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### 1. Introduction

Breast-conserving surgery followed by radiotherapy to the remaining breast has become a standard treatment modality in invasive breast cancer. However, there is convincing evidence that postoperative radiotherapy is overtreatment for more than half of the treated patients and therefore could be avoided in the majority of patients.

Postoperative radiotherapy after breast-conserving surgery is the generally recommended treatment, based on its ability to reduce the recurrence of breast cancer in the treated breast. This knowledge is derived from clinical studies including several well conducted randomised clinical trials [1–6]. But is postoperative radiotherapy always indicated?

The possible merits of postoperative radiotherapy after breast-conserving surgery are freedom from breast

recurrences and a survival benefit. Possible negative factors range from relapses in spite of the therapy, various local side-effects of shorter or longer duration which may endanger the cosmetic result, to possible lifetime reducing side-effects from the radiation of deeper tissues such as the lung and the heart. The cost of the treatment in terms of consumed medical resources as well as the time spent for the treatment belong to the negative effects for both the individual and society.

### 2. What are the effects of postoperative radiotherapy after breast-conserving surgery on survival?

Randomised studies constitute the most important sources of information on survival after breast-conserving surgery with or without postoperative radiotherapy. None of these studies which together included 3500 women with follow-up times ranging from approximately 2 to at least 12 years show any significant survi-

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val improvement after irradiation. The studies are detailed below.

The National Surgical Adjuvant Breast and Bowel Project (NSABP) protocol B-06 included patients with tumours  $\leq 4$  cm, with or without lymph node metastases. The patients were randomised to mastectomy or segmental mastectomy with or without radiotherapy. The segmental mastectomy removed the tumour with enough normal tissue to ensure tumour-free margins. Removal of the pectoral fascia or the skin above the tumour was not necessary. Adjuvant systemic treatment using melphalan and 5-fluorouracil was given in case of nodal involvement. The breast was irradiated with tangential fields to a minimum dose of 50 Gy over 5 weeks. The follow-up at the last report was at least 12 years [1,7].

The Canadian study included patients with tumours  $\leq 4$  cm without lymph node involvement. The patients underwent lumpectomy which consisted of complete removal of the tumour with 0.5–1 cm margins. The resection margins were required to be microscopically free of tumour. Radiotherapy was given by means of tangential cobalt 60 beams to a dose of 40 Gy in 16 fractions to the entire breast followed by a boost dose of 12.5 Gy in five fractions. The median follow-up was 7.6 years [3].

The Swedish study restricted the inclusion to carefully selected patients with tumours  $\leq 2$  cm in diameter without lymph node involvement. The surgical treatment was a sector resection from the plane of the Scarpa's fascia down to and including the pectoral fascia. To ensure complete excision, a specimen radiography was to be taken. Radiotherapy was given through tangential fields and a dose of 54 Gy was given in 27 fractions. The median follow-up time was slightly more than 60 months [4].

The Milan III study was performed on patients with tumours less than 2.5 cm with or without axillary lymph node metastases (very few cases). The patients were treated with a quadrantectomy, in which a total quadrant of the breast tissue was removed with overlying skin and the pectoral fascia. Node-positive patients were treated with adjuvant cyclophosphamide, methotrexate and 5-fluorouracil and sometimes tamoxifen. Radiotherapy treatment consisted of tangential 5 MV linear accelerator beams to a dose of 50 Gy in 5 weeks followed by a boost dose of 10 Gy in five fractions. The median follow-up time was 39 months [2].

The Scottish trial included premenopausal women without lymph node metastases and postmenopausal women with or without involved nodes. The tumours had to be  $\leq 4$  cm and were to be excised with a 1 cm margin, but a microscopically clear margin was not required. All patients received adjuvant medical therapy. If oestrogen receptors were 20 fmol/mg protein or more, or unknown, then 20 mg of tamoxifen was given

for at least 5 years. Otherwise six 3-weekly intravenous (i.v.) injections of cyclophosphamide, methotrexate and 5-fluorouracil were given. In patients randomised to radiotherapy, a dose of 50 Gy in 20–25 fractions was given to the entire breast and a boost to the tumour bed was required. The median follow-up time was 5.7 years [5].

The meta-analysis of patients treated with or without radiotherapy did not reveal any obvious survival difference in the subset of patients who were surgically treated with less than a mastectomy [6]. The Milan III study and the Scottish trial were not included in this meta-analysis. Thus, it is obvious that a survival benefit by adding radiotherapy to the breast is at best small.

Does this mean that allowing suboptimal treatment to the breast is totally without danger to the patient? Distant metastases were in fact significantly or almost significantly more common in some of the studies if radiotherapy was omitted [1,3,5]. An earlier investigation for systemic disease due to breast relapses may at least to some extent account for this increased incidence. Levitt and colleagues used a Bayesian approach to evaluate survival in the randomised trials and came to the conclusion that the probability that there might also be a positive survival benefit with radiation in this situation was high [8]. Even if that is true, the survival benefit in absolute numbers must be very small.

