

FROM THE INSTITUTE OF ONCOLOGY AND RADIOTHERAPY, THE PRINCE OF WALES HOSPITAL, RANDWICK,
NSW, AUSTRALIA.

RESULTS OF BREAST CONSERVING TREATMENT OF BREAST CANCER

C. S. HAMILTON, J. M. NIELD, G. F. ADLER and P. R. CLINGAN

Abstract

Between 1978 and 1985, 247 patients with primary breast cancer have been treated with breast conserving surgery and external beam radiotherapy. Median follow-up is 3 years and 9 months. Actuarial 5-year disease-free survival for the whole group is 72%; 16 patients (6.8%) have relapsed in the breast to date. Of these, 6 (38%) have died from breast cancer. Patients who have experienced a local recurrence have significantly worse survival than those who remain locally recurrence-free ($p < 0.001$). Complication data are presented and shown to be almost entirely mild to moderate and in the range 1–19%. This series shows the breast conserving approach to be effective and at least equivalent to breast ablative procedures in early follow-up.

Key words: Breast cancer, conservation surgery, radiotherapy, local control.

There is now ample evidence from both controlled (1–4) and uncontrolled (5–9) studies to support the combination of breast conserving surgery and radiotherapy as the treatment of choice for early breast cancer. Several authors have shown that local recurrence following breast conservation does not jeopardise survival (5, 10–13). Using adequate radiotherapeutic techniques, a breast preservation rate of approximately 90% at 10 years may be expected (10, 14–16). In addition, studies assessing cosmesis have reported favourable outcomes in the range of 66–82% based on various objective scales (17–20). Patient-based scales produce even better cosmesis ratings (21), consistent with the better psychological and marital adjustment reported in breast conservation patients (22–25).

The purpose of this paper is to report the experience of the Prince of Wales Breast Oncology Group in the conservative management of breast cancer from 1978–1985 in terms of survival, local control and complications.

Material and Methods

During the 8-year period from 1978 to 1985, 247 patients with 249 histologically confirmed primary breast malignancies were referred to the Institute of Oncology and Radiotherapy following breast conserving surgery. All patients were retrospectively staged according to the UICC (26) criteria.

Surgery. Patients were referred from a wide variety of community and hospital-based surgeons following conservative breast surgery. A clinical size limit of 3 cm was applied to the primary tumour although selected lesions in large breasts were also treated conservatively. A macroscopically clear margin around the primary tumour was considered an essential requirement for this treatment approach. Surgical procedures varied but were broadly classified as lumpectomy ($n=187$) or quadrantectomy ($n=60$), based on scar size and the size of the pathological specimen. The axilla was required to be clinically N0 or N1a (UICC), although 12 N1b patients were managed conservatively. Surgical management of the axilla varied from no dissection ($n=134$) to a limited dissection ($n=80$) or a full axillary clearance ($n=33$).

Radiotherapy. All patients were irradiated within 6 weeks postoperatively using 4–6 MV external beam x-rays. Three radiation field configurations were employed. The breast only was treated with tangential fields if the primary was in the lateral quadrants and axillary nodes were pathologically negative. The breast, supraclavicular and internal mammary nodes were treated if the primary was located centrally or in the medial quadrants or the axilla was pathologically positive, regardless of primary site. All the above-mentioned areas, plus the axilla, were treated if there was significant axillary in-

involvement, extra-capsular spread, less than complete dissection of a pathologically positive axilla, or if the axilla was not dissected. All fields were treated to a dose of 50 Gy in 5 weeks (2 Gy/fraction), with the excision site receiving a boost of 10–15 Gy in 1–2 weeks via 6–15 MeV electrons. From 1983 onwards the internal mammary field was treated with a combination of x-rays and electrons to minimise dose to mediastinal structures. The tangential fields employed wedges to compensate for dose inhomogeneity and no skin bolus was used after 1980.

Adjuvant systemic therapy. Adjuvant chemotherapy was not consistently used over the study period. However, among 15 node positive women, the following regimens were employed.

- a) 5MCV: Intravenously 5-fluorouracil 500 mg
day 1 methotrexate 25 mg
vincristine 1 mg
Orally days 1, 3, 5 cyclophosphamide 100 mg
(3 weekly cycles)
- b) LMFP: Orally days 1–8 clorambucil 4 mg/m²
Intravenously methotrexate 40 mg/m²
days 1, 8
5-fluorouracil 600 mg/m²
Orally days 1–14 prednisolone
(4 weekly cycles)

Therapy was given for 1–2 years. In the latter years of the study, adjuvant tamoxifen was also given to 11 node positive, postmenopausal patients.

