LETTERS TO THE EDITOR

RITA trial protocol

Sir,—The merits of a well controlled clinical trial for the assessment of a new treatment in clinical medicine are now generally established. Statisticians and epidemiologists have increasingly laid down more stringent and exacting criteria for conducting these trials and this has led to more valid results and conclusions. Recently, however, there have been examples where the criteria necessary to fulfill the demands of the statistician have been such that the study population recruited no longer represents the intended population and consequently the relevant clinical questions have not been answered.

The randomised intervention treatment of angina (RITA) trial (1989;62:411–4) suffers from a major methodological error in that it imposes on one group of patients—the angioplasty population—a treatment strategy that is not generally practised by the physician performing the procedure. The surgical strategies for revascularisation and the strategies for angioplasty are quite different and it is these strategies that should be compared rather than the likelihood that angioplasty will achieve exactly what the surgeon would wish to achieve.

Coronary artery bypass surgery aims to revascularise all important vessels with lesions that are haemodynamically significant at the time of the procedure or that are thought likely to become so in the future. The strategy of angioplasty varies between operators, centres, and individual patients, but it aims to make the patient symptom free with a pattern of disease that has a good prognosis. Lesions that are not haemodynamically significant are frequently not dilated because of the possibility of inducing a significant restenosis. With angioplasty the operator can postpone treating these lesions and treat them only if they become haemodynamically significant. The surgeon, because of the "cost" of surgery to the patient, does not have this option and therefore has to revascularise all vessels with potentially significant lesions at the time of the initial procedure.

By forcing a treatment strategy on the physician performing the angioplasty that is not widely used and that favours the surgical arm of the trial, the result of the RITA trial, whatever the outcome, will have few implications for clinical practice. It is unfortunate that a large amount of effort and money is being spent on this trial that does not address the clinical problems relevant to coronary artery revascularisation and will not provide reliable information on which the future allocation of resources can be based.  

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This letter was shown to Dr Henderson, who replies as follows:

Sir,—Several of the points raised by Dr Beatte were initially considered very carefully by the Protocol Committee of the RITA trial and his letter does not state the position correctly. Extensive surgical experience has shown the benefits of complete revascularisation and it was felt likely that the extent of revascularisation could allow the patient to be treated by percutaneous transluminal coronary angioplasty. The angioplasty philosophy that only some of the important lesions need be dilated is not universally accepted and attempts to achieve complete revascularisation account for the tremendous increase in multivessel dilatations in the United States. The RITA trial requires that the cardiologist and surgeon do not wish to achieve equivalent revascularisation. There is no commitment for the cardiologist to dilate subclinical lesions that would be graft by the surgeon nor is there a commitment for the surgeon to leave subclinical stenoses ungrafted. For example the surgeon might decide to bypass two tight stenoses and an additional 50% stenosis in another vessel. The angioplasty requirement would be to dilate the two tight stenoses but not necessarily the 50% stenosis.

The question whether incomplete revascularisation by angioplasty can produce results that compare with complete revascularisation by coronary artery bypass grafting is being addressed by other trials, such as the Bypass Angioplasty Revascularisation Investigation (BARI) and the Coronary Artery Bypass Revascularisation Investigation (CABRI), and it has always been recognised that these trials favour the surgical arm. It seems that Dr Beatte has misunderstood that subclinical lesions need not be dilated in the RITA trial and this results in his final comments.

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For the RITA Trial Executive Committee

Major complications of coronary arteriography: the place of cardiac surgery

Sir,—Stewart et al (1990;63:74–7) suggest that it may be more desirable to expand facilities at regional centres rather than to devolve the investigation to district general hospitals, even though suitably trained cardiologists may practice there. Their study does not support this contention at all. It would be of interest to hear from the many hospitals already performing coronary angiography without cardiac surgery on site. Are these to be phased out because they are unsafe?

