A TRIAL OF METHYL POLYSILOXANE IN THE TREATMENT OF ABDOMINAL DISTENSION

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Methyl polysiloxane, a physiologically inert silicone substance, was shown by Rider and Moeller[1] in 1960 to be of value in the treatment of abdominal distension. Many preparations containing methyl polysiloxane, either alone or in combination with alkalis and anticholinergics, have since become available for use in a variety of gastro-intestinal disorders in which flatulence and distension are prominent symptoms. The purpose of the present paper is to report our experience with methyl polysiloxane and, in particular, to present the results of a double-blind trial using this preparation.

MATERIAL AND METHODS

The trial was carried out on 157 patients attending the gastro-intestinal service of the Groote Schuur Hospital. All had abdominal distension as a major or prominent symptom. Their ages ranged from 15 to 84 years, and there was a slight excess of females over males. Many were included in the trial before the final diagnosis was established by means of barium studies, the augmented histamine test, gastric exfoliative cytology and gastroscopy. The 157 patients included 30 with organic disease of the gastro-intestinal tract, 11 who had undergone gastric surgery and 116 considered to have functional bowel disorder.

Of the 157 patients, 57 were subjected to a double-blind study. Methyl polysiloxane (MP), the preparation under trial, was administered in tablet form as Mylicon (MP 40 mg.) or as Telament (MP 50 mg., atropine methyl bromide 0·2 mg. and magnesium oxide and carbonate 300 mg.). The standard dosage was one tablet at mealtimes and before bed, but a few patients were tried on 2 tablets *q.d.s.* Control tablets of these 2 preparations were supplied by the manufacturers; the Mylicon placebo consisted of lactose, and the Telament placebo of magnesium carbonate, 300 mg., aluminium hydroxide and dextrose. Treatment with either the placebo or MP was commenced in a random fashion and continued for an initial period of one week; the alternative preparation was then administered. Response to treatment to one or other of the coded tablets was assessed at the end of each week's therapy.* The majority of patients with constipation were given a bulk purgative in addition to the MP preparation or placebo during the period of trial.

The effectiveness of methyl polysiloxane in distension was further assessed in the remaining 100 patients not subjected to a double-blind trial. These patients were tested with either Mylicon, Telament or Silgastrin Gel. The latter, a liquid alkali—MP preparation containing aluminium hydroxide—magnesium carbonate gel, 5 G; dicyclomine hydrochloride, 5 G; methyl polysiloxane, 50 mg.; sodium lauryl sulphate, 25 mg. and magnesium hydroxide, 85 mg. per 2-teaspoonful dose, was used in a number of patients in whom distension was associated with heartburn. About one-third of the 100 patients were given MP combined with alkalis, anticholinergics, aperients or tranquillizers. These symptomatic measures, when given without PM, had previously failed to relieve the distension satisfactorily in a proportion of cases. Ten of the 100 patients were reassessed with Asilone, a tablet preparation containing a considerably larger amount of MP (MP 250 mg. and aluminium hydroxide gel, 500 mg.).

RESULTS

The results obtained in the double-blind trial are presented in Table I. The 57 patients comprised 32 with functional disorder, 11 following gastric surgery and 14 with organic disease of the gastro-intestinal tract. Thirty-six patients showed a good response to MP, their symptoms being uninfluenced by initial placebo therapy or recurring when the placebo was substituted for MP. A further 5 patients who showed a good response to initial MP therapy remained free of symptoms after substituting the placebo

TABLE I. RESULTS IN DOUBLE-BLIND TRIAL

	MP preferred	*MP induced remission maintained with placebo*	*Equivocal*	*No response to either*	*Placebo preferred*	*Total*
Functional	20	5	4	2	1	32
Gastric surgery						
Postgastrectomy	6		1	2		9
Vagotomy and G/E	1		1			2
Organic						
Hiatus hernia	1			1		2
Peptic ulceration	2				1	3
Small bowel disorder	3					3
Carcinoma G-I tract	3			1	2	6
	36	5	6	6	4	57

*The tablets were sent by the manufacturers in coded packages and the code was broken to the physician only at the end of the trial. The patients were led to believe that all tablets given them were active preparations. The active and placebo tablets were almost identical in appearance, but the placebo preparations dissolved easier in the mouth and tended to crumble with handling.

for MP. Equivocal results were obtained in 6 patients; these included 4 patients given more than one course of MP who showed a variable response on the different occasions. Six patients failed to respond to both MP and the placebo, and a further 4 actually preferred the placebo to the MP in easing their distension.

