Clinics in General Practice

A case of peptic ulcer

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British Medical Journal, 1977, 1, 1017-1019

The trainee's problem

The patient's story is really very straightforward, but it raises several problems of deciding management. He is 52 and has a clerical job in local government with a fair amount of responsibility that he enjoys, and he does not feel he is working under undue stress. He is married with two children, one still at home, and again no obvious problems arise in this part of his life.

He has had intermittent dyspepsia for some 20 years and a barium meal examination 10 years ago showed duodenal scarring. He normally controls exacerbations with milk or by taking baking soda; he drinks little alcohol but smokes about 10 cigarettes daily. He has never lost work because of his symptoms. He consulted yesterday evening because of a two-week long current episode of dyspepsia of greater than usual severity that has not responded to his usual self-medication. He has not vomited but is losing sleep and having considerable epigastric pain as the day wears on. He looks unhappy and has moderate abdominal tenderness localised to the usual peptic ulcer area. He seems thin but says he has not lost weight recently.

I feel reasonably happy that the diagnosis is duodenal ulcer and no doubt antacid treatment would help his pain. I also feel further investigation could reasonably be delayed. Our local gastroenterologist however, has asked for this type of patient to be referred to him because of his co-operation in a trial of one of the new bismuth-containing preparations. This would mean three gastroscopies but equally could help both the patient's illness and the proper evaluation of a possibly important new drug. I find my position between the patient and progress difficult and need advice both in general and particular terms.

General practitioner's comments

From this description it is reasonable to assume that the patient is suffering from an acute exacerbation of his duodenal ulcer and to start treatment with a course of antacids without resorting to further investigations at this stage would be quite appropriate. My only comment on your statement that the case is "very straightforward" is the lack of any indication as to possible reasons for the recent worsening of his symptoms. Anxiety is a frequent precipitating factor, and there are many reasons why a patient may not readily admit to pressures causing psychological stress, especially if relations with his doctor are not yet fully

established as may often be the case during the trainee year. Before too readily accepting the patient's account, it is worth exploring the areas of potential stress very carefully.

The question posed reflects an apparent conflict between your plan for management and the research interests of the gastroenterologist. To resolve this, it is necessary to attempt to balance the benefits that might be derived from the research study—both specifically by the individual patient being referred and more generally by an advancement of medical science—against possible disadvantages that might be experienced by either the patient or the practice.

The critical question is, how is this evaluation to be achieved? An essential first step is to obtain sufficient information about the different facets of the problem, and the following points are suggested as a framework for such inquiry.

FACTORS CONCERNING DETAILS OF THE RESEARCH PROJECT

What is the study attempting to demonstrate? Who is likely to benefit from it and in what way? What is the design of the study, and how relevant are the results likely to be?

FACTORS AFFECTING THE PATIENT

What type of procedure will the patient have to undergo? What specific benefits will be derived from the study? What possible or probable delays will there be before treatment can be started? What limitations may be imposed on other forms of treatment? What inconveniences may he suffer—such as his distance from the gastroenterological unit, the frequency of visits required, and the need for long-term follow-up?

FACTORS AFFECTING THE REFERRING DOCTOR AND HIS PRACTICE

Various possible complications that may arise as to who has overall responsibility for the patient's subsequent management; the availability of the gastroenterologist; the effect of the study on other forms of treatment; what is the patient to be told? any clerical demands on the practice and the possible need to obtain the agreement of other doctors within the practice.

Clearly the relevance of these different factors will vary depending on the individual case, and in coming to a decision it is important to give the appropriate "weighting" to each. The following specific points stand out as needing particular attention in the case described.

The patient will need to undergo gastroscopy. This is hardly an insignificant investigation, and it is essential to be fully aware of the details of the procedure and how it affects the patient. Then there is the question of the type of patient to be studied. This patient is considered to be a suitable person for entry into the trial, and yet he has existed comparatively well for 20 years with minimal recourse to medical care. Are you convinced that he is really likely to be much improved by the new treatment?

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Also, how will he respond to being told of his referral to the study, in view of the fact that he has been comparatively untroubled by his symptoms over such a long period, and how likely is it that he will agree to all three tests being carried out, especially if his symptoms improve? The study is designed to look at those patients referred to the gastroenterologist—not those presenting to you with a particular symptom complex, and therefore you must establish your grounds for selection and exclusion. It is thus important to know the particular reasons for the study population being drawn from general practice, rather than from the hospital outpatient department where the proportion of patients presenting with problems of diagnosis or management will be much greater.

In considering one's approach towards the study, you must remember that research is a necessary and integral part of medical practice, but it is an activity with which few practitioners have much personal experience. As members of the profession, we must contribute to improving medical care, and we have a responsibility to look constructively and critically at requests for our participation in such studies.

