Excerpta Medica

The American Journal of Surgery

The American Journal of Surgery 189 (2005) 429–434
Scientific paper

Surgical versus chemical (botulinum toxin) sphincterotomy for chronic anal fissure: long-term results of a prospective randomized clinical and manometric study

Antonio Arroyo, Ph.D.*, Francisco Pérez, Ph.D., Pilar Serrano, M.D., Fernando Candela, M.D., Javier Lacueva, M.D., Rafael Calpena, M.D.

Coloproctology Unit, Department of Surgery, University Hospital of Elche, Elche (Alicante), Spain

Manuscript received January 28, 2004; revised manuscript June 13, 2004

Abstract

Background: The aim of this prospective randomized trial was to compare the effectiveness and morbidity of surgical versus chemical sphincterotomy in the treatment of chronic anal fissure after a 3-year follow-up.
Methods: Eighty patients with chronic anal fissure were treated by whether open lateral internal sphincterotomy (group 1) or chemical sphincterotomy with 25 U botulinum toxin injected into the internal sphincter (group 2). Clinical and manometric results were analyzed.
Results: Overall healing was 92.5% in the open sphincterotomy group and 45% in the toxin botulinum group ($P < .001$). There is a group of patients with clinical (duration of disease >12 months and presence of a sentinel pile before treatment) and manometric factors (persistently elevated mean resting pressure, % of time presence of slow waves, and number of patients or the time presence ultra slow waves after treatment) associated with a higher recurrence of anal fissure. The final percentage of incontinence was 5% in the open sphincterotomy group and 0% in the botulinum toxin group ($P > .05$).
Conclusion: We recommend surgical sphincterotomy as the first therapeutic approach in patients with clinical and manometric factors of recurrence. We prefer the use of botulinum toxin in patients older than 50 years or with risk factors for incontinence, despite the higher rate of recurrence, since it avoids the greater risk of incontinence in the surgical group.

Keywords: Anal fissure; Sphincterotomy; Botulinum toxin

Anal fissure remains one of the most common proctologic problems manifesting as pain and bleeding on defecation [1,2]. Chronic anal fissures are associated with persistent hypertonia of the internal anal sphincter, and manometric evidence of internal sphincter spasm reflecting elevated resting anal pressures has been reported [3,4].

Over the last century, a variety of surgical methods [5] have been described in order to eliminate this spasm and decrease the elevated anal pressures, thereby allowing the fissure to heal. The objective of all these methods is to obtain a high rate of healing associated with a low rate of morbi-mortality, and lateral internal sphincterotomy has become the procedure of choice with rates of recurrence smaller than 10% [6–8].

However, the high rates of incontinence, as much as 66% reported in the case of surgical sphincterotomy [9], have led to the study and implementation of other alternative medical treatments, mainly botulinum toxin [10–15] and organic nitrate preparations [15–17], that produce reversible reduction in sphincter pressure, allowing the healing of the anal fissure. Of these, botulinum toxin has achieved the lowest rates of recurrence [12] with the fewest side effects [18] when compared with the results described in the case of nitrate preparations.

Thus, the aim of this prospective randomized controlled trial was to compare the effectiveness and morbidity of surgical (ambulatory open lateral internal sphincterotomy realized with local anesthesia) and chemical (botulinum toxin) sphincterotomy in the treatment of chronic anal fissure.

Methods

Between January 1998 and January 2000, 80 consecutive patients with chronic anal fissure were assigned according

* Corresponding author. Antonio Arroyo Sebastián, Av/Oscar Esplá 35.E4.6°D., C.P.03007, Alicante, Spain. Tel./fax: +1-0034-966679108.
E-mail address: arroyocir@hotmail.com

0002-9610/05/$ – see front matter
doi:10.1016/j.amjsurg.2004.06.045

to a computer randomization program to surgical sphincterotomy (group 1, n = 40) or chemical sphincterotomy with botulinum toxin (group 2, n = 40). This study (first visit, sphincterotomy, and postoperative revision) was done in an ambulatory setting in the Coloproctology Unit of Elche University Hospital. The study was approved by the Ethics Committee and each patient signed the informed consent before participating in the study.

First, all patients were diagnosed as having chronic anal fissure based on their medical history and physical exploration, and treated for a minimum of 6 weeks with conservative medical treatment (high residue diet, analgesics, and warm sitz baths) before definitive definition of chronic anal fissure and inclusion in the study. Chronic anal fissure was defined as the presence of a fibrous induration or exposed internal sphincter fibres.

