inhibition of secretion of gastric acid. Omeprazole, which produces more profound and longer lasting inhibition of acid secretion, presumably acts in a similar manner. In this preliminary open study, with a limited number of patients, no differences could be established between the four different doses of omeprazole with respect to inhibition of pentagastrin stimulated secretion of gastric acid and ulcer healing. Thus as all the doses of omeprazole tested appeared to be effective and there was no dose dependent relation with adverse events recorded during the study, larger comparative studies are required to determine the optimal therapeutic dose of omeprazole for ulcer healing.

However effective a drug is in healing ulcers in the short term, patients are liable to relapse once treatment is withdrawn. In this study 11 out of 36 patients (31%) whose ulcers had healed after four weeks of treatment with omeprazole had a symptomatic relapse, diagnosed endoscopically, within six months after stopping treatment. Cumulative incidences of recurrence of 50-60% have been reported six months after successful short term healing with H_2 antagonists.[14-17]

In conclusion, omeprazole 20-60 mg given once daily for four weeks was well tolerated and healed 41 of 43 duodenal ulcers diagnosed endoscopically; 32 patients were asymptomatic within one week. Eleven out of 36 patients had a relapse during the first six months after stopping treatment. Comparative clinical trials will assess the place of omeprazole in treating peptic ulcer.

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Lateral subcutaneous sphincterotomy versus anal dilatation in the treatment of fissure in ano in outpatients: a prospective randomised study

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Abstract

Fifty eight patients with idiopathic chronic anal fissure were included in a randomised prospective trial of lateral subcutaneous sphincterotomy versus simple anal dilatation carried out as outpatient procedures. Operations were performed under local anaesthesia and the patients reviewed 10-30 months later (median follow up time 18 months).

Altogether 30 patients were treated by lateral subcutaneous sphincterotomy and 28 by anal dilatation. No serious complications were observed in either group. One recurrence was observed in the group treated by sphincterotomy, whereas eight occurred in the other group ($p < 0.05$). Functional results with respect to impaired control of flatus and soiling of underwear were significantly better after sphincterotomy ($p < 0.002$).

It is concluded that lateral subcutaneous sphincterotomy is the treatment of choice for idiopathic chronic anal fissure resistant to conservative measures.

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Introduction

Surgical procedures for idiopathic chronic anal fissure resistant to conservative treatment include lateral subcutaneous sphincterotomy and simple anal dilatation. Which of these is the most favourable, however, is a subject of controversy.[1] We have therefore carried out a controlled prospective trial of the two procedures, performed in the outpatient department. The treatments were allocated at random.

Patients and methods

All patients presenting to the clinic with idiopathic chronic anal fissure during June 1980 to December 1982 were considered for the trial. Patients were accepted provided that induration of the edges of the fissure and exposure of the fibres of the internal sphincter in the floor of the fissure were observed on examination.

Patients were admitted to the clinic by their general practitioner.

Altogether 58 entered the trial. Randomisation to treatment by either lateral subcutaneous sphincterotomy or simple anal dilatation depended on whether the patient's registration number was odd or even. Thirty patients were allocated to receive lateral subcutaneous sphincterotomy and 28 to receive simple anal dilatation. The age and sex distribution and duration of symptoms were similar in the two groups (table I). The site of the fissure was posterior in 57 patients, the single patient with an anterior fissure being allocated to anal dilatation.

All operations were carried out under local anaesthesia. An inferior haemorrhoidal nerve block was performed by deep injection of 25-30 ml 2% lignocaine (Xylocaine), without noradrenaline, on each side of the anal canal. Maximal analgesia of the anal skin was ensured by complete infiltration of the subcutaneous tissues.

TABLE I—*Comparability of patients treated by lateral subcutaneous sphincterotomy and by anal dilatation*

	Sphincterotomy	Dilatation
No of patients	30	28
Men:women	18:12	16:12
Median age in years (range)	38 (21-69)	40 (23-74)
Median duration of symptoms, in months (range)	9 (6-30)	11 (5-26)
Median follow up time, in months (range)	18 (10-30)	18 (10-30)

Dilatation of the anal sphincters was performed as described by Watts *et al.*[2] Lateral subcutaneous sphincterotomy was always performed on the left side with the patient in the lithotomy position. A small incision was made lateral to the lower edge of the internal sphincter, which was located by the finger. Sharp Mayo's scissors were introduced and passed up between the internal sphincter and the mucosa with the left index finger inserted into the anus. The intersphincteric groove was identified and the intersphincteric plane separated with the scissors. The internal sphincter was then cut with the scissors up to the level of the dentate line. The division was confirmed by inserting the pulp of the index finger into the defect. The skin incision was partially closed with a single Vicryl suture. In three patients an associated sentinel skin tag was excised just before sphincterotomy (two cases) or anal dilatation (one).

