

SHORT COMMUNICATION

A DOUBLE-BLIND CONTROLLED CLINICAL TRIAL OF MASTIC AND PLACEBO IN THE TREATMENT OF DUODENAL ULCER

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SUMMARY

1. A double-blind clinical trial was carried out on thirty-eight patients with symptomatic and endoscopically proven duodenal ulcer to compare the therapeutic responses to mastic (1 g daily, twenty patients) and placebo (lactose, 1 g daily, eighteen patients) given orally over a period of 2 weeks.

2. Symptomatic relief was obtained in sixteen (80%) patients on mastic and in nine (50%) patients on placebo, while endoscopically proven healing occurred in fourteen (70%) patients on mastic and four (22%) patients on placebo. The differences between treatments were highly significant ($P < 0.01$). Mastic was well tolerated and did not produce side effects.

3. It is concluded that mastic has an ulcer healing effect, but further studies are needed to establish its role in treating peptic ulcer.

Key words: double blind clinical trial, duodenal ulcer, mastic.

INTRODUCTION

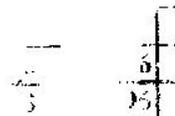
Mastic is a resinous exudate from the plant *Pestacia lentiscus* which belongs to the family Anacardiaceae which is cultivated in Mediterranean countries, particularly in the Grecian archipelago, and specially on the island of Scio in the Aegean Sea (Baily 1935).

Mastic is composed of more than 90% of resins, 2% volatile oil and a bitter principle (Claus 1970). The volatile oil consists of *d*- α -dipnene which gives the balsamic odour to the drug (British Pharmaceutical Codex 1949). The resins of mastic consist of α - and β -masticonic acid (38%), γ - and β -mastininic acid (4%), β -masticoresene and masticolic acid (British Pharmaceutical Codex 1949).

The history of mastic is lost in antiquity but both Pliny and Theophrastus mentioned it and the employment of mastic in medicine dates back to the thirteenth century (Claus 1970). In the

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materia medica of the Arab physician Ibn Al-Baytar (1248) mastic was reported to be useful for the treatment of intestinal ulcers.

Mastic has been used traditionally by oriental women as a masticatory (British Pharmaceutical Codex 1949) and as a breath sweetener (Claus 1970). The oil of mastic is used by Arabs for food and lights (Baily 1935). Mastic is also used in many parts of the Mediterranean region as an ingredient of sweets and drinks (Tanker & Tanker 1976). Mastic is a common article of commerce in oriental bazaars (Claus 1970). In Iraq, mastic was used in a spiritous drink called Arak Al-Mustaki. In many parts of Iraq, particularly in Nineveh, mastic is included in the recipe of many local foods.

Mastic resin by itself or in a spiritous solution is used in dentistry as a filling for carious teeth (Wren 1971; British Pharmaceutical Codex 1949; Martindale Extra Pharmacopoeia 1978). Mastic paint (Pigmentum Mastiche Compositum) is used as a surgical varnish for protective covering for wounds and to hold radium needles in position (Martindale Extra Pharmacopoeia 1978). So far no side effects from the uses of mastic have been mentioned in the literature.

Mastic has been used by traditional healers in many parts of the Mediterranean region for relief of upper abdominal pain and discomfort. In a case that came to our attention a 65 y old female patient who was suffering from both benign gastric and duodenal ulcers which did not respond to the currently used antiulcer drugs was prescribed oral mastic by a local traditional healer and responded dramatically in both relief of symptoms and healing of ulcers.

There is a high incidence of active duodenal ulcers in the Arbil area of Iraq among patients with dyspepsia subjected to upper GIT endoscopy (Al-Habbal & Huwez 1982). The failure of some of these patients to respond to the currently used antiulcer drugs and the occurrence of side effects to those drugs encouraged us to conduct a double blind trial to compare over a 2 week period the effectiveness of 1 g of mastic daily and the same dose of lactose as a placebo on patients with active duodenal ulcers which were proven endoscopically.

METHODS

The study procedure was explained to patients and their consent to participate was obtained. Individuals were excluded if they had been on antiulcer drugs in the preceding month, if they had pyloric stenosis, or if they were incooperative, below 20 y of age, pregnant or lactating.

Sixty patients aged 22-62 y with endoscopically proven duodenal ulcers were entered in the trial. They were randomly allocated to Saladin (mastic) or placebo (lactose) treatment groups. Medication was taken once daily in a single dose before breakfast for a 2 week period and consisted of either 1 g of mastic as a powder or 1 g of lactose as a powder. Antacid tablets (Gastrigel) were allowed on demand through the trial and their intake was recorded, but no drugs which promote healing of ulcers were permitted. Patients were advised to stop smoking, to avoid fried foods, and to avoid aspirin and other anti-inflammatory drugs during the course of the trial.

At the end of the 2 week trial period, clinical examination was given, including reporting of side effects, and endoscopy was repeated by the same endoscopist (FUH). Ulcer healing was reported when the site of the original ulcer was completely replaced by epithelial tissue without appearance of other new ulcers (Chalabi 1979).

Twenty-two patients did not attend for follow up endoscopy (ten on mastic and twelve on lactose), and these were dropped from the trial. The data from the remaining thirty-eight patients were analysed using the z statistic (Hunstberger 1968).

RESULTS

The sex and age range distribution between the two groups of the thirty-eight patients completing the trial are summarized in Table 1. The duration and severity of duodenal ulcer did not differ between the two groups.

The results of treatment are also shown in Table 1. Saladin (mastic) was significantly more effective than placebo (lactose) in giving symptomatic relief from and in healing of duodenal ulcers.

No side effects of treatment were reported.

Table 1. Double blind placebo controlled trial of mastic (1 g orally, daily, for 2 weeks)

	Saladin (mastic)	Placebo (lactose)
No. of patients completing trial	20	18
Male	18	15
Female	2	3
Age range (y)	27-62	22-55
Symptomatic relief: no.	16*	9
%	80*	50
Endoscopic healing: no.	14*	4
%	70*	22

* Significantly greater than placebo ($P < 0.01$, z statistic).

DISCUSSION

The ideal drug for the treatment of duodenal ulcer would be one which relieves the symptoms, heals the ulcer, and prevents relapse. The incidence of breakthrough recurrences and post treatment relapses with cimetidine makes it imperative to develop other drugs without these drawbacks (Warmsley 1980).

The present study was designed to compare the effect of 1 g of mastic to 1 g of placebo given orally as a single dose before breakfast over a period of 2 weeks. The results revealed that mastic is more effective in relieving symptoms and healing of duodenal ulcers than placebo, and the differences were statistically highly significant. However, in this preliminary report, it is not possible to evaluate the effect of mastic in post treatment relapses because the study was not designed for this purpose; yet, even if relapses occur, mastic is worthy of further consideration because of its effectiveness when given in a single daily dose for a short (2 week) course of treatment. Moreover, mastic is safe and cheap, as well as being effective, both in relieving symptoms and in the healing of duodenal ulcers.

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