considered, it was unnecessary as the areas of ulceration healed completely after resolution of the infection.

I agree that cutaneous radionecrosis and osteonecrosis often require excision and the use of myocutaneous flaps. These and other complications of radiotherapy are covered in a subsequent article in the ABC series. Reconstruction of the breast and its complications are also being covered separately. The point of the illustration was to show a good example of cellulitis after surgery and radiotherapy. This cellulitis needs to be controlled by antibiotics before other measures are considered. In this respect I do not believe that the illustration was misleading or inappropriate.

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Macroglossia

Classify the pathology as normal or abnormal

EDITOR,—We agree with P Murthy and M R Laing that the term macroglossia should be restricted to chronic enlargement of the tongue as the differentiation from acute swelling has implications for both the aetiology and management.¹ Having made this distinction early in the paper, the authors later give rise to confusion by listing angio-oedema, Ludwig's angina, and angioneurotic oedema as causes. These conditions are of rapid onset and do not cause true macroglossia. We have reported on a series of patients with acute swelling of the tongue and found corticosteroids useful.² They are unlikely, however, to be of benefit in long standing cases.

In our experience, it is helpful to classify the pathology of macroglossia as normal or abnormal. Biopsy is therefore indicated, particularly if reduction glossectomy is contemplated. The diseased tongue—for instance, in lymphangioma or in amyloidosis—is a hugely vascular structure, and blood loss may be considerable and even life threatening. Possible preoperative precautions include tracheotomy, ligation of the external carotid artery and embolisation of selective branches of the external carotid artery tree. Surgery by laser is a theoretical alternative, but experience is limited.

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Tracheostomy may not be necessary during surgery

EDITOR,—The literature does not usually support P Murthy and M R Laing's view that a tracheostomy is required to maintain the airway during surgery for macroglossia.¹ Two more conservative alternatives exist. Nasal intubation in preparation for surgery is the optimal anaesthetic approach. The airway is then maintained in safety^{2,3} with the endotracheal tube in position for several days after surgery while the child is monitored in a paediatric intensive care unit. This allows the postoperative swelling of the tongue to recede. The other, slightly unconventional method is to secure the tongue with a 2-0 silk suture placed in the tip of the tongue and then tape the suture to the cheek.⁴

Though the latter method may well have a role, the former is logical as any upper airway obstruction due to oedema of the tongue will be only temporary. This approach obviates the need for a tracheostomy at the time of the initial surgery, maintains a safe airway, and allows for the option of a tracheostomy if the oropharyngeal airway is not deemed to be safe at a trial of extubation.

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Confounding and Simpson's paradox

Multiple regression would confound the clinicians

EDITOR,—Steven A Julious and Mark A Mullee discuss confounding and Simpson's paradox, defining confounding as occurring "when the association between an exposure and an outcome is investigated but the exposure and outcome are strongly associated with a third variable. An extreme example of this is Simpson's paradox, in which this third factor reverses the effect first observed."¹ In their analysis of my and colleagues' article on treatments for surgery to remove kidney stones the authors correctly observe that the size of the stones is the single most important factor in determining the success of treatment. The fact that the figures show that open stone surgery has a higher success rate for both small and large stones but that the overall success rate is greater with percutaneous nephrolithotomy is a paradox. This probably reflects the numbers in each group.

The authors' deduction that factors such as the patient's age and characteristics determine treatment does not, however, hold for a historical perspective, when all patients were treated consecutively with the only treatment available at this time. There is no reason to believe that patients treated 10 or 15 years ago had any different characteristics from those of patients presenting for modern day treatments.

The authors' argument that randomised trials are necessary to show any effect of treatment is difficult to accept when you have a new form of treatment that is so clearly superior to all previous forms of treatment that to compare one against the other—that is, open surgery versus lithotripsy—for a small stone would be unethical with regard to morbidity.

The main aim of the paper was not really to compare success rates but more to show that, when success rates were comparable, morbidity and cost to the health service were much reduced. I therefore do not see what purpose could be served by producing a model to include multiple regression or multiple logistic regression in analysing the variance as it would only confound the clinicians.

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Authors' reply

EDITOR,—C R Charig states that the reason why open surgery has a higher success rate for both small and large stones but a poorer success rate overall when compared with percutaneous nephrolithotomy is the numbers in each group. This, however, does not seem to be the case. Substantially more patients having open surgery had large stones, and as the size of the stones is the most important factor in determining success rates it was probably this difference that gave open surgery a poorer overall success rate.

There is reason to believe that patients' characteristics may have changed over time. Altogether 75% (263/350) of patients undergoing open surgery between 1972 and 1980 had large stones, compared with only 23% (80/350) undergoing percutaneous nephrolithotomy between 1980 and 1985. This seems to indicate a change in the ratio of large to small stones treated.

If advances in treatment are to be made it is necessary to establish that "a new form of treatment is so clearly superior to all previous forms of treatment." Sheldon stated, "in non-randomised observational studies... patients receiving different treatments may differ systematically with respect to any number of known and unknown factors that affect prognosis... Although statistical adjustments may be made in an attempt to exclude the effects of these confounders... this assumes both a complete knowledge of the confounding variables and their comprehensive and accurate measurement. Neither is likely to be possible and at least a moderate bias will remain."¹ To avoid bias a randomised controlled trial should be performed to ensure that the new treatment is truly superior. The perils of avoiding or ignoring randomised controlled trials have been further described (G D Smith and T A Sheldon, meeting of the Society of Social Medicine, Cambridge, September 1993). After favourable reports in the 1960s clofibrate came to be widely prescribed and various descriptive and non-randomised studies that purported to show its efficacy were published. After unfavourable results of two large randomised controlled trials were reported, however, clofibrate was rarely used.

It is unethical not to use a new treatment that is clearly superior, but "is it not unethical to advise patients to have an operation that has not been formally tried and tested?"²

Statistical methods, such as analysis of covariance, give the same measure of effect as more simple analyses but have the advantage of having been adjusted for possible imbalances between groups.

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- 2 Surgical innovation under scrutiny [editorial]. *Lancet* 1993;342:187-8.

Matching in case-control studies

EDITOR,—J Martin Bland and Douglas G Altman's review of the advantages and disadvantages of matching in case-control studies omits two important problems.¹

Firstly, matching in case-control studies ensures that the matching factors, such as age or sex, are equally distributed between cases and controls. Although matching thus removes the original