All patients were allowed home within 30 minutes with a dry dressing on the wound and a supply of aspirin tablets. Patients were seen regularly for up to eight weeks and attended for final follow up 10-30 months after treatment (median follow up time 18 months in both groups). No patient was lost to follow up. At follow up symptoms were assessed using a predesigned questionnaire and the anus examined for signs of recurrence.

Statistical evaluation was by Fisher's exact test or the log rank test.[3]

Results

Tables II and III give the results of the two treatments. No differences were observed with respect to immediate relief of pain, healing of the anal fissure, surgical complications, or time off work (Table II). Satisfactory relief of pain and healing of the fissure was achieved in all but one of the patients treated by dilatation. The remaining patient was retreated four weeks later by lateral subcutaneous sphincterotomy. One patient treated by anal dilatation developed brisk haemorrhage from the fissure within a few hours after the procedure and was admitted to hospital by his general practitioner. The bleeding was stopped by firm pressure and the patient discharged from hospital next day. Among the 28 patients treated by anal dilatation, eight had symptoms and signs of recurrent fissure 10 to 12 months later. Of the patients in the other group, only one was observed to have a recurrence ($p<0.05$). All patients with recurrent fissures underwent lateral subcutaneous sphincterotomy.

TABLE II—*Results of treating chronic idiopathic anal fissure by lateral subcutaneous sphincterotomy and by anal dilatation*

	Sphincterotomy	Dilatation	Significance
No of patients with immediate relief of pain	30	27	NS*
No of complications	0	1	NS*
Median time of healing, in weeks (range)	3 (1-6)	3 (2-5)	NS*
No of recurrences	1	8	p < 0.05†
No of patients satisfied with local anaesthesia	24	23	NS*
Median No of days off work (range)	2 (1-4)	3 (0-6)	NS*

* Fisher's exact test.
† Log rank test.

TABLE III—*Functional results of lateral subcutaneous sphincterotomy and of anal dilatation for chronic anal fissure*

	Impaired control of		Faecal soiling of underwear
	Flatus	Faeces	
Sphincterotomy (n = 30)	0	0	1
Dilatation (n = 28)	8	2	11
Significance	$p<0.002$	NS	$p<0.002$*

* Fisher's exact test.

The functional results were significantly better after sphincterotomy than after anal dilatation (table III). A functional defect was observed in only one patient treated by lateral subcutaneous sphincterotomy (3·3%). This patient complained of anal discharge and faecal soiling of underclothes 10 months after treatment. By contrast, in 11 of the 28 patients (39%) treated by anal dilatation faecal soiling was a major problem. Furthermore, eight of the patients treated by dilatation (29%) had impaired control of flatus at the time of follow up, whereas none of the patients treated by lateral subcutaneous sphincterotomy suffered from this complication ($p<0.002$). Impaired control of faeces was present in two of the 28 patients (7·1%) treated by dilatation compared with none of the patients in the other group.

Of all the patients in the sphincterotomy and dilatation treatment groups, 24 (80%) and 23 (82%) respectively were satisfied with the treatment under local anaesthesia (table II) and would have the procedure repeated if necessary.

Discussion

These findings show that lateral subcutaneous sphincterotomy is better than simple anal dilatation for chronic anal fissure in outpatients treated under local anaesthesia. The recurrence rate of the fissures was significantly higher after anal dilatation than after sphincterotomy, and the functional results with respect to control of flatus and soiling of underwear were significantly better in patients treated by sphincterotomy. Both procedures, however, gave the same degree of immediate relief of pain and healing of the fissures.

The study is open to at least one criticism: anal dilatation was done under local anaesthesia and although it was performed carefully, some believe that local anaesthesia does not permit thorough stretching of the sphincters and that deep general anaesthesia is required.[1] All but one of our patients treated by anal dilatation under local anaesthesia, however, had immediate relief of pain and healing of the fissure within five weeks. It was only in the longer term that the procedure was seen to be inferior to sphincterotomy with respect to the recurrence of fissures. Furthermore, the high incidence of impaired control of flatus and faecal soiling after anal dilatation suggests that the sphincters had been sufficiently stretched despite the use of local anaesthesia. It is also noteworthy that no complications were observed during the stretching of the sphincters and that most patients in each group were satisfied with the treatment and would accept further treatment under local anaesthesia if the alternative meant delay and admission to hospital.

This prospective randomised study has to a great extent confirmed the findings of a recently published retrospective comparison of the two procedures performed under general anaesthesia.[4] Our procedure for lateral subcutaneous sphincterotomy was easily performed without the use of an anal speculum as advocated by most workers[4-6] and the results compare favourably with other series.[4-7] Moreover, most of our patients required only one or two days off work.

