

Optimal timing of operation for bleeding peptic ulcer

SIR,—Doctors have waited a long time for a trial like that of Mr D L Morris and his colleagues (28 April, p 1277) but it is a pity that the trial was closed before a clear conclusion was possible. The claim of benefit from early surgery depends on the analysis of outcome in patients over 60 years of age. There were three deaths in 48 such patients randomised to the early operation group and seven in 52 patients randomised to the delayed treatment group. This difference is not statistically significant, and the probability value (not given by the authors) is 0.19 using a two tailed Fisher's test.

It is both conservative and safer to analyse data by reference to an intention to treat but the authors have transferred one patient from the early treatment to the delayed treatment group. Even with this transfer the result is statistically insignificant ($p=0.07$), and only becomes significant ($p=0.03$) when a further death with a bleeding colonic polyp is removed from the early surgical group. In general, intention to treat analyses should be accepted, warts and all, as valuable unbiased measures of outcome. The removal of patients should rarely be necessary, and the transfer of cases from one group to another for analytical purposes must be dangerous. One of the basic tenets of controlled trials is that patients be randomly allocated so that groups of equivalent disease severity result; by randomisation we seek to balance between our test and control groups whatever factors, known and unknown, affect outcome.

Having analysed their trial in this way the authors compare their results favourably with reported findings. The comparisons are, at least in part, unfair. Thus Dronfield and others are credited with a mortality rate of 20% (true) in 188 patients classed as treated conservatively (not true, the data compared hospitals using more and less aggressive policies).¹ Dronfield and others tried to ensure that all patients with gastric and duodenal ulcers admitted to their hospitals directly from general practitioners were included. Mr D L Morris and others excluded "patients . . . if judged too ill to undergo operation" and they do not tell us how many patients were excluded. Even if we did know we could not be sure that these equated with the patients thought "unrescuable" (20% of the deaths) by Dronfield and others. Mr Morris and his colleagues might be right that early surgery is preferable, but a case made after manipulation of data once collected must be suspect.

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¹ Dronfield MW, Atkinson M, Langman MJS. Effect of different operative policies on mortality from bleeding peptic ulcer. *Lancet* 1979;i:1126-8.

SIR,—A major finding of the trial by Mr D L Morris and others (28 April, p 1277) was that patients over 60 years of age are more likely to die after delayed surgery than after early surgery. The causes of death included "massive" bleeding, myocardial infarction, cerebrovascular accident, adult respiratory distress syndrome, pneumonia, and sepsis. The reasons for these complications were not discussed. A likely reason was that because

haemodynamic and haematological monitoring was inadequate these patients suffered from unrecognised hypovolaemia and anaemia and from the effects of major surgery, for which they were ill prepared.

Elderly patients tolerate the combination of hypovolaemia and anaemia poorly and must be well prepared for major surgery. Vascular surgeons now recognise that preoperative blood volume should be optimal for preserving cardiac and renal function during and after major surgery.^{1,2} In some centres, including my own, the high risk patient is admitted to the intensive care unit on the night before operation for blood volume expansion guided by pulmonary artery wedge pressure.

It is important that blood volume and haemoglobin concentration in the elderly patient with a bleeding ulcer are maintained during the period of observation, and this requires effective monitoring. Unfortunately, the traditional methods are usually inadequate. Pulse rate and arterial blood pressure are often little affected by slow bleeding, and central venous pressure is both difficult to measure accurately in the general ward and an unreliable guide to the adequacy of blood volume in the elderly patient with cardiac disease. Furthermore, the facilities for patient observation in the general ward are often inadequate, particularly at night and over weekends. Slow bleeding may continue unrecognised for a long time until cardiovascular collapse occurs. Typically, a misdiagnosis is then made of acute massive blood loss.

Monitoring of these patients is probably best carried out in a high dependency area. Hourly urine output is a sensitive guide to hypovolaemia (provided that glycosuria is excluded) and blood volume can be expanded as required to maintain urine output at a rate of at least 40 ml/min. Twice daily haemoglobin concentration estimations guide the prompt replacement of blood using packed red cells to keep the haemoglobin concentration at about 13 g/dl. Thus optimum oxygen delivery to the tissues is ensured, recurrent or continuing bleeding is recognised early, and the decision to operate is not needlessly delayed. Attention to haemostasis is also important and replacement of coagulation factors is guided by daily analysis of the coagulation profile including the platelet count.

Rather than accepting the conclusion that early surgery is the correct policy in patients over 60 years with a bleeding peptic ulcer, it seems reasonable to suggest that a prospective trial be conducted to analyse the outcome of early and delayed surgery in patients in whom monitoring and blood volume and haemoglobin replacement are exemplary during the period of observation. The latter may be shown not only to prevent unnecessary surgery, but also to be cost effective. Use of the facilities of a high dependency area in the manner described may be less demanding on resources than their prolonged use to manage postoperative patients who came to surgery ill prepared.