The organic disease sub-group of 14 patients all had distension as a major or prominent symptom. The distension was clearly improved in 1 of the 2 patients with hiatus hernia, in 2 of the 3 with peptic ulceration and in all of the 3 patients with the small bowel disease. The latter consisted of 1 patient with Crohn's disease, 1 with multiple adhesions and 1 with tapeworm infestation. The good results among the 6 patients with carcinoma occurred in 3 patients with early carcinoma of the stomach; the remaining 3 included a fourth patient with gastric carcinoma, a patient with pancreatic carcinoma and another with carcinoma of the colon.

Table II shows a breakdown of the results obtained with the two preparations of MP utilized in the double-blind study. While the number of good responses were similar, the table shows that the 4 patients who preferred the placebo were in the Telament group. These 4 patients were impressed, and possibly biased, by the ease with which the placebo tablets dissolved in the mouth.

TABLE II. BREAKDOWN OF RESULTS OBTAINED WITH THE TWO MP PREPARATIONS

	Good response with				
Drug	*MP*	*Placebo*	*Equivocal*	*No response*	*Total*
Mylicon	27*	0	5	5	37
Telament	14	4	1	1	20
	41	4	6	6	57

*Includes 5 patients in whom remission was maintained after initial MP.

The results obtained in the 100 patients not subjected to a double-blind trial are presented in Table III. Good results were obtained in 75 patients, including 8 with organic disease of the gastro-intestinal tract. Fifteen patients showed minimal improvement, and the remaining 10 did not benefit from the MP in any discernible way. It should be noted that MP was of value in 80% of the patients with functional distension, but in only 50% of those with distension attributable to organic disease.

TABLE III. RESULTS IN PATIENTS NOT SUBJECTED TO DOUBLE-BLIND TRIAL

	Improvement with MP	*Improvement with MP+Rx*	*Equivocal*	*No response*	*Total*
Functional	41	26	9	8	84
Organic	7	1	6	2	16
	48	27	15	10	100

The 10 patients in whom the larger dose of MP (Asilone, 250 mg.) was substituted comprised 8 who had previously improved on one of the 40 or 50 mg. preparations and 2 who had failed to respond to Telament. Of the 8, 4 claimed a greater degree of improvement with the 250 mg. dose, 2 considered both tablets to be equally effective and 2 preferred the 50 mg. preparation. One of the 2 patients who had failed to respond to Telament was improved by a larger dose of MP.

CASE REPORTS

Case 1

A 42-year-old postman who had had a gastrectomy 6 years previously presented with a long history of intermittent nausea and upper abdominal distension associated with borborygmi and left anterior chest pain. Belching or the passage of flatus afforded some relief. His bowel actions were normal. There was no history of a postgastrectomy syndrome or recurrent ulceration, and both physical and special investigations failed to reveal any evidence of organic disease. Mylicon tabs, 1 *t.d.s.*, gave dramatic relief which was not maintained when the lactose placebo was administered. A further course of Mylicon again produced a satisfactory result. The effect of MP was described by the patient in a vivid but ungrammatical manner as follows: 'When you've got winds inside and feel blown up and sore in the chest and back and you take the tablet and you can hear the winds travelling and out they come and you feel fine—fine tablets those for moving winds, whew! They certainly make the winds travel.'

Case 2

A 48-year-old housewife presented with a 6-month history of troublesome abdominal distension aggravated by meals and associated with slight epigastric discomfort. The distension coupled with frequent belching proved embarrassing in company. Physical examination and barium meal were noncontributory. Mylicon tabs, 1 *q.d.s.*, produced a symptomatic remission, but symptoms recurred on being given the placebo. These results were reproduced on 3 occasions, although on one of these occasions the excellent MP response was interrupted by a stressful encounter with the police. She observed that the MP remissions were associated with the passage of increased amounts of flatus and with a considerable diminution in belching and in the degree of distension. During one of the courses of therapy the patient noted tapeworm segments in her stools and a complete remission of symptoms occurred after the worm had been eradicated. No further therapy has since been necessary.