Increasingly, general practice is being used for research projects, and many of these are planned and designed by those who do not themselves provide primary care. There are specific differences between the setting of general practice and that of the hospital, and if the research is to be successful it is important that these are fully understood. Do not overlook the fact that if consulted early enough you may have an important positive contribution to make in the planning stage of a research study, either as an individual or through such representative bodies as the local medical committee or the Faculty of the Royal College of General Practitioners.

Ultimately, once all the factual and objective information of the different aspects of the study has been obtained, one is left to make a subjective evaluation of the issue as a whole. As general practitioners we are privileged to be the principal protector of our patients' interests in our capacity as their personal physician. In attempting to find the right path to follow it is perhaps helpful to consider what action one would take if the research project was being undertaken by a close colleague and one's patient was a personal friend.

If you decide to enter this patient into the trial you will need to decide how you are to introduce the idea to him. It will be a rare patient who would accept to undergo the series of investigations mentioned if he did not believe he would personally be likely to benefit, and therefore it will be necessary to emphasise this aspect. On the other hand, it will also be important to ensure that he understands that it is a research project, partly because he is likely to hear this at some later stage and also to attempt to reduce the likelihood of him defaulting before the programme is completed.

As a final point, if you have any doubts as to whether it should be you or the gastroenterologist who should discuss these issues with him, you should remember that it is to you he has come for advice and help, and therefore from you that he should receive the reasons for your decisions. These should be given in a way that ensures that he still feels free to accept or reject them.

Consultant's comments

There are two distinct questions to be answered: firstly, "how should this patient with an exacerbation of dyspepsia best be managed?" and secondly: "how does the doctor reconcile research with the clinical care of his patient, when that research means submitting the patient to investigations that might not otherwise be done?"

The first is the easier. This patient's presumptive duodenal ulcer has given him little trouble over 20 years, and the symptoms have hitherto been easily controlled. Why has there been a change recently? Now, duodenal ulcers may produce occasional attacks whose severity is out of character, but other

possible explanations are that a complication has arisen—penetration into the pancreas, impending duodenal stenosis, perhaps—or that there is another diagnosis—a coincident gastric ulcer, for instance. So, while symptomatic treatment as a duodenal ulcer should begin (bedrest, hourly antacids, etc) further investigations should not be long delayed. A barium meal examination is needed first; it will probably show a duodenal ulcer or a gastric ulcer if either (or both) is present, and it gives rough information about gastric emptying. If, however, the local gastroenterologist prefers (and is willing) upper alimentary endoscopy may be performed instead. This is slightly better at diagnosing an ulcer or oesophagitis but gives little information about gastric function.

If it were confirmed that he simply has an uncomplicated duodenal ulcer in severe exacerbation there is no strong reason to consider surgery yet; this severity of relapse will not necessarily recur. Today the medical treatment most likely to cut short the attack is cimetidine, given for four to six weeks and then stopped. In normal clinical practice there is no virtue in trying to confirm healing of a duodenal ulcer, either by x-ray examination or endoscopy, provided the symptoms are fully relieved. (Gastric ulcer healing should always be verified, by endoscopy, of course, because of the malignancy risk.)

That brings us to the second and more difficult question, which involves the ethics of research. Without any doubt the efficacy of a new drug today always needs assessing by careful observation, usually by some form of controlled trial. This is particularly so in conditions such as peptic ulceration when symptoms are intermittent and subject, in any case, to spontaneous remission. Only comparison between treated and control groups of adequate size can compensate for this. Verifying ulcer healing (as opposed simply to symptom relief) needs serial assessment and, preferably, measurement of the ulcer. For gastric ulcers, radiology may be fairly accurate, but change in duodenal ulcer size can only be assessed accurately through the endoscope. Thus, as new drugs alleged to aid ulcer healing pour on to the market, adequate trials need to be carried out if we are to use them wisely.

Unfortunately, a patient is more interested in getting relief of his bellyache than with the niceties of medical science and might reasonably maintain that he consulted his doctor to obtain the best advice, not to be a piece of research fodder. Nevertheless, most patients are surprisingly agreeable to participating in such a study if its aims are explained honestly. This good will must not be abused. The experiments must be properly constructed to ensure that a clear result is likely to emerge and that the control aspects are adequate. (It is difficult, for example, to design a "placebo" for comparison with a drug like bismuth that produces such obvious signs as black stools.) No more tests than necessary should be used and the purpose of the investigations (and any hazards that it adds over and above normal clinical practice) must be explained. This trial is probably well constructed, but in other cases one should make sure it is a proper trial and not just a "try-on." Some less scrupulous pharmaceutical companies persuade doctors to use their drug in the guise of a "trial" from which controls and accurate measurements are notably absent.