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¹ Silverstein PR, Caldera DL, Cullen DJ, Davison JK, Darling RC, Emerson CR. Avoiding the hemodynamic consequences of aortic crossclamping and unclamping. *Anesthesiology* 1979;50:462-6.

² Bush HL. Renal failure following abdominal aortic reconstruction. *Surgery* 1983;93:107-9.

SIR,—Mr D L Morris and others (28 April, p 1277) concluded that patients under 60 years of age with bleeding peptic ulcer should be managed conservatively (late surgery), while older patients should be managed aggressively (early surgery). The recommendation about the younger patients is based on a comparison of the death rates for the two

groups that was performed at an interim analysis. A negative result derived from a small number of patients raises the possibility of a type II error. What criteria were used to avoid recruiting patients under 60 years of age? What possible difference in death rates was thought to be clinically significant? What is the statistical reliability of the authors' conclusions?

An interim analysis was performed 15 months after the study began. By then 42 of the 102 patients under 60 years of age had been studied. The accrual rate for patients over 60 years of age for that period was four per month. A total of 100 patients over 60 years of age were studied so the accrual rate for the last 21 months of the study was 1.9 per month. Why did the rate drop by more than half? Was it a result of the interim analysis? Did the participants have access to the results of that analysis?

Why was 60 years of age used as a cut off level? It makes little clinical sense to make decisions about the need for surgery based on a consideration of age alone. If the criteria for delayed treatment are accepted for the younger patients then "endoscopic stigmata" and "previous upper gastrointestinal haemorrhage plus two year history of dyspepsia" will be ignored when making decisions about surgery.

There was no control group in this study. By convention the control group should receive the current standard treatment but most doctors manage patients according to various pressures and biases so that some have an early operation and others a late one. It would be interesting to know the value of the set protocols compared to clinical judgment. For at least one patient in this study clinical judgment took precedence over the protocol.

Can we be sure that "The patients in each group were similar in regard to the principal prognostic factors?" They were not divided into risk groups. The authors have only presented haemodynamic measurements at the time of entry into the study and subsequent events must also be of prognostic significance. The authors have also presented many of the results as means and standard deviations. Since two standard deviations encompass about 95% of the observations in a normal distribution this implies that most of the patients received 5.7 ± 12 units of blood—a nonsensical range.

The topic of this paper is of great importance but before doctors are influenced by its recommendations they must appreciate that the only important positive finding relates to patients over 60 years of age with gastric ulcers. The total number of patients in this subgroup was 40.

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SIR,—Mr D L Morris and others (28 April, p 1984) conclude that an aggressive surgical approach to haemorrhage from a peptic ulcer is justified in patients over 60 years of age. We would agree with this proposal, and in a recent review of patients over 65 years with bleeding duodenal ulcers in this hospital about 50% came to surgery, with an operative mortality of 10%. The overall mortality in the group managed conservatively was 20%, although this group included some patients who were unfit for surgery. We consider that a single episode of rebleeding, the presence

of "endoscopic stigmata," or considerable blood loss would be indications for surgery.

Interestingly in Mr Morris's study the results in the elderly duodenal ulcer group treated conservatively do not support the authors' conclusion. Despite these patients being denied operation until their second rebleed or until they had sustained a considerable overall volume loss, apparently over 70% settled without surgery. Moreover, the mortality of this group was similar to that of those managed more aggressively.

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SIR,—Mr D L Morris and others (28 April, p 1277) do not make clear the criteria by which patients were judged "unfit" for surgery. Obviously a small number of patients with coexisting perforations could impair the homogeneity of either trial cohort and it is therefore tempting to exclude them. This, however, merely shows the difficulty of deriving clinical policies from the outcome of trials. If the three "unfit" and the three "perforated" patients had been included in the early surgery group (as under non-trial conditions they might have been) there would have been not a 2/48 but a 5/54 (9.3%) mortality from early surgery—much more similar to that of delayed surgery.

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* * Mr Morris and his colleagues reply below.
—ED, *BMJ*.

SIR,—Professor M J S Langman and others make important points, most of which are covered in our own discussion. We agreed that intention to treat is a more desirable base for analysis than treatment received, and have presented all the data to enable the reader to make his own judgment. The question posed at the inception of the study was: Should a patient admitted with acute upper gastrointestinal haemorrhage be managed by an aggressive or conservative surgical policy? We still feel that inclusion of patients (n=3) with coexistent perforation and haemorrhage would only have clouded the issue and would have been inappropriate as surgery is almost always indicated urgently.

Prospective randomised trials are the only satisfactory way of approaching these questions. We therefore have grave reservations about the conclusions of Dronfield and others. (When does less aggressive become conservative?) The policies of the doctors in the hospitals which they studied were not defined or standardised, and so cannot be used to benefit others. In our study randomly allocated patients were managed by the same doctors using defined policies and we hope others may be able to repeat this study.

