

Long-term prospective randomised clinical and manometric comparison between surgical and chemical sphincterotomy for treatment of chronic anal fissure

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Aim. To compare surgical and chemical sphincterotomy for treatment of chronic anal fissure.

Methods. The 160 patients studied were randomly divided into four equal groups, treated by lateral internal sphincterotomy (group S), local diltiazem ointment (group D), local glyceryl trinitrate ointment (group GTN), or injection of botulinum toxin into the internal anal sphincter (group BT). Anal manometry was performed before and 3 months after treatment. Patients were followed up for 5 years.

Results. Complete pain relief was achieved in means (\pm standard deviation) of 5.7 \pm 7.8 days (group S), 15.7 \pm 5.9 days (group D), 15.6 \pm 5.9 days (group GTN) and 2.7 \pm 3.6 days (group BT). The mean times to healing were 4.5 \pm 1.2 weeks (group S), 5.1 \pm 1.1 weeks (group D), 5.0 \pm 1.1 weeks (group GTN) and 5.1 \pm 1.3 weeks (group BT). Mean resting and squeeze anal pressures decreased significantly after sphincterotomy. Recurrence rates were 10% in group S, 65% in group D, 57.5% in group GTN and 52.5% in group BT.

Conclusion. Lateral internal sphincterotomy is an easy procedure with satisfactory results, minimal complications and a low recurrence rate. Medical sphincterotomy is safe and easy, with mild complications. Its effect is reversible, and relapse is common. We recommend that medical sphincterotomy be tried before surgery or in patients who are unable or unwilling to undergo surgery.

Anal fissure is a common and painful condition resulting from poor anodermal perfusion due to an elevated resting anal pressure.¹ The aim of treatment is to lower resting sphincter pressure to increase perfusion and promote healing.²

Chronic anal fissure has traditionally been managed with lateral internal sphincterotomy, a simple operation that provides rapid pain relief. Most patients are satisfied with its results,¹ but it may be associated with permanent incontinence. It does not take into account weakening of the sphincter with age, possible future anorectal surgery or obstetric trauma.²

Less invasive strategies have been adopted for sphincter relaxation, including local application of nitroglycerin³ or diltiazem hydrochloride⁴ and injection of botulinum toxin into the internal sphincter,⁵ resulting in a temporary chemical or medical sphincterotomy until the fissure heals. These methods are increasing in popularity.⁶

This study aimed to compare the efficacy of surgical versus chemical sphincterotomy for treatment of chronic anal fissure.

Patients and methods

The study was carried out in the Department of General Surgery, Tanta University, Egypt, from April 2002 to September 2008. One hundred and sixty patients with chronic anal fissure were divided into four equal groups of 40 each by means of a computer randomisation programme (www.randomization.com). Patients with other anal pathology or cardiac problems and women who were pregnant or planning a pregnancy were excluded from the study. The planned procedures were explained in full and patient consent was obtained before inclusion. The study protocol was approved by the Ethics Committee of the Department of General Surgery, Tanta University Hospitals.

The study groups were as follows: group S – patients treated by open lateral internal sphincterotomy; group D – treated by local application of 2% diltiazem ointment twice a day for 4 – 6 weeks; group GTN – treated by local application

of 0.2% glyceryl trinitrate ointment twice a day for 4 - 6 weeks; and group BT – treated by injection of botulinum toxin into the internal anal sphincter. Type A lyophilised botulinum (Botox, Allergan Inc., Irvine, Calif., USA) was diluted in saline to a concentration of 50 U/ml immediately before injection. Using a 25G needle, 20 U was injected into each side of the internal anal sphincter. No sedation or local anaesthesia was used during the procedure.

The patients evaluated the pain experienced, using a pain visual analogue scale every day at home. Healing was defined as complete re-epithelisation of the fissure and absence of symptoms. A fissure was defined as having recurred if found on anatomical exploration, whether or not it caused symptoms.

All the patients were followed up by means of visits at 2-week intervals for 8 weeks, then every month for 6 months. Telephonic follow-up was then done every 3 months for a further 5 years. Thirteen patients who were lost to follow-up were excluded from the study and replaced by new patients receiving the same treatment.

Anal manometry was performed before and 3 months after treatment using Sandhill anorectal manometry (Sandhill Scientific, Colo., USA) with a solid-state anorectal manometry probe.

Results

One hundred and sixty patients (88 males (55%) and 72 females (45%)) were included in the study. Their ages ranged from 17 to 70 years (mean 34.4±20.6 years). Pain on defecation was the main presenting symptom in all patients. Constipation, bright red bleeding, pruritus and mucous discharge were less common presentations.

Complete pain relief was achieved in a mean (± standard deviation (SD)) of 5.7±7.8 days in group S, 15.7±5.9 days in

group D, 15.6±5.9 days in group GTN and 2.7±3.6 days in group BT. The differences were statistically significant except for group S versus group BT and group D versus group GTN ($F=50.94$, $p<0.001$)

The mean time to healing was 4.5±1.20 weeks in group S, 5.1±1.13 weeks in group D, 5.0±1.1 weeks in group GTN and 5.1±1.3 weeks in group BT. The difference between the four groups was not statistically significant ($F=2.43$, $p=0.067$).

