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Hydrotalcite in the treatment of bile vomiting

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SUMMARY

Seventeen patients have completed a double-blind cross-over study of hydrotalcite against placebo in the treatment of bile vomiting after surgery for peptic ulcer. Overall there was no significant difference between the two treatments, with 9 patients improving on hydrotalcite and 5 on placebo. The original operation had been performed less than 3 years before the study in 9 patients; in this subgroup there was an improvement on hydrotalcite treatment in 8 patients but in only 1 on placebo. These differences are statistically significant ($P < 0.005$). Nausea, vomiting, heartburn and epigastric tenderness were improved although gastritis and endoscopic changes were not affected. It appears that hydrotalcite can help palliate symptoms of bile vomiting occurring soon after surgery for peptic ulcer.

THERE is a need for effective palliation of the bile vomiting symptoms that trouble patients in the early months after a primary gastric operation. Cholestyramine binds bile acids in the stomach but also in the small intestine, and so may lead to malabsorption. Hydrotalcite (Altacite) binds bile acids in the stomach but not at the higher pH of the small intestine (Mendelsohn and Mendelsohn, 1975). We have, therefore, performed a double-blind study of hydrotalcite against placebo in the treatment of bile vomiting.

Patients and methods

Patients with symptoms of bile vomiting and dyspepsia after an operation for peptic ulcer were included in the study if biliary disease and recurrent ulcer had been excluded. Hydrotalcite (1 g four times a day) and a placebo were given, each course of treatment lasting 6 weeks. Symptomatic assessment, endoscopy and biopsies from six points in the stomach were performed before and after each 6-week period of treatment.

Seventeen patients (5 female) completed the study; the average age was 42·8 years (range 21–93). Six patients had undergone two gastric operations; the last operation was vagotomy and pyloroplasty in 7, vagotomy and antrectomy in 5, proximal gastric vagotomy in 1, Billroth II partial gastrectomy in 3 and Billroth I in 1. The original operations had been performed on average 3·8 years previously (range 6 months to 10 years). Fisher's exact test has been used for the statistical analysis.

Results

There was no significant difference in the patients' overall symptomatic assessment after treatment with placebo or hydrotalcite when all patients were considered, though heartburn and nausea were significantly more frequently relieved by hydrotalcite than by placebo (*Table I*). However, there was a significant overall improvement after treatment with hydrotalcite in patients whose operations were performed less than 3 years previously. Vomiting and epigastric fullness were improved as well as nausea and heartburn. No patient became free of all symptoms.

Examination of gastric biopsies taken from the distal stomach before treatment showed chronic superficial gastritis which was severe in 10 and mild in 5; 2 were normal. In the proximal stomach 6 biopsies showed severe chronic superficial gastritis with 7 mild, while 4 were normal. The gastritis was active proximally in 5 and distally in 10. There were minor changes in severity seen in subsequent biopsies, but no change in the type of gastritis.

There was erythema of the gastric mucosa of all patients seen during the first endoscopy; it was considered mild in 2 patients, moderate in 11 and severe in 4. There was no change in assessment on

Table I: EFFECT OF HYDROTALCITE ON SYMPTOMS

	All patients		Operation within 3 yr	
	Hydrotalcite	Placebo	Hydrotalcite	Placebo
Initial treatment	9	8	5	4
Overall result				
Improved	9	5	8	1
Unchanged	3	2	1	2
Deteriorated	5	10	0	6
	(n.s.)*		$P<0.005$*	
Dyspepsia				
Abolished	2	2	1	0
Improved	7	3	6	2
Worse/unchanged	5	9	2	7
	(n.s.)		(n.s.)	
Vomiting				
None	3	3	2	2
Abolished	4	2	4	1
Improved	4	4	3	1
Worse/unchanged	6	8	0	5
	(n.s.)		$P<0.05$	
Bile regurgitation				
None	4	4	2	2
Abolished	5	2	3	0
Improved	2	2	2	4
Worse/unchanged	6	9	2	3
	(n.s.)		(n.s.)	
Nausea				
Abolished	6	2	2	0
Improved	6	2	5	1
Worse/unchanged	5	13	2	8
	($P<0.05$)		($P<0.05$)	
Heartburn				
None	3	3	2	2
Abolished	8	1	4	0
Improved	3	1	2	0
Worse/unchanged	3	12	1	7
	($P<0.02$)		($P<0.05$)	
Epigastric fullness				
None	1	1	0	0
Abolished	4	3	2	0
Improved	7	4	4	1
Worse/unchanged	5	9	3	8
	(n.s.)		($P<0.05$)	

* Difference between symptoms improved or abolished and those unchanged or worse using Fisher's exact test.
n.s., not significant.

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subsequent endoscopies in 14 patients but an improvement of one grade was seen in 2 patients—1 patient showing a change from severe to normal. This improvement occurred during hydrotalcite treatment in 2 patients and with placebo in 1. Bile reflux was seen in all patients on initial endoscopy but was seen in both subsequent endoscopies in only 11 patients. Bile reflux was absent after hydrotalcite in 4 and after placebo in another 4. Erosions were seen in 4 patients initially; these disappeared after placebo in 2 and after hydrotalcite treatment in 1. Erosions appeared in 1 patient on placebo.

Discussion

Bile vomiting, with associated dyspepsia, commonly occurs after surgery for peptic ulcer (Bushkin et al., 1974). These symptoms can be distressing but may improve within 6–18 months of surgery (Capper and Welbourn, 1955; Griffiths, 1974). Bile diversion operations may improve symptoms (Herrington et al., 1974; Van Heerden et al., 1975) but should be postponed until there is no longer any chance of spontaneous improvement.

Though hydrotalcite offered no significant advantage over placebo when all patients were considered, nausea and heartburn were improved. The effect on heartburn suggests a possible role for hydrotalcite in the treatment of oesophagitis caused by bile reflux. In patients whose operations were performed less than 3 years previously hydrotalcite was superior to placebo overall and in its effects on nausea, vomiting and epigastric fullness. These are the patients in whom spontaneous improvement can occur and for whom medical treatment is most needed. Gastritis and endoscopic hyperaemia were not changed. There was variation in the endoscopic assessment of bile reflux between examinations, and it is therefore an inaccurate method to assess bile reflux. Hydrotalcite is not ideal as no patient in our series became symptom-free, and more effective medical treatment is required. There is no other proved remedy. The beneficial effect of cholestyramine has been reported (Eckstam et al., 1975) but there have been no double-blind studies. Hydrotalcite has been shown by this double-blind study to be a useful medical treatment, which palliates the symptoms of bile vomiting occurring soon after gastric surgery.

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