Topical Nifedipine With Lidocaine Ointment *vs.* Active Control for Treatment of Chronic Anal Fissure.

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Abstract

Purpose: Chronic anal fissure may be treated by chemical or surgical sphincterotomy. The aim of this study was to test the efficacy of local application of nifedipine and lidocaine ointment in healing chronic anal fissure.

Methods: The study was performed according to a prospective, randomized, double-blind design. One hundred ten patients who gave informed consent were recruited. They received a clinical examination, a questionnaire to evaluate symptoms and pain, anorectal manometry, and anoscopy. Healing of anal fissure at Day 42 of therapy was defined as the primary efficacy variable of the study. Patients treated with nifedipine (n = 55) used topical 0.3 percent nifedipine and 1.5 percent lidocaine ointment every 12 hours for 6 weeks. The control group (n = 55) received topical 1.5 percent lidocaine and 1 percent hydrocortisone acetate ointment during therapy. Anal pressures were measured by recording resting and maximal voluntary contraction pressures at baseline and at Day 21. Long-term outcomes were determined after a median follow-up of 18 months.

Results: Healing of chronic anal fissure was achieved after 6 weeks of therapy in 94.5 percent of the nifedipine-treated patients (P < 0.001) as opposed to 16.4 percent of the controls. Mean anal resting pressure decreased from a mean value +/- standard deviation of 47.2 +/- 14.6 to 42 +/- 12.4 mmHg in the nifedipine group. This represents a mean reduction of 11 percent (P = 0.002). Changes of maximal voluntary contraction in nifedipine-treated patients were not significant. No changes in mean anal resting pressure and maximal voluntary contraction were observed in the control group. We did not observe any systemic side effect in patients treated with nifedipine. After the blinding was removed, recurrence of the fissure was observed in 3 of 52 patients in the nifedipine group within 1 year of treatment, and 2 of these patients healed with an additional course of topical nifedipine and lidocaine ointment.

Conclusions: Our study clearly demonstrates that the therapeutic use of topical nifedipine and lidocaine ointment should be extended to the conservative treatment of chronic anal fissure.