TOPICAL NIFEDIPINE FOR ANAL FISSURES


Topical nifedipine with lidocaine ointment vs. active control for treatment of chronic anal fissure: results of a prospective, randomized, double-blind study.


Divisione VII, Chirurgia Gastroenterologica, A. Cardarelli Hospital, 2nd University of Naples, School of Medicine, Via Domenico Fontana 39, 80128 Naples, Italy.

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.


Topical nifedipine vs. topical glyceryl trinitrate for treatment of chronic anal fissure.
PURPOSE: Nifedipine (administered orally or applied topically) has been effective for nonsurgical treatment of anal fissure. We compared the efficacy of nifedipine vs. glyceryl trinitrate for chemical sphincterotomy of anal fissure.

METHODS: In a prospective, double-blind trial, 52 patients suffering from chronic anal fissure were randomly and equally allocated to receive either glyceryl trinitrate or nifedipine, both applied topically to the perianal region. The end point of the study was healing within a predetermined period (6 months).

Variables assessed included demographic data (age, gender), symptoms associated with the fissure, duration of treatment, percentage of healing, untoward effects of treatment, pain scores, duration of follow-up, recurrence, and need for complementary means of treatment. Descriptive data are presented as mean +/- standard deviation and quantal data as percentage. Inference analysis was performed using the Student's t-test for the descriptive data and the chi-squared or Fisher's exact test for nominal variables.

RESULTS: No significant differences were recorded with regard to age, gender, symptoms associated with the fissure, or duration of treatment. Healing rate was higher \( P < 0.04 \) with nifedipine (89 percent) as compared with glyceryl trinitrate (58 percent). Treatment side effects (headache, flushing) were more frequent \( P < 0.01 \) with glyceryl trinitrate (40 percent) as compared with nifedipine (5 percent). Pain scores were significantly lower \( P < 0.03 \) on completion of treatment in both groups (3.2 in glyceryl trinitrate and 3.4 in nifedipine vs. 6.2 and 6.1, respectively), but did not differ between the two groups. Recurrence occurred in 31 percent of patients treated with glyceryl trinitrate and 42 percent of those treated with nifedipine after a mean period of 18 +/- 3 weeks and 12 +/- 4 weeks, respectively.

CONCLUSION: Topical application of nifedipine for management of chronic anal fissure was more effective and had fewer side effects than topical glyceryl trinitrate. Recurrence was frequent with both drugs.


Aggressive treatment of acute anal fissure with 0.5% nifedipine ointment prevents its evolution to chronicity.


Department of Endoscopy and Motility Unit, Central Hospital, Ethnikis Aminis 41, TK 54635, Thessaloniki, Greece. akis_katsinelos@yahoo.gr

Abstract

AIM: To investigate the efficacy of topical application of 0.5% nifedipine ointment in healing acute anal fissure and preventing its progress to chronicity.

METHODS: Thirty-one patients (10 males, 21 females) with
acute anal fissure from September 1999 to January 2005 were treated topically with 0.5% nifedipine ointment (t.i.d.) for 8 wk. The patients were encouraged to follow a high-fiber diet and assessed at 2, 4 and 8 wk post-treatment. The healing of fissure and any side effects were recorded. The patients were subsequently followed up in the outpatient clinic for one year and contacted by phone every three months thereafter, while they were encouraged to come back if symptoms recurred. RESULTS: Twenty-seven of the 31 patients completed the 8-wk treatment course, of them 23 (85.2%) achieved a complete remission indicated by resolution of symptoms and healing of fissure. Of the remaining four unhealed patients (14.8%), 2 opted to undergo lateral sphincterotomy and the other 2 to continue therapy for four additional weeks, resulting in healing of fissure. All the 25 patients with complete remission had a mean follow-up of 22.9 +/- 14 (range 6-52) mo. Recurrence of symptoms occurred in four of these 25 patients (16%) who were successfully treated with an additional 4-wk course of 0.5% nifedipine ointment. Two of the 27 (7.4%) patients who completed the 8-wk treatment presented with moderate headache as a side effect of nifedipine. CONCLUSION: Topical 0.5% nifedipine ointment, used as an agent in chemical sphincterotomy, appears to offer a significant healing rate for acute anal fissure and might prevent its evolution to chronicity.


Topical 0.5% nifedipine vs. lateral internal sphincterotomy for the treatment of chronic anal fissure: long-term follow-up.


Department of Endoscopy and Motility Unit, Central Hospital, Ethnikis Aminis 41, 54635 Thessaloniki, Greece. papaziog@med.auth.gr

Abstract

BACKGROUND: The aim of this study was to compare the efficacy of the local application of 0.5% nifedipine ointment vs. lateral internal sphincterotomy in the healing of chronic anal fissure. PATIENTS AND METHODS: Sixty-four patients with symptomatic chronic anal fissures were randomly assigned to 0.5% nifedipine ointment (n=32) every 8 h for 8 weeks or lateral internal sphincterotomy (n=32). Both groups received stool softeners and fiber supplements and were assessed at 2, 4, 6, and 8 weeks. Long-term outcomes were determined after a median follow-up of 19 months (nifedipine group) and 20.5 months (lateral internal sphincterotomy group). RESULTS: Complete healing at 8 weeks was achieved in 30 out of 31 patients (96.7%) in the nifedipine group and 32 out of 32 patients (100%) in the lateral internal sphincterotomy group (p=0.49). The overall healing rates at the end of follow-up were 28 out of 30 (93%) vs. 32 out of 32 (100%) in the nifedipine and sphincterotomy groups respectively (p=0.48). Two of the 30 patients in the nifedipine group relapsed whereas none in the sphincterotomy group did. Sixteen patients (50%) developed side effects in the nifedipine group, compared with six patients (18.7%) in the sphincterotomy group. CONCLUSIONS: Topical application of 0.5% nifedipine ointment represents a new, promising, easily handled, effective alternative to lateral internal sphincterotomy.