developed a reasonably high index of suspicion. It may well be more prevalent than we think. It is one of the few diseases of middle and later life the treatment of which is eminently satisfying to patient and doctor alike. It would be of interest to have observations on similar age groups in different parts of the country. It is suggested that this could be a useful exercise for the Royal College of General Practitioners.

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**CLINICAL TRIAL**

# *One tablet dyspepsia study—Pro-banthine*

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THIS IS A REPORT OF A pilot study into the value of various medications in the treatment of indigestion. A drug known to be active in this respect (15 mg tablets of 'pro-banthine') was chosen in order to validate the technique and estimate the variability.

## Method

Five general practitioners contributed to this study.

Patients were only admitted to the trial if they were male, over 16 years of age and were suffering from indigestion at the time they were seen by the doctor. If the patients were agreeable they were randomly given, according to a prepared list, either one 15 mg tablet of 'pro-banthine' or an identical placebo tablet. The tablets were taken with a small drink of water.

Patients were excluded from the trial if they had taken food or medicine within two hours of the test.

Indigestion for the purpose of this study was defined as pain or discomfort occurring in the upper abdomen or lower thorax, which was centrally sited and had occurred in the previous six months. The character of the pain was judged to be immaterial so long as it did not clearly arise from organs other than the upper gastro-intestinal tract.

Five minutes, 10 minutes, 15, 20, 30, 40, 50, and 60 minutes after the tablets had been given to the patients they were asked whether they still had the pain, and they were asked to reply yes or no. To help accurate timing a ringing alarm clock, such as is used in cooking, was provided. During the period of the test patients were left alone in a room to their own devices.

## Results

Data on 27 patients were received and all of them have been used in this analysis.

*Comparability of the two groups.* The comparability of the two groups was measured with respect to age range, mean age and standard deviation of the age. Inspection of the data presented in table I reveals that they are comparable. A larger number of patients in the actively

treated group (five out of 14) had radiological evidence of peptic ulcer, compared with the placebo treated group (two out of 13).

*Rate of pain relief.* Table II records the number of patients who had lost their pain by the times of asking which are indicated. When the number of patients in each group who have improved 15 minutes after receiving the medication is compared it reveals a difference statistically significant at the five per cent level.

*Side effects.* Two patients only complained of side effects. Both were in the actively-treated group. One patient complained of a feeling of dizziness and nausea, and the other of a feeling of warmth all over.

TABLE I
COMPARABILITY OF GROUPS

| | *Placebo (Group A)* | *Active (Group B)* |
|---|---|---|
| No. of patients .. .. | 13 | 14 |
| Age range .. .. | 28–56 | 23–63 |
| Mean age (years).. .. | 40.5 | 38.1 |
| Standard deviation .. | 8.4 | 14.0 |
| Nos. (percentage) with radiological evidence of peptic ulcer .. .. | 2 (*15*) | 5 (*35*) |

TABLE II
PATIENTS WITH RELIEF OF PAIN

| | *Placebo (Group A)* | *Active (Group B)* |
|---|---|---|
| Patients with pain relief at baseline | 0 | 0 |
| ,, ,, ,, at 5 mins. | 0 | 1 |
| ,, ,, ,, at 10 mins. | 0 | 2 |
| ,, ,, ,, at 15 mins. | 2 | 7 |
| ,, ,, ,, at 20 mins. | 4 | 7 |
| ,, ,, ,, at 30 mins. | 6 | 8 |
| ,, ,, ,, at 40 mins. | 7 | 9 |
| ,, ,, ,, at 50 mins. | 7 | 9 |
| ,, ,, ,, at 60 mins. | 7 | 8 |

## Discussion

This trial, which is believed to be the first of its kind, has demonstrated the value of 15 mg tablets of 'pro-banthine' in alleviating indigestion. It has further shown that this trial technique is practical and from it statistically significant results can be obtained.

It now remains to test other drugs in a similar way to see whether the clinical impressions of their effectiveness can be borne out by controlled double-blind clinical trials.

## Summary

Fifteen mg tablets of 'pro-banthine' have been shown to alleviate indigestion more rapidly than identical placebo tablets. This difference is statistically significant.

## Participants

Drs I. K. Lee, nr. Goole; G. F. G. Marshall, Rossington; J. E. Murphy, Northampton; K. L. Oldershaw, London.