Data were collected from radiotherapy case notes and from referring surgeons and entered onto a data base for analysis. All patient status data was analysed using the date of the first radiotherapy treatment as time zero. Survival curves were drawn using the Kaplan-Meier method (27). Curves were compared using the log-rank test (28) and Cox' regression analysis (29).

Results

Patient characteristics. All surviving patients have been followed up for 2–8 years (median 3 years 9 months). Follow-up is complete for 98% of the study group. The age range of the study population is 26–86 years with a median age of 54 years. The patient referral pattern by year is shown in Table 1. Oestrogen receptor (ER) studies were performed in 108 patients and of these 57 were ER positive (53%), 42 were ER negative (39%) and 9 (8%) were equivocal. Distribution of cases by TNM stage is shown in Table 2.

Pathology. Representative slides from all tumour specimens were reviewed by the Pathology Department of the Institute and the review diagnoses are shown in Table 3. Histological examination of the primary tumour demon-

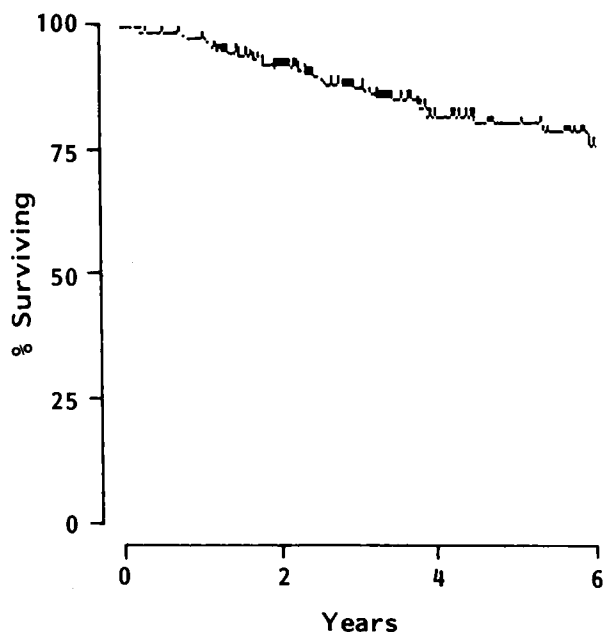


Fig. 1. Survival for all patients including deaths not due to breast cancer.

Table 1
Patient referral by year

Year	No. of patients
1978	3
1979	3
1980	26
1981	30
1982	32
1983	40
1984	52
1985	61

Table 2
TNM staging

	NO	N1a	N1b
T0	8	0	0
T1	36	18	8
T2	52	5	3
T3	3	0	0

strated infiltrating ductal carcinoma in 155 cases (78%). 50 cases had no specific histological subtype specified. There were 9 cases of ductal carcinoma in situ (DCIS) and 3 cases of lobular carcinoma in situ (LCIS). These patients have been excluded from survival, disease-free survival and local recurrence analysis, but included for complication analysis. Adequate information regarding the pathological margin of excision was given in 90 cases and

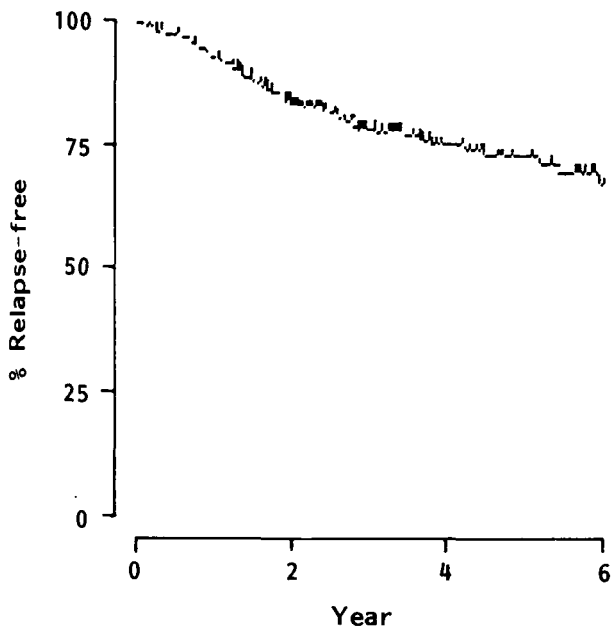


Fig. 2. Disease-free survival for all patients.