If, as this patient's doctor, you are satisfied that these criteria are met (and you might like to ask why there are to be three endoscopies rather than two, and what the likelihood is of his receiving inactive placebo rather than active drug) then it is reasonable to refer him. You can explain to him that it is a new drug whose efficacy the profession needs to know, and that his progress will be carefully monitored. If he responds poorly the code should be broken to find whether he was on active drug or not. It may be worth ensuring that he has the initial gastroscopy before finally agreeing to participate, for if he finds it intolerable he may not complete the study, which might then be spoiled.

One final point about relations between general practitioner and consultant regarding such therapeutic trials. Ideally, it is desirable for a consultant proposing to include a patient in such

a trial to obtain the agreement of his general practitioner. It is accepted practice, however, (particularly now that every hospital has its own committee to scrutinise trial protocols to ensure their ethicalness) that formal agreement is not always obtained. But it is also important for the patient's safety as well as professional politeness that the general practitioner should be informed that the patient is in such a trial, what the nature of the agents under test is (and any expected hazards), and what supervision the hospital staff is giving.

Postscript to the problem

The full implications of the proposed referral and its under-

lying research nature were explained to the patient by the general practitioner and the specialist. The patient has agreed enthusiastically and has in no way been deterred by his first and second gastroscopies. The study is a comparison of two different regimens, not one of active against placebo; it is regarded by the "experts" as adequately designed and has received ethical committee approval. In this case all appears to have worked well: the consultant has recruited a suitable patient and the community may benefit; the general practitioner's co-operation has improved professional relations and job interest; and the patient has had serious disease excluded and a diagnosis confirmed. His symptoms have rapidly improved, and he is pleased to have "been given the opportunity" to contribute to medical progress.

Letter from . . . Dublin

Politicians and medicine: a changing role?

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British Medical Journal, 1977, 1, 1019-1020

Last year, 1976, was a dull and somewhat disappointing year for Irish medicine. Drastic financial restrictions caused near panic in the hospital services, while the Minister for Health, Mr Brendan Corish, confidently reassured a not unduly anxious public that the standard of health care would not be affected. In this he was correct—at least for 1976—but what of 1977 and 1978, when the unserved and poorly manned health machine splutters slowly to a standstill? But perhaps by then both the medical profession and the politicians will have learnt a few lessons, and things will be different. Certainly the financial hardship of the past year has forced doctors to think carefully about the cost of the health services they distribute, and they have realised—a little belatedly perhaps—that the age of plenty has passed and that the financial splurge of the 'sixties is well and truly over.

Paradoxically these restrictions may have brought politicians and doctors closer together by focusing their attention on the priorities of health care. Both sides have probably come to realise that the one cannot do without the other in deciding what is best for the health of the community. There has been much talk about taking medicine out of politics, but this would be even more difficult than taking politics out of medicine—and what is really being sought is co-operation between the government and the profession in health-care planning. It would now appear that Mr Corish is aware of the importance of broadening the base of future planning and by so doing he may well be taking medicine out of party politics, which is, of course, quite different from taking medicine out of politics. Two examples serve to illustrate Mr Corish's genuine desire to co-operate: firstly, he established a working party consisting of

members of his department and the medical and pharmaceutical professions to advise him on drug prescribing; and more recently he has called for all-party discussions on the health services and the emotive contraceptive issue.

Drug prescribing

The Minister can thank his working party for confirming his fears that doctors overprescribe, often prescribe badly, and really have little regard for the cost of what they prescribe. It would have been interesting to compare prescribing habits in private practice with those in the public sector but unfortunately figures were not available for contrast. Mr Corish will have been disappointed if he had hoped that his working party would solve the problem of our soaring drug bill, which is now £15.2 million a year and has doubled in two years. The working party recommended tighter control of the premarket pricing of new drugs, and had misgivings about the pharmaceutical industry's methods of advertising and selling drugs to the profession. Both the imposition of prescription charges and the restriction of the number of drugs available were rejected as effective remedies for reducing drug costs (although it was suggested that hospitals might consider stocking only one specific type of each drug), and the working party concluded that the Minister should concentrate on educating both the public and the profession about the cost of drugs and the need for restrained prescribing.

These recommendations are sound but none will, as the report admits, have any immediate effect on the drug bill. Education of both the profession and the public as to the cost of treatment is long overdue and should be beneficial, but it will be many years before this is evident. Why, one wonders, did the working party suggest a limited drug list for hospitals while rejecting this option for general prescribing? Would there not, in fact, be a stronger case for limited prescribing in general practice rather than in the hospitals? Few doctors could argue against the feasibility of listing a limited number of drugs of approved effectiveness to deal with most illnesses, though

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