In group S, wound infection occurred in 2 patients (5%). Temporary incontinence to flatus was experienced by 2 patients (5%), both of whom became completely continent within 12 weeks. In group D, headache occurred in 2 patients (5%) and hypotension in 1 (2.5%), in group GTN headache occurred in 6 patients (15%) and hypotension in 2 (5%), and in group BT 3 patients (7.5%) developed a haematoma after injection.

Recurrence occurred in 4 patients (10%) in group S, 26 patients (65%) in group D, 23 patients (57.5%) in group GTN and 21 patients (52.5%) in group BT. Most patients refused to continue the medical therapy and were referred for lateral internal sphincterotomy.

Mean resting anal pressure decreased after sphincterotomy in all groups, by 41.5% in group S, 27.2% in group D, 33.1% in group GTN and 35.2% in group BT. Mean squeeze anal pressure decreased by 16.0% in group S, 4.5% in group D, 6.1% in group GTN and 7.4% in group BT (Table I).

Discussion

In our surgically treated group, complete pain relief was obtained in a mean of 5.7±7.8 days. Ho and Ho⁷ reported relief of pain in 92% of patients after 2 weeks. Of our patients, 95% experienced complete healing of their fissures in 8 weeks; Hananel and Gordon⁸ reported a healing rate

TABLE I. MEAN RESTING AND SQUEEZE ANAL PRESSURE (mmHg) (± SD) BEFORE AND AFTER TREATMENT

		Group S	Group D	Group GTN	Group BT
Mean resting anal pressure	Before treatment	122.49±14.45	120.03±20.57	123.43±15.09	116.89±13.32
	F	1.32			
	p	1.32 (not significant)			
	After treatment	71.59± 9.89	87.42±14.85	82.54±10.65	75.72±7.94
	F	16.03			
p	<0.001 (significant)				
Bonferroni test	All differences significant except group S v. group BT				
Mean squeeze anal pressure	Before treatment	207.67±18.71	201.58±14.68	198.81±9.34	197.73±14.84
	F	3.64			
	p	0.014 (significant)			
	Bonferroni test	Group S v. group GTN significant, group S v. group BT significant			
	After treatment	174.41±8.53	192.57±16.83	186.62±12.09	183.03±10.72
F	14.96				
p	<0.001 (significant)				
Bonferroni test	All differences significant except group D v. group GTN and group GTN v. group BT				

of 94.4% in 8 weeks, and Lewis *et al.*⁹ a total healing rate of 95.4%. The early postoperative complications in our study were wound infection (5%) and temporary incontinence to flatus (5%). Hoffmann and Goligher¹⁰ reported a 12% incidence of temporary incontinence of flatus. The recurrence rate in our study, 10% after 5 years, is higher than rates reported by Lewis *et al.*⁹ (4.6%) and Hananel and Gordon⁸ (1.4%). Differences in the duration of follow-up between the studies may account for these variations.

Of our patients treated with diltiazem ointment, 80% showed complete healing after 8 weeks of treatment, a figure similar to the 75% reported by DasGupta *et al.*¹¹ after the same period of time.

Treatment with nitroglycerine ointment resulted in complete healing in 90% of our patients after 8 weeks. Waston *et al.*¹² treated 15 patients with nitroglycerine ointment, of whom 69.2% of patients healed completely by 6 weeks, and Fruehauf *et al.*¹³ concluded that nitroglycerin ointment was superior to the more expensive and invasive botulinum toxin injection for initial healing of chronic anal fissure.

Our recurrence rate after botulinum toxin injection was 52.5%. All recurrences occurred during the first year. Studies with long follow-up have shown a tendency to progressive recurrence over time after botulinum toxin treatment. Minguez *et al.*¹⁴ reported that 41.5% of their patients had relapsed by 42 months, and Arroyo *et al.*¹⁵ also showed a progressive rate of recurrence, the figure reaching 53% at 3 years. They related this to the temporary reversible effect of botulinum toxin, in contrast to surgical sphincterotomy.

Some studies describing clinical factors related to recurrence^{14,16} have indicated that the more chronic the fissure has become, the less likely it is that reversible sphincterotomy will achieve definitive healing. Recurrence was closely related to persistence of anal spasm.¹⁷

Conclusion

We believe that lateral internal sphincterotomy is a satisfactory treatment for chronic anal fissure, being quick and easy to perform with minimal complications. Recurrence after this mode of therapy is uncommon.

Medical sphincterotomy is an accepted method of treatment. It is safe and easy to use, with rapid relief of pain, mild side-effects and no risk of anaesthetic or operative

complications. Compared with surgical sphincterotomy its effect on the internal sphincter is reversible, but relapse is very common.

We recommend that medical sphincterotomy be tried before surgery or in patients who are unable or unwilling to undergo surgery.

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