Indeed, several centres are performing not only coronary angiography but coronary angioplasty without on site facilities for cardiac surgery. Richardson et al recently reported the Belfast experience for percutaneous transluminal coronary angioplasty without on site facilities for cardiac surgery and concluded "With careful selection of patients coronary angioplasty may be safely performed in a hospital without on site cardiac surgery facilities, provided that these are available at a nearby centre." We are in an era of trying to improve the availability of coronary investigations to increased numbers of the population but this demand cannot be met solely by the regional centres. To avoid unnecessary delay it seems reasonable for properly trained cardiologists to perform coronary angiography locally at district general hospitals provided the images obtained are of diagnostic quality. In my opinion this proviso is the limiting factor. A study is currently under way at Maidstone and Guy's Hospital and preliminary results suggest that coronary angiography at district general hospitals is safe, reliable, feasible, affordable, and diagnostic.

The debate will clearly continue as Mills suggested in his editorial in the British Heart Journal. The outcome may indirectly impact upon the practice of cardiology in the United Kingdom.

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2 Mills P. Should coronary angiography be performed in district hospitals? Br Heart J 1990;63:73.

Catheters or isotopes in the district general hospital?

Sir,—Stewart et al highlighted the potential problems of "routine" coronary angiography performed without surgical cover (1990;63:74–7), and Mills has used their findings to fuel the debate about the safety of coronary arteriography in the district general hospital (1990;63:73). I believe that the debate is academic.

In patients with stable coronary artery disease diagnostic and therapeutic decisions can usually be made by the history, examination, electrocardiography, and non-invasive assessment of myocardial perfusion by thallium-201 or one of the newer technetium isonitriles. But cardiologists who are unaware of the high quality of modern emission tomography feel the need to resort to coronary arteriography to be on safe ground. Non-invasive tests alone, however, can be used to decide who is at high risk of future cardiac events and could presumably benefit from intervention and who may continue on medical treatment. Indeed, myocardial perfusion imaging is better than coronary arteriography for predicting outcome. A knowledge of the coronary anatomy (as opposed to function) is needed only to guide the interventional cardiologist or the cardiac surgeon and should be limited to the specialist centre. Here the decision to intervene has usually been made before referral and coronary arteriography cannot be avoided; but myocardial perfusion imaging remains important as an objective indicator of the site, extent, and depth of ischaemia.

Good quality nuclear cardiology is available only in a few district hospitals because many see it as a specialist technique that should be practised only in a specialist centre. The opposite is the case and the technique is most effective in aiding triage in hospitals without access to coronary arteriography. Most districts do have access to nuclear medicine equipment but a recent survey showed considerable underuse of nuclear cardiology in the United Kingdom. Only inertia and poor training in nuclear techniques can explain this.

Some cardiologists dismiss these views as those of an enthusiast. It is true that enthusiasm is an important part of providing a reliable nuclear cardiology service, but those
that doubt the effectiveness of non-invasive techniques forget that it is their unfamiliarity that limits the value of myocardial perfusion imaging and not the technique itself. Instead of ignoring it they should follow the practice of their colleagues who are able to manage patients with objective measurements of myocardial perfusion rather than subjective impressions of the severity of disease made from the coronary arteriogram. They might then find that they can make many therapy decisions without the need to repeat for their catheters, and we shall be spared the debate about the role of cardiac catheterisation in the district general hospital.

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Acromegalic heart disease

Sir,—We disagree with several of the statements in the article by Rodrigues et al entitled "Subclinical cardiac dysfunction in acromegaly: evidence for a specific disease of heart muscle" (1989;62:195-94).

In the summary Rodrigues et al say that "...this is the first study to find evidence of subclinical cardiac dysfunction in acromegaly", and in the discussion they say that "Left ventricular diastolic function has not previously been studied in acromegaly". I would like to draw attention to the paper of Bertoni and Morandi entitled "Impaired left ventricular diastolic function in acromegaly: an echocardiographic study", in which relaxation abnormalities of the left ventricle were shown in acromegalic patients in 1987.1 On the basis of the paper by Lie and Grossman,2 Rodrigues et al suggest that the fibrosis which is partly responsible for the diastolic filling disturbance is a consequence of an inflammatory process. Van den Heuvel et al took biopsy specimens of the right ventricle of an acromegalic patient and later examined abnormalities of the left ventricle were shown in acromegalic patients in 1987.1 Both specimens showed the same changes: hypertrophic myocardial fibres and some fibrous thickening of the endocardium. There was no evidence of any inflammatory changes.1 In rats with myocardial hypertrophy caused by tumours producing growth hormone Gilbert et al found direct evidence that there was no underlying inflammatory process.