### 3. Recurrence of tumour in the ipsilateral breast

Whilst survival is similar whether postoperative radiotherapy is added to breast-conserving surgery for invasive breast cancer or not, all five randomised studies mentioned show beyond any doubt that radiotherapy reduces the frequency of breast relapses in all subgroups. Adjuvant medical treatment could not replace radiotherapy [5,9] but adjuvant medical treatment may enhance the effect of radiotherapy. The series of studies on breast-conserving treatment (BCT) in Milan show that the surgical technique is very important in this respect and that the hazards of non-radical surgery cannot be totally compensated for by radiotherapy [10].

Most of the relapses occur in the vicinity of the scar which suggests that they often are true relapses of the original tumour [11]. When follow-up times are longer, recurrence of tumour in other quadrants seems to be as frequent as in the quadrant of the primary tumour and may represent new tumours [12,13]. The time course of ipsilateral breast cancer recurrence may be different in radiated and in non-irradiated patients since most of the protection of radiotherapy seems to occur during the first 5–10 years after treatment [14]. A short follow-up time may therefore give relatively higher rates of recurrence in only surgically treated patients compared with those also treated with radiotherapy.

The true frequency of ipsilateral breast cancer recurrence after BCT may be slightly overestimated in some studies since other disease events or death have often been treated as censoring events and not as competing risks. It is not always possible to determine from published papers how the risk of breast relapses was calculated. It is in the Ontario study stated that distant metastasis prior to a local recurrence censored the follow-up time [3]. Cumulative incidence curves were used in the last report from the NSABP B-06 study which should reduce this problem [1]. Whatever the technique used for calculation of ipsilateral breast relapses, it is clear from all studies that the majority of the patients had little benefit from radiotherapy. Within 12 years after treatment 65 per cent of the women randomised to BCT alone in the NSABP B-06 study had not developed an ipsilateral breast recurrence. In spite of postoperative radiotherapy, 10% of the women had such a recurrence [1]. Thus, more than two-thirds of women could — and should if possible — be spared the addition of postoperative radiotherapy. The urgent problem is how to select women who after surgery for breast cancer need radiotherapy because of a high risk of relapse and in whom remaining cancer will be eradicated by radiotherapy.

There is a vast literature on risk factors for an ipsilateral relapse and here there is not the space to review it all. As mentioned above, the type of surgery seems to have a definite bearing upon the risk of breast relapses, whether radiotherapy is given or not, and this is not entirely linked to involved specimen margins [15]. All the randomised trials, as well as many non-randomised studies, have found an consistent increase in breast relapses in the young age group, but without a threshold age [3,10,11,16]. The size of the tumour has been found to influence the relapse rate [10,17] as well as lymph node involvement [1,5]. Various morphological features of the primary tumour [16,17] and oestrogen receptor status [5] have been related to recurrence. Age *per se* should not influence the recurrence rate, but probably relates to biological features which are not fully explained by the present evaluations of the primary tumour. There are few studies on factors that are predictive for a response to radiation therapy. Early results of *TP53* status may indicate the possibility to identify such factors in breast cancer in the near future [18,19].

Even if recurrence rates in similar subgroups in all randomised studies on postoperative radiotherapy after breast-conserving surgery are lower, in only two of them, was the recurrence rate in the subgroups so low that radiotherapy could be considered superfluous. The breast recurrences in women over 55 years of age treated with quadrantectomy in the Milan III study may be such a group [10]. A subgroup of women > 60 years of age, without comedo or lobular cancers were found in the Swedish study to have a low risk (5.9%) of breast recurrence after 5 years [16].

#### 4. Disadvantages and side-effects

It goes without saying that if there were no disadvantages of using postoperative radiotherapy after breast-conserving surgery for breast cancer, then there would be no reason to object to such treatment for all patients. Although radiotherapy is not a very expensive treatment modality *per se*, the resources for radiotherapy are scarce and there is a need for them as the numbers of patients with cancer increase. BCT of breast cancer has been introduced during the last decades and is offered in many communities to more than half of the patients with breast cancer, many of whom would not otherwise have been treated with radiotherapy. A retrospective cost-effectiveness analysis of routine postoperative radiotherapy in the Swedish trial indicated that the cost per avoided local recurrence at 5 years was approximately \$50 000. This cost was estimated to be \$180 000 in a retrospectively defined subgroup, namely in women > 60 years of age with tumours of low grade ductal malignancies comprising 40% of patients. All patients in this study had tumours less than or equal to 2 cm with no involved lymph nodes [20].

