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Feature Articles

U.K. DCIS Trial—Time for Review?

Hazel Thornton

INTRODUCTION

THE REPORT by van Dongen *et al.* [1] summarises the findings of the 55 participants who met to reach agreement about what is currently known about ductal carcinoma *in situ* (DCIS) with reasonable medical certainty and to define what questions remain unanswered.

DCIS has now been shown to have remarkable radiological, histological and biological diversity and the uncertain clinical implications of this heterogeneity indicate a tremendous need for continued research to determine patient management after breast-conserving surgery, particularly as many more cases are being found as a result of the breast screening programme. This heterogeneity, and indeed the problem of accurate diagnosis, is not a problem when mastectomy (which is almost 100% successful) is employed.

Disturbingly, many countries reported a reluctance of both physicians and patients to accept entry into these trials, but due to the heterogeneity of DCIS, ever larger numbers of participants will be required to achieve statistical power in the resultant subclassifications. It is, therefore, vital to determine causes for this reluctance by consideration of the patient's viewpoint [2] and an examination of the U.K. DCIS Trial which is precipitate, flouts World Health Organization (WHO) princples, has very unequal treatment options and wide participant entry.

THE UNACCEPTABLE ASPECTS OF THE PROTOCOL [3]

van Dongen reports: "The main endpoint of studies of breast conserving therapy (BCT) in DCIS should be prevention of deaths from invasive breast cancer, and not just progression to invasion or recurrent DCIS", and states that "much longer follow-up is needed...especially as radiotherapy might be associated with a delay in recurrence, and the median time to recurrence is very long anyway." The current U.K. DCIS trial does not have survival as its endpoint and the trial protocol itself acknowledges that, "Radiotherapy might be considered as over-treatment", and forsees the possibility of an unbalanced entry at 2 years with resultant closure of one arm of the trial.

It is surely questionable that radiotherapy is an appropriate treatment for a non-invasive carcinoma that may not progress to an invasive phase during the patient's lifetime, particularly as it

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is now suspected that only certain types of asymptomatic DCIS may progress.

A further argument against the use of radiotherapy in these screen-detected cancers is that salvage is successful when recurrence occurs (as confirmed in Appendix 1 of the protocol by Schnitt *et al.*) [3]. They also found that the breast may be conserved for longer if radiotherapy is withheld until further excision upon recurrence.

The findings of Fentiman [4] indicate that DCIS may be less radiosensitive than invasive ductal carcinoma and that the appropriate dosage possibly lies in the range 46–60 Gy. Yet the protocol indicates a dosage of 50 Gy or 40 Gy which is presumably likely to be ineffective but carries with it the possibility of short-term morbidity and more serious long-term after-effects after 10 years, which a healthy woman with a non-invasive cancer is more likely to experience, to which Fentiman refers in his guest editorial in the *British Journal of Cancer* [5].

FAILURE TO OBSERVE PRINCIPLES IN THE FORREST REPORT [6]

Most women entering the trial do so as a direct result of the screening programme. Charles Hamilton [7] draws attention to the Forrest Report comments, based on WHO recommendations, cautioning against over-treatment of patients, the potentially harmful effects of radiation, the possible consequent psychological harm to patients and our relative ignorance of the natural history of screen-detected DCIS.

The problem of informed consent and ethical considerations

The requirement of the physician to explain to a patient that he or she does not know which treatment is best and then to offer her the alternative of choosing to go on the trial or decide her own treatment, can carry the implication that the physician's concern is not solely with the patient but with future patients, confirmed by passing some of that responsibility to her by requesting her participation. It is difficult to find the middle ground between the old paternalism and the new notion that the patient has a right to make decisions about her own body. Nevertheless, the high ideal of a common quest in research with a partnership between the medical profession and the patient demands understanding and generosity of spirit from both parties if we are to progress. Regrettably, trust and confidence in the profession have been undermined by aggressive demands of patients to express autonomy and by the profession itself in only paying lip service to this new notion of a partnership in research.

It is essential that the patient is provided with adequate information about the treatment options promptly, accurately and seriously (or advised where she may obtain such information); also with the facts of her case to enable her to make a reasonable assessment. The information leaflet for patients is inadequate and conveys the false impression of near ignorance of the condition, and ought now to be revised.

VARIABILITY OF LOCAL ETHICS COMMITTEES

Inevitably, even with the new Department of Health stipulations for membership, these committees will still have disparate membership, variable standards, an independent outlook, and a tendency not to question the scientific reliability of multicentre trials. There is a need for ethical and technological examination of trials at national level, perhaps as suggested by Baum [8]. A real danger is that the unacceptability of this trial will jeopardise public confidence in trials in general, which will be difficult to reverse.

Poor communication/insufficient training and knowledge

Even given a well-balanced, timely, acceptable trial, there still remains the problem of presentation by the physician to the patient—many do not possess this skill. A high degree of professionalism is required from all members of the team as well as acceptance of its ethics, a full commitment to its aims and a full knowledge and understanding of the trial as laid down in the trial protocol. They must also judge just how much information each patient requires to come to an understanding of the proposition being put to her in a moment of shock.

If the medical team are committed to the trial it will be difficult for them to discuss the treatment options without revealing individual preferences and there is a need for absolutely independent counselling and advice. In this partnership between physician and patient the scales are very unevenly weighted, the patient needing all the help that can be given. It is preferable that she be clothed when the invitation to participate is given, and certainly that she is not supine on the examination couch, thus emphasising her vulnerability and inequality. Above all there must be accuracy and honesty and an honest description of all possible known side-effects and hazards. If the medical profession is to have the confidence of patients it must never fob them off with half truths or avoid unpleasant aspects. The trial proposition should be broached to your otherwise healthy woman when the results of her mammogram are discussed. This demands a high level of diagnostic skill and a good understanding of the natural history of this heterogenous condition of DCIS.

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