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TREATMENT OF PEPTIC ULCERS WITH "ROTTER" TABLETS

BY

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"Rotter" tablets were introduced into this country from Holland in 1948 for the treatment of peptic ulceration, and are still widely prescribed in spite of being classified in Group 6 by the Cohen Committee. Tablets with similar formulae are being manufactured in this country under the names tabs. bismuth subnitrate co. (B.D.H.; Kirby), tabs. stomachic co. (Duncan, Flockhart), and tabs. frangula co. (Evans; Woolley; Cuxson, Gerrard). No report on their use has appeared in the British medical press, but in view of the fact that the tablets contain bismuth subnitrate, which has the reputation of causing serious toxic effects, the need for an inquiry into their use is indicated.

Composition.—The tablets contain magnesium carbonate pond. (400 mg.); sodium bicarbonate (200 mg.); calamus (25 mg.), an aromatic bitter said to act as a carminative (*B.P.C.* 1923); frangula, which has a mild purgative action similar to cascara (*B.P.C.* 1954); and bismuth subnitrate (350 mg.), which is widely prescribed on the Continent for dyspepsia, although its action is unknown. In recent years bismuth subnitrate has fallen into disrepute in this country and America following the publication of reports of a number of fatal cases of nitrate poisoning. Marcus and Joffe (1949) stated that the use of bismuth subnitrate as a therapeutic agent is unnecessary, unwarranted, and hazardous.

Material

The clinical material for these notes was derived from my general practice in Hawick, Scotland (population 17,000), famous for its hosiery industry, which employs a large number of both married and single women. The number of patients at risk in this series is 3,700, and the period of observation is one year. The cases treated include 79 which presented with active symptoms of peptic ulcer, proved radiologically, and 19 of "presumptive peptic ulcer" (Doll and Avery Jones, 1951), with a history suggestive of peptic ulcer, in which the barium-meal examination was negative.

Incidence of Peptic Ulcer

The overall incidence of active ulcer (Table I) in this series is 2%, or 2.9% over the age of 20, which is in general

TABLE I

Ages:	0-14	15-19	20-34	35-54	55+	Totals
Total population	774	188	760	1,016	963	3,701
Active ulcers ..	0	0	19	42	18	79
% with ..	0	0	2.5	4.1	1.9	2.0
Presumptive ulcers	0	0	6	9	4	19
Total ..	0	0	25	51	22	98
% with ..	0	0	3.3	5.0	2.3	2.6
Male ..	395	80	354	446	354	1,629
Active ulcers ..	0	0	13	31	12	56
% with ..	0	0	3.7	6.9	3.4	3.4
Female ..	379	108	406	570	609	2,072
Active ulcers ..	0	0	6	11	6	23
% with ..	0	0	1.5	1.9	1.0	1.1

agreement with Ivy *et al.* (1950), who quote a figure of 1-3% for the latter age group. Table I further illustrates that the condition is more common between the ages of 35 and 54, and after 55 the incidence is reduced by one-half in both men and women.

The sex ratio of active ulcers is 3 male to 1 female, and of five new cases presented during the year four were women. An unusual feature is the low incidence of gastric ulcers, only two cases occurring in the whole series.

The average duration of symptoms in the active ulcer group, dating from the first attack of indigestion, was 12 years: 25 patients (18 M., 7 F.) with a history of less than 5 years, 38 patients (27 M., 11 F.) with a history of less than 10 years, and 41 patients (29 M., 12 F.) with a history of over 20 years.

Previous treatment comprised advice regarding diet and frequent feeds, with the addition of magnesium trisilicate powder and small doses of phenobarbitone. The main cause of unsatisfactory results was failure on the part of the patient to adhere to the dietary restrictions.

Method and Dosage

The tablets used were specially prepared by F.A.I.R. Laboratories, varying in shape from the original tablets and bearing no trade name. The patients were instructed to take two tablets three times a day after food for three weeks; thereafter one tablet three times a day for a period of two months. Fifteen cases with a long history of frequent relapses were instructed to continue on a maintenance dose of two tablets daily for the full period of one year. This is below the dosage recommended by the makers, who suggest two tablets three times a day for the first three months, followed by one tablet three times a day for the next three months, and thereafter one tablet daily for a further three months.

