroimidazoles: metronidazole or tinidazole. Some patients are hypersensitive to nitroimidazoles, however, and research into alternative treatments—such as metronidazole desensitization and intravaginal treatments—has been limited.

To determine which alternative treatments are most effective, researchers from the CDC and Emory University, both in Atlanta, GA, looked at treatment and outcome data for 59 patients who had both the disease and suspected metronidazole hypersensitivity. These data were collected from providers who contacted the CDC between September 2003 and September 2006 for advice on treating such patients. The patients' suspected reactions to metronidazole included urticaria and facial edema.

Of the 41 patients who were treated for *T. vaginalis* infection following their providers' consultations with the CDC, nine were given metronidazole or tinidazole because they had no clear history of metronidazole hypersensitivity. Seventeen patients were treated with one of a variety of intravaginal drugs, and outcome data were available for 12 of these patients. Fifteen patients were treated with oral or intravenous metronidazole desensitization, and outcome data were available for all of them.

Metronidazole desensitization proved to be extremely effective: All of the patients who received it were cured. Furthermore, only two of these patients experienced adverse effects, which the researchers describe as "minimal." (One patient developed a pruritic rash and another experienced mild urticaria and pruritus that was managed with diphenhydramine.)

Intravaginal drugs, in contrast, cured only five (42%) of 12 patients. *T. vaginalis* was eliminated in three of four patients who received a povidone-iodine douche, one of four who received paromomycin, and one of two who received clotrimazole. Neither of the two patients who received furazolidone was cured.

The researchers say that, while these results support the effectiveness of metronidazole desensitization, their study was limited by its passive inclusion strategy and the inconsistent methods used to define a cure.

Source: *Am J Obstet Gynecol.* 2008;198(4):370.e1–370.e7. doi: 10.1016/j.ajog.2007.10.795.

Targeting BP and LDL in Patients with Diabetes: How Low to Go?

Aggressively lower targets for low-density lipoprotein cholesterol (LDL-C) and blood pressure (BP) showed impressive results for slowing the progression of subclinical atherosclerotic disease in 499 American Indian adults with type 2 diabetes, say researchers from the Stop Atherosclerosis in Native Diabetics Study (SANDS). This three-year, randomized trial, which was conducted at four clinical centers in three states, is the first to compare predefined treatment targets for both LDL-C and systolic BP (SBP).

Researchers randomly assigned patients, who were aged 40 and older and had never experienced a cardiovascular disease (CVD) event, to the aggressive group (with mean targets of 70 mg/dL or lower for LDL-C and 115 mm Hg or lower for SBP) or the standard group (with mean targets of 100 mg/dL or lower for LDL-C and 130 mm Hg or lower for SBP). Both groups reached the mean LDL-C and SBP goals and maintained them until the study's end, while also maintaining baseline mean weight, body mass index, waist circumference, and fasting glucose level.

Although eight participants died over the course of the study, CVD event rates were low in both groups. At 36 months, ultrasound revealed that the mean carotid intimal medial thickness progressed slightly from baseline in the standard group and regressed in the aggressive group—a significant difference. Plaque score increased slightly in both groups at the 36-month follow-up, and left ventricular (LV) mass and LV mass index decreased slightly in both groups (but to a greater degree in the aggressive treatment group).

The mean (SD) numbers of lipid-lowering and antihypertensive medications used were 1.5 (0.75) and 2.3 (1.3), respectively, in the aggressive group and 1.2 (0.73) and 1.6 (1.2), respectively, in the standard group. Patients in the aggressive group experienced significantly more adverse events with antihypertensive medications than the patients in the standard group. Even so, the researchers say these rates were similar to rates seen in other trials of these drug types.

Although the total number of CVD endpoints did not differ significantly between the two groups, the researchers say the data suggest that targeted treatment of LDL-C and SBP improved surrogate measures of CVD—with greater benefits associated with the lower target levels. ●

Source: *JAMA.* 2008;299(14):1678–1689.