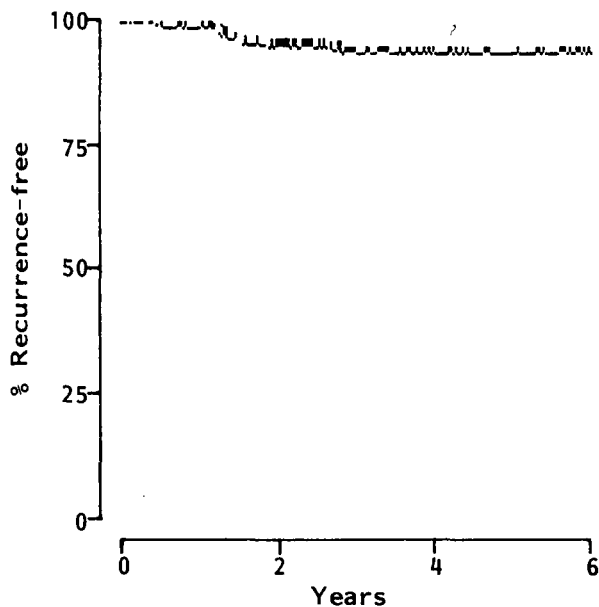


Fig. 3. Local recurrence-free survival for all patients.

of these 13 cases had cancer reaching the margins. Local re-excision was performed in 5 of these cases. The median number of nodes identified after axillary surgery was 12 and the median number histologically positive was 3. The axilla was histologically positive in 45 of 113 cases (40%).

Survival. The 5-year actuarial survival for the entire group is 79% (Fig. 1) and the 5-year actuarial disease-free survival is 72% (Fig. 2). Pathologically node-positive cases (pN+) had a 5-year actuarial survival of 65% (n=45). Node-negative and unstaged cases (pNx) had

Table 3

Histological types

	No.	(%)
Invasive carcinoma		
Infiltrating ductal	155	78
Infiltrating lobular	8	4
Medullary	6	3
Mucinous	4	2
Papillary	4	2
Undifferentiated	10	5
Non-invasive carcinoma		
Ductal carcinoma in situ	9	5
Lobular carcinoma in situ	3	2

5-year actuarial survivals of 81% and 84% respectively. At the time of analysis there were 197 patients (83%) with no evidence of disease, 26 (11%) had died from breast cancer, 10 (4%) had died from other causes and 14 (6%) were alive with loco-regional and/or distant disease.

Loco-regional recurrence. At the time of analysis there have been 13 local recurrences, 6 regional recurrences and 3 combined loco-regional recurrences. The crude local recurrence rate is therefore 16/235 (6.8%). The group as a whole has a 94% actuarial freedom from local recurrence at 5 years (Fig. 3). This figure is derived assuming that salvage mastectomy restores local control. The risk of local recurrence was analysed with respect of the following clinical, surgical, pathological and technical factors: Age, T stage, excision margin, extent of radiotherapy, N stage, breast size, node positivity, ER status, total tumour dose, type of primary surgery, axillary surgery. None of these factors were found to be statistically significantly associated with an increased risk of loco-regional recurrence. Of the total of 16 local recurrences, 9 were at or close to the primary site and 7 were elsewhere in the breast.

Six patients who relapsed locally have died from breast cancer (6/16 = 38%). Of those who have not failed locally, 30 have died from their disease (30/231 = 13%). Transient state analysis (30) reveals this difference to be highly statistically significant ($p < 0.001$). Salvage mastectomy has rendered 7/16 (44%) patients disease-free. At the time of analysis a further 2 were alive with loco-regional disease and 1 alive with distant disease (Table 4).

Complications. There was a 9% crude incidence of clinically apparent arm oedema which was related to the extent of axillary dissection and irradiation of the axilla, Tables 5 and 6. No cases of arm oedema were seen when the axilla was electively irradiated. There were 34 cases of breast retraction (14%). The use of surgical procedures greater than lumpectomy alone and lumpectomy with incision dissection of the axilla increased the risk of retraction, but not to significant levels. There was a 12% crude incidence of breast oedema, with all cases occurring in medium to large sized breasts and there was a non-sig-

Table 4
Patient's and outcomes of loco-regional recurrence

No. of patients	Type of recurrence	Salvage mastectomy	Status
8	Local only	7	7 alive and well 1 with persistent local disease
3	Synchronous local and distant	—	All dead breast cancer
2	Synchronous, local nodal and distant	—	All dead breast cancer
2	Local, with delayed distant	1	1 alive with distant disease 1 dead breast cancer
1	Local, with delayed supraclav.	—	Alive with persistent regional disease

nificant trend toward increasing risk of breast oedema with size of breast pretreatment. Other complications are listed in Table 6.