All but five of the 98 cases were ambulant throughout their treatment and no instructions were given as to rest. They were advised to take an average diet but to avoid fried foods.

Results

The immediate clinical results were assessed after the first month's treatment in four main groups: (A) pronounced relief (symptom-free); (B) definite relief (minor symptoms with no pain); (C) doubtful relief (symptoms persisting but improved); (D) no relief.

Table II shows that 81% of cases became symptom-free—70% of them during the first week and 30% during the second week; a further 9% were relieved of the majority of their symptoms. Thus there was a satisfactory response in 90% of cases.

Four of the nine cases in groups C and D have elected to go to surgery, and one of the remaining cases has a hiatus hernia as well as a duodenal ulcer. Experience of treating these "failures" over the past six years leads one to believe that no form of medical treatment will be effective and that surgery is the only hope of relieving their symptoms. In 75% of the cases the patients were of the opinion that the

TABLE II

Group	Active Ulcers	Presumptive Ulcers	Totals
A	63 (79.6%)	17 (89.0%)	80 (81.7%)
B	8 (10.2%)	1 (5.5%)	9 (9.2%)
C	6 (7.5%)	1 (5.5%)	7 (7.1%)
D	2 (2.5%)	0 (—)	2 (2.0%)
Totals	79 (100%)	19 (100%)	98 (100%)

tablets were superior to alkaline powders, and they found that they were able to take foods which they had avoided for years.

The absence of controls is unfortunate, but their use in general practice is beset with difficulties, and recently the Medical Defence Union has advised the College of General Practitioners that patients should be advised when controls are being used. However, Ivy *et al.* (1949) have pointed out that in a chronic condition such as peptic ulcer it is possible to use the patient as his own control, working on the assumption that a patient who shows a pattern of frequent recurrence over a period of four years or longer is unlikely to show spontaneously a marked diminution of frequency of recurrence on ambulant management.

Fifteen cases with an average duration of symptoms of 10 years have been kept on a maintenance dose of two roter tablets a day for one year, and a record kept of the number of relapses—a return of even mild ulcer distress constituting a relapse. This was compared with the number of relapses recorded in the previous year. Patients shown with “six” relapses a year were known regular attenders at the surgery, and, although stating that their discomfort was more or less continuous, averaged six acute episodes. Table III shows that with this regime there was a reduction in the number of relapses from an average of four a year to less than one a year. Those which did occur rapidly responded to increased dosage.

TABLE III

Age	Duration of Symptoms (Years)	Relapses	
		1953	1954
39	10	(6)*	1
51	11	(6)	Nil
43	8	(6)	1
41	16	(6)	1
38	4	5	1
35	10	5	1
52	12	5	Nil
29	10	4	1
42	4	4	2
44	18	3	Nil
43	18	2	1
25	5	2	1
37	7	2	1
31	9	2	Nil
37	8	2	1
Averages: 40	10	4	0.73

* Average of acute episodes.

The relapse rate at the end of one year in a further 43 cases (group A) whose treatment was stopped at the end of three months was 57%; however, as patients were instructed to report immediately on return of symptoms, many of these were mild and in each case responded satisfactorily to further treatment.

Toxic and Side-effects

Possible toxic effects from the use of roter tablets arise from their content of bismuth subnitrate, although the intake of 0.7 g. is within the limits set by the B.P.C.

The literature contains numerous references to methaemoglobinaemia following its use: Miller (1945), in a review of the subject, quotes six cases, four of which were fatal. Since then further cases have been reported by Wallace (1947) and Marcus and Joffe (1949). Analysis of these cases shows that all but one of the fatalities occurred in infants aged 1 week, 3 weeks, 5 weeks, 1 month, and 1½ years. The adult suffered from intestinal obstruction. Diarrhoea was present in five of the cases, and in three the bismuth subnitrate

was administered rectally. Thus it appears that, while bismuth subnitrate may be highly toxic in infants, particularly in the presence of diarrhoea, its use in adults is not contraindicated, and the statement of Marcus and Joffe, quoted by Martindale (1952), is unduly pessimistic.