The exclusion criteria were associated anal pathologies (any degree of stenosis due to anatomic alteration regardless of an hypertonic anal sphincter, abscess, fistula, and any degree of symptomatic hemorrhoids), associated conditions (inflammatory bowel disease, acquired immunodeficiency syndrome, tuberculosis, sexually transmitted disease, and immunosuppression), anticoagulative therapy, allergy to local anesthetics, and pregnancy.

All patients were treated by the same surgeon using a uniform method in the prone jackknife position. All patients had a pulse oxymeter monitor and did not need preoperative laboratory tests, enema preparation, antibiotics, or intravenous access.

In the surgical sphincterotomy, the open lateral internal sphincterotomy was performed under local anesthesia (20 mL mepivacaine 2%) using a 25-G needle. The anesthetic was injected into the skin, intersphincteric plane, internal sphincter, and submucosa on the right and left side. The fissure furrow was also infiltrated. The open technique was performed by exposing the right lateral anal region with an anal retractor, and a 1- to 2-cm skin incision was made in the intersphincteric groove. The anal mucosa was separated from the internal sphincter all the way down to the dentate line. The intersphincteric plane was entered and the sphincters separated. The distal internal sphincter was incised under direct vision using electrocoagulation. The skin incision was not closed and direct pressure was applied for 5 minutes.

In the chemical sphincterotomy group, the 100-U vials of type A lyophilized botulinum (BOTOX, Allergan, Inc, Irvine, CA) were stored at a temperature of −20°C and diluted in saline to 0.1 mL/2.5 U on the day of injection. With a 25-G needle, a total of 25 U was injected into the internal sphincter guided under direct vision and digital examination (8-U dose into each lateral side of the sphincter and 9 U into the anterior verge).

In both groups, the patients were discharged with instructions concerning high residue diet, analgesics (oral metanizol 1 capsule [575 mg] every 8 hours alternating with oral ketorolac 1 capsule [10 mg] every 8 hours), and warm sitz baths. Early complications were collected at 1 week revision. Information regarding sex, age, symptoms, bowel habits, examination findings, manometric values, fissure healing, and recurrence was collected at the time of admission and at 2-month, 6-month, 1-, 2-, and 3-year follow-up visits. Follow-up evaluation was performed by other different surgeon attached to the Coloproctology Unit. Healing was defined as complete re-epithelization of the fissure and absence of symptoms. Recurrence of fissure was defined by persistence of fissure in anatomic exploration whether associated with symptoms or not. The Cleveland Clinic Scoring System was used for assessment of incontinence [19].

Anorectal manometry was performed using a low-compliance water perfusion system with a filled 6-lumen catheter (external diameter, 4 mm) having radially arranged ports in cross-section. Pressures were recorded by means of a pressure situated within each infusion line and connected to a recording chart. With the patient in the left lateral position with flexed knees and hips, the probe was introduced 6 cm into the anal canal then withdrawn at 1-cm intervals and ultra slow waves, slow waves, mean squeeze pressure, and mean resting pressure in mm Hg were recorded. The results were compared with the normal range for our laboratory in 100 healthy patients (control group): mean resting pressure = 66 ± 23 mm Hg and mean squeeze pressure = 164 ± 60 mm Hg (control group).

Generally, there were not significant difference between the 2 groups in the characteristics of patients, symptoms, and anal exploration before treatment (Table 1).

Statistical analysis

The data were analyzed by standard statistical methods and the results expressed as means ± SD. Differences between manometric data were compared using Student *t* test for paired and unpaired samples, whereas differences between percentages were analyzed using Fisher exact test. Probability values of less than .05 were considered significant. Analysis of variance was used to compare variables between the groups.

Results

Complications and results of treatment are listed in Table 2. We found 2 patients (5%) with an hematoma wound (1 in the surgical sphincterotomy group and 1 in the chemical sphincterotomy group) and only 1 patient with a self-limited bleeding wound in the surgical sphincterotomy group. There were no anal abscesses, hemorrhoid thromboses, perianal fistulae, or urinary retention.

There was persistence or recurrence of the fissure in 1 patient (2.5%) in the surgical sphincterotomy group and in 6 patients (15%) in the chemical sphincterotomy group ($P > .05$) at the 2-month visit, and 1 more patient in the surgical sphincterotomy group (overall, 5%) and 6 more