Case 3

A 21-year-old female with an almost lifelong tendency to constipation presented with a 2-year history of increased constipation and marked distension associated with vague abdominal pains, biliousness and heartburn. The distension sometimes necessitated her wearing loose clothes, occasionally resulted in shortness of breath and was eased by the passage of flatus or a normal bowel action. Physical examination was unremarkable apart from the presence of abdominal distension and an easily palpable descending colon. Special investigations were negative. The distension was considered to be due to a combination of aerophagy and the increased constipation, both of which could be attributed to domestic tension over the previous 2 years. The constipation was controlled and the distension considerably improved by a regime consisting of a bulk purgative, a mild tranquillizer and Mylicon tabs, 1 *q.d.s.* Replacement of the Mylicon with a placebo was associated with a return of the distension despite continuation with the rest of the treatment. The re-introduction of Mylicon was again followed by prompt improvement in the distension. Mylicon therapy was necessary for a few months, but could be discontinued once her domestic stresses had resolved.

Case 4

A 48-year-old housewife presented with a 4-month history of postprandial distension and belching, a nagging left subcostal discomfort about an hour after meals, nocturnal borborygmi and a 13-pound loss of weight. These symptoms developed against a background of financial difficulties and were associated more recently with a cancerophobia. Physical examination was noncontributory but the haemoglobin was 10·6 G/100 ml. and the ESR 50 mm./hr. She had a histamine-fast achlorhydria and the diagnosis of carcinoma of the cardia of the stomach was confirmed by radiology and gastroscopy. A

short course of telament tabs 1 *q.d.s.* given before the diagnosis was established was associated with a marked reduction in the amount of distension and belching and an increase in the passage of flatus.

DISCUSSION

Distension and belching, occurring alone or in combination with other gastro-intestinal symptoms, are frequently encountered in medical practice. These symptoms may be due to functional or psychogenic disorders of the gastro-intestinal tract or, less frequently, to intra- and even extra-abdominal organic disease. Chronic constipation is a commonly associated symptom in all the groups, and is an important predisposing cause in patients with functional distension. In the psychogenic group tension factors may manifest as aerophagy or a spastic bowel, both of which contribute to the accumulation of air in the gastro-intestinal tract.

The treatment of patients with distension unassociated with evidence of underlying organic disease thus frequently resolves itself into the management of chronic constipation and tension factors. In addition, an adjustment in the diet with special reference to the limiting of starch intake is sometimes helpful. These measures suffice for the majority of patients, but an appreciable proportion fail to respond satisfactorily. It would appear, therefore, that a need exists for a more specific therapeutic approach in patients who prove relatively refractory to the conventional measures. Methyl polysiloxane, a physiologically inert silicone defoamer, has been claimed to fill this need.

The present study supports the findings of previous workers regarding the efficacy of methyl polysiloxane in the treatment of distension. A double-blind trial with 2 MP preparations in 57 patients with distension showed that MP was clearly effective in controlling the symptom, and that 72% preferred the MP preparation to the placebo. An uncontrolled trial was carried out in a further group of 100 patients. MP administered alone or in combination with other therapy achieved good results in 75% of these patients, some of whom had failed to respond to treatment before the administration of MP. Many patients commented on the fact that while distension improved on MP, flatulence in the sense of the excessive passage of flatus actually increased.

Although the group of patients with functional or psychogenic distension had a higher percentage of good results than those with organic disease of the gastro-intestinal tract, it should be stressed that distension in patients with serious and indeed malignant disease may be improved following MP. This underlines the importance of considering the possibility of an organic cause in every case of distension, particularly in those with a recent history.

SUMMARY

The efficacy of methyl polysiloxane in the relief of distension was tested in 157 patients with functional and organic disease of the gastro-intestinal tract. Of these, 57 were subjected to a double-blind trial with MP and a placebo. The results of the double-blind trial confirmed the value of MP in the relief of distension, and the findings in the remaining patients showed MP to be a useful addition to the therapeutic regime in patients with distension.

The methyl polysiloxane used in this study was supplied as Mylicon by the Stuart Company, Pasadena, Calif., as Telament by Saphar Laboratories Limited, Johannesburg, as Silgastrin-Gel by S.C.S. Pharmaceutical Laboratories (Pty.) Limited, Johannesburg, and as Asilone 250 mg. by Berk Pharmaceuticals, London.

REFERENCE

1. Rider, J. A. and Moeller, H. C. (1960): J. Amer. Med. Assoc., **174**, 2052.