Methaemoglobinaemia arises from the conversion of the nitrates into nitrite by nitrate-splitting organisms in the intestine. The urine and faeces were tested daily after the taking of two roter tablets three times a day for two months, but no nitrites were detected using the α -naphthylamine sulphanilic acid method. This, however, may be due to the destruction of the nitrites by other micro-organisms, as pointed out by ZøBell (1932). Two patients, however, complained of a “thumping headache,” which ceased when the drugs were withheld, raising the possibility of nitrite being actively present in the blood stream. The stools became “muddy”-coloured owing to the presence of bismuth, but this can be easily distinguished from the “tarry” black stool of a melaena; benzidine tests of the stools were negative, although a very late positive does sometimes occur. Three patients complained of diarrhoea, due possibly to frangula, requiring the tablets to be withheld in one case. Thus, in the 98 cases treated, no serious toxic effects have been observed, and the roter tablets appear to be safe in the doses recommended.

Comments

Psychologically, roter tablets are an ideal drug, combining the essentials of expensiveness, taste, and colour with an unusual discoloration of the stools following their use; and we are presented with the problem of how much their effect is purely psychological and how much due to physical properties as yet unknown. Little information is obtained from a study of the individual drugs. The content of magnesium carbonate and sodium bicarbonate is too small to have any effect on the gastric juice, while calamus appears to be contraindicated in view of its action as a bitter, and the only known effect of frangula is to relieve constipation. The effect of bismuth subnitrate demands more attention. Used in the treatment of dyspepsia since its introduction by Odier in 1776, it is still widely prescribed on the Continent, where it is preferred to the carbonate. It has been suggested that, like the carbonate, it lines the ulcer; yet Pygott (1954), using 20 g. of bismuth carbonate, was able to demonstrate this in only two out of nine cases of duodenal ulcer. The effect on the stomach of the slow but continuous absorption of nitrite has not yet been investigated, although Brun (1942) reports the relief of ulcer pain following the use of glyceryl trinitrate, and Steigltz (1928) has used this effect of bismuth subnitrate in the treatment of hypertension. The therapeutic tests are handicapped by the absence of controls, but a 90% satisfactory response obtained in ambulant patients in the absence of dietary restriction or other drugs is encouraging; and the reduction of the average number of relapses in the 15 patients kept on a maintenance dose confirms my own view that the beneficial effect of roter tablets cannot be explained on purely psychological grounds. A 57% relapse rate at the end of one year in those cases receiving only three months' treatment indicates that roter tablets do not influence the relapse rate in the dosage given, although in part this may be due to inadequate dosage.

The treatment is ideal for general practice, where its simplicity appeals to both patient and doctor, and, although its mode of action remains an unsolved problem, this should not deter its use in a condition the cause of which remains a riddle. Finally, while the possibility of toxic effects does arise, none have been reported or found in this series; but, as a precaution, the tablets should not be administered to young children.

Summary

Seventy-nine cases of peptic ulcer and 19 of presumptive peptic ulcer have been treated with roter tablets. Immediate clinical response was satisfactory in

90% of patients, with a relapse rate of 57% in the first year; a reduction in the average number of relapses was recorded in 15 cases kept on a maintenance dose for one year. The mode of action of the tablets and the possibility of toxic symptoms arising are discussed.

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THE TREATMENT OF SIMPLE RIB FRACTURES

A CRITICISM OF A "LAISSEZ-FAIRE" POLICY

BY

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The treatment of simple rib fractures appears to have remained unchanged for many years, and has commanded no great attention among recent surgical writings in this country. Strapping, binding the chest, or some other form of support remains the sheet anchor in therapy as recommended by the majority of writers. This article draws attention to the frequency with which these fractures occur, and advocates a better method of initial treatment; it is concerned only with simple uncomplicated rib fractures, and not with crush injuries of the chest.

About 80 cases of simple rib fractures are seen every year in this unit, and it is calculated that about 15,000 occur every year in Great Britain. This represents a formidable mass of suffering and disability, sufficient to justify far more care and attention than this problem usually receives.

Most medical students in this country seem to be taught to use some form of strapping as the main and usually the only method of treatment, while 33 out of 40 British and American surgical textbooks which have been consulted make similar recommendations.

