Scales and variable-height trolley being used to weigh patient.

Comment

By using this method the weight of a bed-bound patient may be measured with an average error of 0.36 kg. We believe that this is an adequate method of assessing the trend of a patient's weight even during a period of immobilisation. This is of particular value to any clinician who must provide nutritional support for the patient.

In the present atmosphere of restricted budgets the cost of weigh-beds or even "sitting scales" may be prohibitive, especially for smaller hospitals. All hospitals, however, would have the equipment needed for the method described here.

We thank John N Livingstone of Vicarey Davidson & Co, surgical instrument makers, for supplying the scales.

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Maintenance of remission in ulcerative colitis with oral preparation of 5-aminosalicylic acid

Sulphasalazine (salazopyrin) is the most effective agent for maintaining remission in ulcerative colitis,¹ but its use is limited by side effects. It consists of sulphapyridine and 5-aminosalicylic acid joined by a diazo bond, which is split by bacteria in the colon releasing the constituents.² 5-Aminosalicylic acid is the active compound that probably has a topical effect,³ while sulphapyridine serves as a carrier molecule and is probably responsible for the side effects.

5-Aminosalicylic acid cannot be given by mouth since it is unstable in acid and is absorbed by the small intestine. We recently described a colonic delivery system whereby drugs coated with an acrylic-based resin were carried intact to the colon and then released.⁴ This study compares 5-aminosalicylic acid coated in this way with sulphasalazine for maintenance of remission in colitis.

Methods and results

We studied 72 patients (36 men, 36 women). All were in remission with ulcerative colitis or proctitis and had passed three or less stools daily without blood or slime during the previous month; were taking at least 2 g salazopyrin daily; and gave their informed consent. Admission to the trial depended on normal sigmoidoscopic findings. Rectal biopsy specimens were taken, coded,

and later reviewed by a pathologist, who graded them from 1 (normal) to 2 to 4 for mild, moderate, or severe inflammation.

Patients were seen after four, 12, and 16 weeks and completed diary cards throughout. Sigmoidoscopic examination was repeated at the end of the trial and in all patients with recurrent symptoms. Relapse was defined as a recurrence of symptoms with sigmoidoscopic changes, including contact or spontaneous mucosal haemorrhages, pus, or ulceration.

The study was randomised and double blind, using identical placebo tablets for both sulphasalazine and 5-aminosalicylic acid. All patients were given two sets of tablets, either active 5-aminosalicylic acid and placebo sulphasalazine, or placebo 5-aminosalicylic acid and active sulphasalazine. Trial tablets were based on the patient's usual dose of sulphasalazine. Tablets of 5-aminosalicylic acid contained 400 mg, equivalent to 1 g sulphasalazine; at least three tablets of 5-aminosalicylic acid were taken daily with an increase of one tablet for each gram of sulphasalazine above the entry dose of 2 g for patients taking high doses of sulphasalazine. Compliance was checked at each hospital visit. 5-Aminosalicylic acid powder was obtained from Aldrich Chemicals and the tablets coated with an acrylic-based resin (Eudragit S) between 100 and 130 μ thick.⁵

Five of the 72 patients (four women, one man) were withdrawn because of pregnancy in two, constipation in one, and failure to comply in two. Of the remaining 67 patients, 15 relapsed and 52 completed the trial (table). Nine

Details of patients treated with 5-aminosalicylic acid or sulphasalazine during 16-week trial

	5-Aminosalicylic acid	Sulphasalazine
No of patients	34	33
Sex (M:F)	14:20	21:12
Mean ($\pm$ SD) age (years)	44.9 $\pm$ 15.3	50.2 $\pm$ 15.6
Mean ($\pm$ SD) duration of disease (years)	7.2 $\pm$ 5.5	9.3 $\pm$ 6.4
Mean ($\pm$ SD) time since last attack (years)	1.6 $\pm$ 1.4	2.1 $\pm$ 2.3
No of patients with:		
Proctitis	17	19
Left-sided disease	13	5
Extensive disease	4	9
No of patients relapsing	9	6

patients taking 5-aminosalicylic acid and six taking sulphasalazine relapsed; the difference was not significant (χ^2 test).

Headache, nausea, or indigestion were reported by 16 patients, with no difference between groups. Satisfactory biopsy specimens from 61 patients confirmed the absence of inflammation in most (51). Four showed grade 2 and six grade 3 changes.

Comment

This study showed that 5-aminosalicylic acid coated with an acrylic-based resin (Eudragit-S) was as effective as sulphasalazine in maintaining remission in colitis. In our patients relapses occurred over 16 weeks, an adequate period since previous studies have shown that most relapses occur within 12 weeks.¹

This preparation is an important advance in the management of colitis since it may be given to patients unable to take sulphasalazine and greater doses may be tolerated.

We thank Regent Laboratories, who produced both active and placebo tablets of 5-aminosalicylic acid, and Boots Pure Drug Company, Nottingham, for placebo sulphasalazine tablets.

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⁴ Dew MJ, Hughes PJ, Lee MG, Evans BK, Rhodes J. An oral preparation to release drugs in the human colon. *Br J Clin Pharmacol* 1982;14: 405-8.

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