We conclude that compared with anal dilatation lateral sub-

cutaneous sphincterotomy is the treatment of choice for patients with chronic anal fissure. Both procedures are easily and safely performed in the outpatient department under local anaesthesia, thereby avoiding the costs and disruption of admission to hospital.

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SHORT REPORTS

Current practice of diagnostic lumbar puncture

About 30% of patients have a headache after lumbar puncture,[1] and many studies have examined its cause and prevention. As some of these studies have been imprecise or contradictory we surveyed current practice for diagnostic lumbar puncture.

Method and results

We contacted a junior doctor from each of the neurology departments of 15 London teaching or postgraduate institutions and 13 provincial university hospitals. These 28 doctors, most of whom worked for more than one neurologist, completed a telephone questionnaire. All 28 had performed a lumbar puncture: six estimated that they had performed fewer than 10, four from 10 to 20, three from 20 to 30, six from 30 to 40, five from 40 to 50, and four more than 50. Twenty four of the doctors had forewarned their patients of the possibility of headache. Seventeen used 18 or 19 standard wire gauge (SWG) needles, six 20 SWG needles, and five 22 SWG needles. The amount of cerebrospinal fluid removed was: 1·5 ml (one doctor), 2-3 ml (one), 3-5 ml (10), 6-10 ml (14), and 15 ml (two). To help prevent headache three doctors allowed immediate mobilisation, one advised half an hour of bedrest, one advised two hours, two advised three hours, two advised four hours, seven advised six hours, one advised eight hours, three advised 12 hours, and eight advised 24 hours. Ten doctors advised drinking plenty of water.

All the doctors agreed on bedrest and analgesia when the patient had an established headache. In addition, one doctor used the head down position and three prescribed steroids. Epidural blood patching was not used. Only seven doctors claimed to have received any instruction on policy from senior colleagues (five from registrars and two from consultants).

Comment

The cause of headache after lumbar puncture is persistent leakage of cerebrospinal fluid through the dural puncture hole made by the spinal needle. This produces cerebrospinal fluid hypotension, intracranial venous dilatation, and headache due to stimulation of pain sensitive nerve endings. There is no difference in the incidence of headache whether dural puncture is made alone or up to 25 ml fluid is removed, emphasising the magnitude of the leak.[2] Surprisingly, 12 doctors of the 28 said that they took only 5 ml or less cerebrospinal fluid for diagnostic purposes, a small quantity for adequate analysis. Warning patients of the possibility of headaches increases their incidence, so there appears to be no merit in doing this.

Theoretically, the smaller the needle the smaller the dural hole and fluid leak. A reduced incidence of headache has been shown with a 26 SWG needle, but this is technically difficult to use.[3] It is doubtful, however, whether many patients would be spared a headache by use of a very small gauge needle, though a 20 or 22 SWG needle may be recommended after limited experience with an 18 or 19 SWG size.

Bed rest for 24 hours is still arbitrarily recommended as a means of preventing headache but does not do so,[1] for the dural hole will take longer than 24 hours to heal. Clearly, however, an established headache is relieved by increasing the cerebrospinal fluid pressure with bedrest. Early mobilisation is practised exclusively by some doctors in both inpatients and outpatients, though the use of small needles has added to their confidence in doing so. There is a theoretical possibility of subdural haematoma complicating spinal puncture, though patients reported on had had spinal anaesthetics and some had predisposing causes.[5] This has not been reported as a complication of routine diagnostic lumbar puncture despite many severe headaches, which suggests that it is rare. The value of increasing hydration has not been adequately assessed.

Our practice is to explain the purpose and procedure to the patient and tell outpatients that should they develop a headache they should be recumbent and be reassured that it is self limiting. We use 19-22 SWG needles and collect 10-15 ml cerebrospinal fluid, after which the patient is allowed up; should a headache develop then strict bedrest is instituted for the duration of the pain, with regular simple analgesia if required.

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Oral contraceptives and stroke: findings in a large prospective study

The suggestion that use of oral contraceptives might increase the risk of stroke was first made over 20 years ago, but controlled studies of this problem are few. We have therefore reviewed the data on stroke that have accumulated in the Oxford Family Planning Association contraceptive study.

Subjects, methods, and results

The methods used in the Oxford Family Planning Association study have been described.[1] The investigation includes over 17 000 women who, when recruited between 1968 and 1974, were all married and aged 25-39. Fifty six per cent were using oral contraceptives, 25% a diaphragm, and 19% an intrauterine device. During follow up, among other items, data are recorded about changes in contraceptive methods, hospital referrals, and deaths. Discharge summaries are obtained for inpatient spells and as much information as possible is collected about fatal illnesses.

At the end of January 1984 data accumulated during 192 000 woman years