A Criticism of Strapping

As a method of treatment for these fractures I believe strapping of any type has several major disadvantages.

1. *It is an Inefficient and Inadequate Method.*—I do not believe it is ever possible to immobilize a rib fracture completely except by internal fixation, which indeed is advocated by certain American writers for this very reason. Strapping provides inadequate support, only partial immobilization, and fails to stop the acute pain suffered with every full inspiration, attack of coughing, or energetic movement. One of the pressing worries to the patient is inability to sleep with any degree of comfort, a complaint of which hardly any mention is ever made in standard textbooks. I have seen patients bound in strapping who still cannot sleep at all adequately or comfortably two or three weeks after the injury. A method of treatment which fails to ensure a good night's rest two or three weeks after the injury should be discarded.

2. *It is an Uncomfortable Method.*—Nearly every patient from whom I have removed previously applied strapping has been profoundly relieved to be rid of it. Many find it extremely irritating, and a high proportion develop skin rashes under the strapping, even in a few days. This point, too, is glossed over in most textbooks.

3. *It is a Lazy Method.*—Undoubtedly many doctors apply the strapping themselves; quite certainly, many delegate it usually to one of the nursing staff. To give an order is in this case less trouble than to carry it out.

4. *It may even be a Dangerous Method.*—Hirsh and Ellis (1940) record the cases of two patients who developed bilateral oedema of the legs and ankles following fixation of the chest for rib fractures. While this must be a rare occurrence, it is yet a warning of what can happen.

Injection as a Primary Treatment

Zoppi (1936) was apparently the first to advocate local analgesic injection, using procaine. Strong support for this came from Hamon *et al.* (1942), and Smith (1942) drew attention to two distinct causes of pain: (1) the dull ache of muscle and ligamentous injury, and (2) the sharp stabs of bone pain. Other writers in favour are Homans (1945), Bancroft and Murray (1945), Ferguson (1947), Naylor (1952), and Belsey (1953). Roualle (1952) suggested using "efocaine" as a long-acting analgesic, while Winkler (1951) used a long-acting analgesic in treatment by means of intercostal nerve blocks. Yet, despite this not inconsiderable body of evidence in favour of injection treatment as a primary procedure, what Belsey calls the "time-honoured treatment by strapping" remains the predominantly taught and, I believe, practised treatment in this country. In my opinion it is a method honoured by nothing but time.

Smith's paper first brought injection treatment to my notice some years after its publication; he pointed out that, although in theory one injection of a short-acting analgesic such as procaine should last for only a few hours, in practice it often sufficed to relieve bone pain not only completely but permanently. For a number of years I treated these fractures by direct injection into the fracture site of 1-2 ml. of 2% procaine with no external support whatever, and was satisfied that Smith's claims were fully justified. More recently a long-acting local analgesic was substituted, using a benzocaine-urethane solution as advocated by Rutter (1952).

During the early months of this year efocaine was used for direct injection to each fracture site, but although no untoward sequelae have occurred the use of efocaine has now been abandoned in favour of the benzocaine-urethane solution in view of the serious complications reported by Clarke *et al.* (1955) and Parsonage *et al.* (1955).

I believe injection is the treatment of choice in almost every patient; it abolishes bone pain completely and it can be easily repeated if necessary. Injection takes no longer than does the application of strapping, there is no interference with the patients' bathing, and they can sleep in comfort.

The symptoms and signs of these fractures are adequately described in textbooks and need not be reiterated here, but the most important and valuable finding does not normally receive adequate emphasis. This is extreme local tenderness at the fracture site. Smith stressed this years ago, and I am convinced it is of fundamental importance. The patient who is thoroughly bruised but without a fracture does not have this extreme local tenderness; in those with a fracture one can accurately locate the fracture site(s) in a few moments.

Use of Radiographs in Rib Fractures

It is commonly advised that every suspected rib fracture should be radiographed, and it is often admitted that only 50% of these fractures are seen on the x-ray plates. I believe the true figure is much smaller and that too much importance is placed on x-ray films in uncomplicated rib fractures, despite their supposed importance from the