These results prove that the main pathological background to acromegalic heart disease is left ventricular hypertrophy, with some contribution from myocardial fibrosis and the increased collagen content of the myocardium. We found the diluted form of the disease in a few of our patients not to be associated with inflammatory process; these patients were burned-out cases with lower serum concentrations of growth hormone than those with hypertrophy.3

Rodrigues et al cited the second edition of Feigenbaum's Echocardiography (not published in 1979 but in 1976) as saying that echocardiography is an insensitive method of assessing left ventricular function. However, this is not the opinion given in the fourth edition published in 1986.4 Echocardiography is probably a better method of assessing the ejection fraction than echocardiography. But because there are several other indices of left ventricular function (for example, enlargement of the left ventricle and segmental wall movement abnormalities) echocardiography cannot be deemed to be an insensitive method of evaluating left ventricular function.

In Rodrigues et al's paper apart from 13 self-citations, there are only three references from 1982-84 and one abstract, dated 1986. The references I cite were published between 1983 and 1987.

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This letter was shown to the authors, who reply as follows:

Sir,—In reply to Csanyi's letter we would like to make the following comments. Bertoni and Morandi published a paper on left ventricular diastolic function in 1987,6 but our study was largely completed in 1986 and was presented in part to the British Cardiac Society in December 1986.6 Csanyi was not involved in the seminal work on pathological findings of Lie and Grossman in favour of the necropsy findings in a patient described by van den Heuvel et al.6 Necropsy findings in only one patient were not described in the echocardiographic study, which was a study of 10 acromegalic patients. Furthermore, in our study we tried to assess the influence of myocardial hypertrophy by studying left ventricular mass derived by echocardiography and showed that the echocardiographic investigation did not show any correlation between peak filling rate abnormalities and left ventricular wall thickness or left ventricular mass. Therefore, it is unlikely that the abnormal peak filling rate seen in our patients was merely a reflection of hypertrophy.

Though we agree that echocardiography can be used not only to measure ejection fraction but also to assess the anatomical consequences of left ventricular dysfunction, such as left ventricular enlargement and wall motion abnormalities, the point we made in our discussion was that subtle changes in diastolic relaxation were shown better by radionuclide ventriculography. Indeed, Feigenbaum pointed out the imperfections and pitfalls of calculating ejection fraction by cross sectional echocardiography and did not go into any detail about the assessment of subtle abnormalities of left ventricular diastolic function. We referred to our previous validation studies in the text to establish the quantitative success and reproducible nature of the radionuclide technique for assessing subtle diastolic left ventricular dysfunction. Many methods have been used to study a large group of patients with a rare condition. Previous studies did not deal with the same patients as our study. Echocardiography using M-mode imaging was used to exclude obstructive coronary artery disease.6 Thus our suggestion that radionuclide ventriculography is better than echocardiography for picking up subtle left ventricular diastolic dysfunction is valid.

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Severe haemolytic anaemia after replacement of the mitral valve by a St Jude medical prosthesis

Sir,—The interesting case report by Feld and Roth (1989;62:475-6) of severe haemolytic anaemia after mitral valve replacement with a St Jude medical prosthesis highlights the difficulty in detecting mitral paraprostatic leaks. Despite clinical evidence of mitral regurgitation in their patient, careful echocardiography with Doppler studies failed to detect any prosthetic abnormality and left heart catheterisation was required to show severe paraprostatic regurgitation.

We recently encountered a patient with echocardiography with a 5 MHz phased array trans-oesophageal transducer (HP 21362A)7 was helpful in nine patients (mean age 59 years) with mitral prosthetic regurgitation. One of them also had severe haemolytic anaemia after the insertion of a 27 mm St Jude mitral prosthesis. Mitral regurgitation was detected by transthoracic echocardiography, includ-
Acromegalic heart disease.

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Updated information and services can be found at:
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