Inherent in our approach was careful monitoring in a specific high dependency area, a point clearly made by Dr Bruce Pardy. Admitting all such patients to an intensive

care unit is impractical and a selective policy presumes that high risk patients can be identified, which may be more difficult prospectively than it is in retrospect.

Exclusion of patients has been as much an anxiety to us as to our readers but is inevitable where agreement has to be obtained from all teams in hospital. We did state clearly the numbers excluded and reasons. The assessment that patients were too ill (n=3) for surgery was made by the admitting doctor, not the authors. As all patients were excluded before randomisation we may expect that their inclusion would not have affected the difference in mortality between our two management groups. Even if the three deaths among the 25 patients excluded had been inevitable their inclusion would have had a minor effect on mortality rates. To have proceeded to perfect statistical conclusions would have necessitated extending the study from three years to six, with decreasingly tight control and increasing rebellion from contributing consultant staff. We have therefore adopted the policy outlined, will continually audit our results, and intend eventually to submit this audit for publication.

We can reassure Dr J Hall that all patients admitted to the hospital and eligible for the study were included and agree that any age (such as 60) has to be chosen somewhat arbitrarily. We have examined other risk factors and found no significant difference in the composition of the groups. Further subdivision and analysis would require much larger numbers. With regard to the possibility of a type II error in the 37 duodenal ulcer patients under 60 years of age, we accept that a sizable reduction in a very low mortality rate could be missed. Perhaps the important finding, however, was the difference in operation rates of 47% (early) and 6% (delayed) in these patients due to the lower rebleeding rate in the younger group. With no mortality in either management group we felt unable to justify the high operation rate and closed this part of the study after the interim analysis.

We would join the chorus of request for a further and larger study; whether the complicated questions of collaboration, consent, and control can be adhered to in such an extension remains to be answered.

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Major disaster planning

SIR,—I read with interest the paper of Mr Anthony R Bliss (12 May, p 1433) on my return from Majorca, where I had been a medical coordinator after the recent coach accident. The accident occurred at 0400 hours some 50 km from Palma, the nearest major hospital centre. There were nine fatalities and 36 people injured.

Lives were undoubtedly saved by the rapid implementation of the local Majorcan disaster plan. The first ambulance attendant to arrive on the scene (15 minutes after the accident) acted as incident officer. He performed on site triage. This resulted in the injured being distributed among three hospitals in Palma according to their medical needs, and resulted in none of the hospitals receiving more than

16 patients. All the injured were removed from the scene within one hour and 30 minutes.

The language, cultural, and subsequent repatriation problems posed by having 35 patients in three hospitals and the subsequent arrival of 51 relatives could have caused serious coordination problems. Fortunately the cooperation between the Majorcan hospitals, doctors, ambulance services, the United Kingdom tour operators concerned, and many other tour operators and airlines enabled these problems to be contained.

I arrived in Majorca seven hours after the accident and by working with the Majorcan services was able to resolve many of the problems and relieve them of many of the communication problems to allow them to care for the injured. Within 16 days of the accident 32 of the injured had been repatriated, 19 by air ambulance and 13 on regular flights—seven on stretchers and six seated.

For the first four days after the accident a full time member of the operations staff was needed to handle liaison with the press. The Majorcan hospitals and the operations centre were besieged by the United Kingdom and Spanish press and the role of an efficient press officer cannot too strongly be emphasised. In the accident the structure of the coach remained intact. Most of the injuries were caused by movement of the passengers within the structure. It would seem that many of the injuries could have been avoided if the passengers had been wearing seat belts and the seats had been efficiently secured to the structure of the coach.

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Is obstetrics and gynaecology a specialty in jeopardy?

SIR,—Mr M Brudenell highlights the academic approach to the future of obstetrics and gynaecology. I was present at the Royal Society of Medicine meeting that voted for the proposition that the attraction of obstetrics and gynaecology as a specialty is in jeopardy. I would like this opportunity to put my views.

Mr Brudenell wishes to brush away the majority vote that was for the proposition by informing us that there were 112 applicants for eight posts as surgical house officers in obstetrics and gynaecology at King's College Hospital and of these 37 wished to specialise in obstetrics and gynaecology (20 from the United Kingdom and 17 from overseas). Later in the same paragraph we are told that only 30 consultant posts become vacant in the United Kingdom each year. This emphasises the need for rationalising careers advice. If the 20 British graduates alone were after eight posts how many does this make nationwide? I agree this is a point in favour of the specialty being attractive to the uninitiated but this wears off the further on you go in the career structure.

The competitiveness at the top means that second qualifications are now the order of the day. The specialty is, therefore, looking for an academic doctor who has the stamina for one of the most demanding junior hospital jobs, can write papers, and also get an MD—What kind of people are we going to produce? The specialty is certainly making it harder for women to succeed unless they are prepared to forego family life. We have already seen