Clinical Digest

Obstetrics

Preeclampsia and Thrombophilia: Reconsidering the Link

Recent research has attempted to identify the role of inherited or acquired thrombophilia in the development of preeclampsia (PE), but results have been controversial due to sample sizes, heterogeneity, and inclusion criteria. Now, investigators from University of Florence; University of Turin; University of Modena and Reggio, Emilia; and University of Brescia, all in Italy, say their study demonstrates a significant association.

Researchers enrolled 808 white women with PE and 808 white women with uneventful pregnancies, the latter of whom would act as controls. The two groups were matched for age and parity. The women in the PE group—who had no previous thromboembolic disorders, chronic hypertension, or diabetes—had the severity of their condition diagnosed according to American College of Obstetricians and Gynecologists criteria. Severe PE was diagnosed in 406 cases and mild PE in 402. (The researchers note that this high incidence of severe PE does not represent the population at large, as many of their patients had previous adverse obstetric outcomes and were referred to them at tertiary care hospitals.)

Study investigators then compared the prevalence of eight thrombophilic defects—including factor V Leiden, factor II G20210A, methylenetetrahydroflate reductase C677T, proteins S and C, antithrombin III deficiency, anticardiolipin antibodies, lupus anticoagulant, and hyperhomocysteinemia—in the severe PE, mild PE, and control groups. They found that 51% of the patients with severe PE had one or more thrombophilic defects, compared to 17% of the matched controls. By contrast, in the cases of mild PE, the prevalence of thrombophilic defects was similar to the control group (16.7% versus 14.9%). In addition, the risk of carrying combined thrombophilic defects was 17 times higher in the patients with severe PE.

Women with a positive first-degree family history of PE had a 5.8-fold risk of thrombophilia. A positive family history of thromboembolism was associated with an 8.6-fold risk.

The researchers say their data may explain why other studies, which didn't exclude certain forms of hypertensive disorders of varying severity, have shown no association between severe PE and thrombophilia. They also note that pooling mild and severe PE together, along with gestational hypertension and chronic hypertension, is unlikely to result in accurate determinations of the impact of thrombophilic defects. Their findings indicate, they add, that only severe PE is associated with maternal thrombophilia.

Source: *Hypertension.* 2005;46:1270–1274.

Diabetes Management

MIRE vs. Placebo

Using monochromatic infrared energy (MIRE) to improve lower-extremity sensation in patients with diabetic peripheral neuropathy may be futile, according to researchers from University of Tennessee Health Science Center, Memphis and Pulaski Physical Therapy, Pulaski, TN.

Approved to increase circulation and reduce pain, devices producing MIRE have been used to treat patients with wounds, soft-tissue trauma, and, more recently, lower-extremity sensory neuropathy. Uncontrolled studies have found significant improvement in sensation in patients with peripheral neuropathy after 10 to 12 MIRE treatments. A smaller study of 18 patients, in which researchers found significant improvement in sensation, was placebo-controlled for only six of 12 treatments. But when the Tennessee researchers conducted an eight-week, randomized, double-blind study of 39 patients, they concluded that MIRE was no more effective than placebo.

In this study, patients received 30-minute treatment sessions of active or placebo MIRE three times per week for four weeks. MIRE treatment included the placement of four pads—one each on the distal posterior and anterior leg, the plantar foot over metatarsal heads, and the plantar arch of the foot—according to the manufacturer's instructions. Plantar sensation was tested with monofilaments at the beginning of the study, after four weeks of treatment, and a third time, following four weeks with no treatment.

The investigators found no significant differences in sensation gain between groups at any measurement points. In both treatment and control groups, there was an increase in the average number of sites at which patients could sense. The researchers suggest two reasons for their findings: (1) a Hawthorne effect and (2) the participants' use of lotions, creams, and the information on foot care they had been given.

"If our study had been done without a placebo control," the researchers note, "the active MIRE treatment would have appeared to be therapeutically effective."

Source: *Diabetes Care.* 2005;28:2896–2900.