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CORRESPONDENCE

Because we receive many more letters than we have room to publish we may shorten those that we do publish to allow readers as wide a selection as possible. In particular, when we receive several letters on the same topic we reserve the right to abridge individual letters. Our usual policy is to reserve our correspondence columns for letters commenting on issues discussed recently (within six weeks) in the BMJ.

Letters critical of a paper may be sent to the authors of the paper so that their reply may appear in the same issue. We may also forward letters that we decide not to publish to the authors of the paper on which they comment.

Letters should not exceed 400 words and should be typed double spaced and signed by all authors, who should include their main degree.

Stones, lithotripters, trials, and arguments

SIR,—The reason for the formal assessment of new medical techniques is that the risks and benefits are not so obvious as Mr J E A Wickham implies (26 April, p 1134), even to such an experienced surgeon as himself.

Not long ago laser coagulation of bleeding peptic ulcers was introduced, supported by many of the arguments now put forward by Mr Wickham as reasons for not requiring a formal evaluation of lithotripsy. The underlying theory was elegant and convincing, investment in developing the equipment had been prodigious, German doctors reported a high level of satisfaction with the technique, endoscopy was clearly preferable to gastrectomy, and early clinical results were encouraging.[1] In spite of all this a formal evaluation showed that the method was ineffective and not without danger.[2] The technique is now little used in Britain.

It may be that Mr Wickham is correct when he says that lithotripsy constitutes a major advance in the management of renal stones, but we have yet to see the kind of evidence that would be expected to support his assertion. The trivial issues that he raises in his letter, including Dr Challah's and Professor Dudley's experience of renal surgery, the number of lithotripsies performed in Egypt, the extent of Dornier's investment, and the supposed motives of the DHSS, are entirely beside the point. As for having to wait five years to assess the medium term consequences of lithotripsy, the choice is between waiting five years in the reasonable expectation of knowing then what the consequences are and waiting five years and still not knowing. It is depressing that these sophistries should be used by an academic unit. It is even more depressing that they should have played a part in preventing the scientific assessment of lithotripsy.

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1 Laurence BH, Vallon AG, Cotton PB, *et al.* Endoscopic laser photocoagulation for bleeding peptic ulcers. *Lancet* 1980;i: 124-5.
2 Vallon AG, Cotton PB, Laurence BH, *et al.* Randomised trial of argon laser photocoagulation in bleeding peptic ulcers. *Gut* 1981;22:228-33.

SIR,—Many clinical investigators believe that bias in the judgment of the outcome of a new surgical technique can be overcome only by the discipline of the randomised controlled trial. We have followed the correspondence on lithotripsy (19 April, p 1076; 26 April, p 1134; 3 May, p 1198) with a certain amount of gloom and despondency. A group of ophthalmic surgeons in the United States of America have sued academic units who proposed a randomised controlled trial of radial keratotomy, alleging restraint of trade. We hope our lithotripters are not contemplating similar action.

Sometimes the truth can be arrived at by complete audit of the outcome of a new technique, comparing it with that of either historical or contemporary non-random controls. Bias can, however, arise because of selection of patients for the new procedure and comparison of their outcome with that of all patients traditionally treated.

An example of this bias has recently come to our attention. We have used the technique of intraoperative prograde colonic lavage[1] in 43 patients with colonic obstruction, and nine (21%) died, one from peritonitis and eight from cardiovascular disease. When we came to compare this mortality rate with those reported from St Mary's Hospital (3%), Aberdeen (8%), Gloucester (4%), and Portsmouth (3%) we were aghast. We took heart, however, after reading that the mortality rate was 23% in 713 consecutive patients with obstruction in the multicentre large bowel cancer project.[2] It appears, therefore, that patients were actively or passively selected in the other reported series.

By all means let audit take the place of the randomised controlled trial in certain circumstances, but let it be complete, or misleading conclusions may be drawn from unbalanced data.

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1 Dudley HAF, Radcliffe AG, McGeehan D. Intraoperative irrigation of the colon to permit primary anastomosis. *Br J Surg* 1980;67:80-1.
2 Phillips RKS, Hittinger R, Fry JS, Fielding LP. Malignant large bowel obstruction. *Br J Surg* 1985;72:296-302.

SIR,—Dr S Challah and Mr N B Mays succinctly state the case for randomised trials of new technology (29 March, p 877) and the "barriers which exist to proper evaluation of a new technique." Unfortunately, these barriers—despite no lack of medical intellect and skill—remain a serious medical behavioural problem[1] because too many doctors remain incorrigible on that score.[2]

One of the effects of the campaigns of the 1970s to remedy this situation[3] has been the attachment to uncontrolled or inadequately controlled studies of "sanitising" statements to the effect that the results would remain inconclusive pending an appropriately designed randomised controlled trial.[4] A case in point is coronary bypass during acute myocardial infarction. The original report in 1979 called for this kind of study.[4] Four years later, when over 600 additional patients were reported, the same statement was attached.[5] Challenged on this score, the authors laid the blame at the feet of their hospital administrators.[6] This could not have happened had they been obliged to "randomise the first patient."[7]

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1 Spodick DH. Barriers to acceptance of controlled phase III clinical trials: behavioral factors. *Biomed Pharmacother* 1983; 37:60-1.