Eur J Cancer, Vol. 29A, No. 3, p. 430, 1993.
Printed in Great Britain

0964-1947/93 $6.00 + 0.00
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The Defence for the U.K. DCIS Trial

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INTRODUCTION

THE U.K. ductal carcinoma *in situ* (DCIS) trial started in May 1991, after a gestation period of 36 months, having been designed by a multidisciplinary committee. This comprised clinicians with a particular interest in DCIS and included surgeons, radiotherapists, pathologists, statisticians and data centre coordinators. The aim of the study was to investigate treatment options for women with screen-detected DCIS. The study sought to determine whether progression to invasive breast cancer could be diminished by either radiotherapy, tamoxifen or a combination of the two. At the time of setting up of the trial there were two on-going trials examining treatment for DCIS. The one in Europe was EORTC Trial 10853, whose coordinator was also a member of the U.K. DCIS Trial Committee. The other trial in the U.S.A. was NSABP B-17. Both studies compared wide local excision alone with wide local excision and radiotherapy to the breast giving a dose of 50 Gy in 25 daily fractions over 5 weeks.

H. Thornton (this issue, pp. 428–429) for reasons that are not entirely clear, has a distrust of radiotherapy and therefore questions the validity of a trial in which this is an intrinsic part. She describes the trial as being precipitate and one which flouts laid-down principles. H. Thornton has allowed prejudice to distort and misperceive the openhanded way in which the trial has been presented to both clinicians and patients.

THE UNACCEPTABLE ASPECTS

As all are agreed, the ultimate end-point in studies of DCIS is prevention of deaths from invasive breast cancer. Even with the anticipated large number in the U.K. DCIS Trial this is not a reasonable end-point to aim for in this study alone. At the Second EORTC Consensus Meeting on DCIS, which H. Thornton quotes, there was a considerable amount of discussion on this particular point and trialists have agreed to pool their data in order that a meta-analysis can be conducted once sufficient time has elapsed.

H. Thornton is clearly opposed to the use of radiotherapy in patients with DCIS. This view may or may not ultimately prove to be valid but at least as a result of this study we should be in a position to determine whether there is actually an effect. However, it has to be stated that the recently published results of DCIS cases treated in NSABP trial B-06 suggest that there may be a benefit [1]. Thus of 21 patients treated by lumpectomy without radiotherapy there were 9 relapses (4 DCIS, 5 invasive), whereas among those 27 treated by lumpectomy with radiotherapy there were 2 relapses (1 DCIS, 1 invasive). Overall relapse rate for no radiotherapy was 43% compared with 7% in the radiotherapy arm. This effect of radiotherapy parallels that seen in patients with invasive breast cancer and therefore provides some support for the idea of the use of radiotherapy. H. Thornton also appears to have no perception of the significance of a dose of radiotherapy. Radiation dose expressed as so many Gray has no meaning unless total duration and fractionation are also given. 30 Gy can be radiobiologically much more aggressive than 60 Gy. We are accused of flouting the principles of the Forrest Report but this appears to be based on WHO principles of screening and the exact flouting remains unspecified.

THE PROBLEM OF INFORMED CONSENT

It is always going to be difficult in a multicentre study to make sure that all patients have the same fully informed consent. Indeed this can never happen. What has to be done is to lay down principles of informed consent and to produce an information leaflet, described by H. Thornton as inadequate and conveying the false impression of near ignorance. Despite H. Thornton's perusal of the literature she does not appear to have appreciated that we do not base principles of treatment on single published studies and that the cases of DCIS emerging from screening are an entity about which we have no more than anecdotal knowledge.

POOR COMMUNICATION

H. Thornton presumably speaks from her own experience of how she was asked to participate in the trial. We are all agreed that no patient should be asked to take part in a trial whilst partially clothed, additionally no clinician should be asking patients to participate unless they are convinced of the validity of the trial. It is unethical for any clinician to place patients into a study of which they themselves have doubts. Despite this there has actually been a very good uptake of agreement to participate by surgeons and radiotherapists involved in screening.

One aim of the study design was to keep matters as simple as possible. Wide excision is the standard treatment that would be used in removal of mammographically detected lesions and therefore for the majority of patients a one-stage rather than a two-stage procedure would be needed. H. Thornton says some women would have preferred not to have had an excision. Potential patients who have had screening mammograms in which an abnormality, usually microcalcification, has been found are in an extremely anxious state. They may not have a surgical emergency but for the woman who suspects that she has a cancer, it is a psychological emergency for which sympathetic and effective determination of the diagnosis is required as rapidly as possible. It takes a long time to explain to patients the reason why we would like them to take part in the DCIS Trial. If this were to be carried out with even more women who have any kind of screen-detected abnormality no time would be available for carrying out any treatment.

H. Thornton's viewpoint indicates the need for better presentation of the problem of DCIS to women who have this histological diagnosis made as a result of breast screening. Far from being ill-judged, precipitate and flouting laid-down principles, this study is an honest attempt to look at the problem of DCIS in a national context and H. Thornton's comments, although indicating some of the problems of communication, are not a valid reason for either re-evaluating or discontinuing this important trial.

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Received 19 June 1992; accepted 20 June 1992.

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