The cosmetic result after BCT is described as good or excellent in the majority of patients. Randomised trials should offer the best opportunity to evaluate the contribution of postoperative radiotherapy in this respect to that of surgery. Contour differences, oedema and mammillary deviation in some cases in the Swedish study negatively affected the cosmetic appearance to a moderate extent after postoperative radiotherapy [21]. The cosmetic results seem to be moderately inferior in women with large breasts [22] and is negatively influenced by the radiation technique. Large individual doses and the addition of a boost significantly worsened the evaluation of the cosmetic appearance in one study [23]. Pre-existing collagen vascular disease may increase the risk for severe breast fibrosis, retraction and pain in the breast which may necessitate mastectomy [24].

> A common complaint is tenderness in the breast, which is usually mild. Whether this complication is more common after radiotherapy than after surgery alone has not been reported from the randomised comparisons between BCT with or without radiotherapy.

Severe local complications seem to be few in most series and are usually described in case reports. Amongst such complications are fat necrosis or fibrosis which may mimic a recurrent cancer [25,26], and infectious complications such as abscesses or cellulitis, which may occur after or before radiotherapy [27,28]. An unusual oedematous and indurated erythema which may resemble both cellulitis and inflammatory recurrence of the tumour is a rare event [29]. Rib fractures occur in a few patients, especially when both the breast and the regional nodes are irradiated [26,30].

Late complications include radiation-related pulmonary and cardiac disease and secondary neoplasms. Short-term decrease in pulmonary function has been noted, but is reversible [31,32]. The frequency of late effects is not known but should be small due to the small part of the lungs included in the tangential beams. Irradiation of the heart may be a more serious problem in the ageing population. This problem is well known and is related to the volume of the irradiated heart [33]. The volume of the heart which is within the tangential beam volume is quite small in most cases. However, it was found in a series of patients that 6% received doses to a substantial part of the heart so that future problems are probably due to the anatomical configuration of the chest [34].

Radiation-induced malignancies are probably rare after tangential field radiation of the breast. However, there are several reports of angiosarcomas in the treated breast, which may mimic late radiation dermatitis [35]. Angiosarcomas of the arm are closely linked to the oedema, but not to the radiation dose *per se* [36]. Thus, it is possible that angiosarcomas in the breast may be only indirectly linked to the postoperative radiotherapy.

## 5. Conclusions

Groups of patients with a low risk of breast relapse without postoperative radiotherapy have been identified retrospectively in some of the randomised trials [10,16]. The criteria were based on the age of the patient, the size of the tumour and histopathological features of the primary tumour. These two series differ from the others regarding the selection of patients (essentially node-negative patients with tumours less than  $\leq 2.5$  and  $\leq 2$  cm). Further, the surgical resection seems to have been more extensive with removal of a whole sector of the breast including the pectoral fascia in contrast to the other three studies where a resection of breast tissue with microscopically free margins was used. The difference in surgical technique may be important. It should be remembered that an attempt to define such patients in a prospective series of patients treated with excision with free margins was prematurely interrupted because the breast relapse rate turned out to be higher than anticipated [37].

It is obvious that postoperative radiotherapy to the breast after breast-conserving surgery for breast cancer increases the disadvantages of the treatment. Furthermore, it is clear, that between half and two-thirds of the patients obtain little benefit from the treatment. There are many reasons to avoid radiotherapy when it is unnecessary. When the patient is given full information about the risks for a local recurrence in her situation after or without radiotherapy, she may well elect for treatment without radiotherapy with a negligibly increased risk for dissemination of the disease.

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When the use of breast conservation in Europe was still in its formative stages, local tumour excision was introduced during the 1960s as an adjunct to radical radiotherapy in order to allow local control to be achieved more reliably with lower doses [1,2]. Subsequently, the notion that conservative surgery might be considered a ‘radical’ operation was suggested by Veronesi and associates [3], and the National Surgical Adjuvant Breast and Bowel Project (NSABP) popularised the concept of microscopically ‘clear’ excision margins in their B-06 Trial [4]. As a consequence since the 1980s breast-conserving therapy is generally no

longer thought of in terms of ‘primary radiotherapy’. Surgeons have largely abandoned excisional biopsy in favour of wider excisions, with the intention of obtaining negative margins, and radiotherapy is now sometimes deferred for months to allow the timely administration of cytotoxic chemotherapy. Despite incontestable evidence from multiple randomised trials that breast irradiation dramatically reduces the rate of ipsilateral breast tumour recurrence (IBTR) by a factor of approximately 4-fold [5–8], the question continues to be raised as to whether or not breast irradiation can be dispensed with altogether, at least in a subset of favourable patients.

The benefits and disadvantages of breast irradiation have been extensively discussed in the two position

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