Discussion

The change in the management of early breast cancer toward breast conservation is clearly seen in the referral pattern by year, Table 1. The 5-year actuarial disease-free survival rate of 72% compares favourably with other series of similar patients reported in the literature (1–5, 8, 31, 32). TNM staging was found to have no effect on survival in our series. Of note, however, is the 100% disease-free survival of the 12 cases of DCIS and LCIS. Other authors have found excellent control rates for intraductal disease with conservation treatment (33, 34). This contrasts with the 23% local recurrence rate reported when marked intraductal disease is found within and adjacent to the tumour in palpable disease (9).

The local recurrence rate of 6.8%, during a median observation of 3 years 9 months, compares well with the 9–18% local recurrence rate after radical mastectomy (35–47), and the 10–24% seen following modified radical mastectomy (35, 38–40). It also compares favourably with reported local recurrence rates from other conservation series (1–10, 15, 31).

The follow-up period in our series is still quite short and in view of the significant continuing risk of local recurrence beyond 10 years seen by others (9, 32, 41), this figure must be regarded as premature. Calle et al. (5) have shown a higher rate of loco-regional relapse in women under 33 years of age. We found no influence of age on loco-regional relapse nor overall survival. Similarly, T and N stage and a clear pathological margin were found not to influence the risk of local recurrence. The extent of the primary surgical procedure did not alter the risk of local failure in common with reports of other (7, 42).

Table 5

*Incidence of arm oedema with number of axillary nodes dissected and axillary irradiation (n=90)**

Axillary irradiation	No. of nodes dissected	
	≤5	>5
Yes	0/16 (0%)	5/24 (21%)
No	1/3 (33%)	6/47 (13%)

* 23 cases did not have the number of nodes specified.

Some evidence exists that the total radiation dose relates to local control (7, 41, 43). Our data show no effect of total tumour dose on the risk of local recurrence.

The finding of this series that local recurrence is associated with a poorer survival is at variance with other papers (5, 7, 10–12, 31), where 10-year survivals of the order of 70% are reported following local recurrence. Clark et al. (44) have found a 10-year survival of 49% following breast relapse and 23% following axillary (±breast) relapse in their conservation series, in which only 75% of the patients were irradiated in the first instance. The J.C.R.T. data (9) are similar, with a non-significant difference in freedom from distant relapse of 50% and 33% for breast and axillary relapses respectively. The poor survival of patients in our series who experienced a local recurrence may reflect a similar phenomenon, as 3 local recurrences were associated with nodal recurrences. In Clark et al.'s paper (44), patients who relapsed locally and distantly in synchrony were scored as distant failures, which was not the case in our series. Finally, the small numbers of patients involved in our series may explain the poorer survival of our patients who recurred locally.

The challenge for the clinician is obviously to be able to select that subgroup of patients with the biological potential for both a local and systemic problem and hence

Table 6*Complication rates for breast conserving surgery and radiotherapy (n=247)*

Complications	Mild	Moderate	Severe	Total
Arm oedema	12 (5%)	10 (4%)	0 (0%)	22 (9%)
Breast retraction	25 (10%)	10 (4%)	0 (0%)	35 (14%)
Breast oedema	25 (10%)	4 (1.7%)	1 (0.3%)	30 (12%)
Local fibrosis	38 (15.5%)	6 (2.5%)	2 (1%)	46 (19%)
Local pain	17 (7%)	6 (2.5%)	4 (1.5%)	27 (11%)
Telangiectasia	20 (8%)	7 (3%)	0 (0%)	27 (11%)
Acute pneumonitis				4 (2%)
Sternal fracture				2 (1%)
Rib fracture				2 (1%)

choose local and systemic modalities more effectively. Although only small numbers were involved, there was found to be no increased risk of local failure when nodes were pathologically positive.

The 9% crude incidence of arm oedema falls within the range quoted by several authors (9, 45–47). In common with these authors we found that the major determinant of arm oedema is the extent of axillary dissection, as measured by the number of nodes identified by the examining pathologist. The majority of patients in this study had elective nodal irradiation which produced no arm oedema and an overall axillary relapse rate of only 4/247 (1.6%). This figure compares well with other series demonstrating 5-year axillary relapse rates of 1–1.2% (48). Nodal positivity had no effect on the risk of arm oedema contrary to Pezner et al. (49). Other complication rates are within previously reported ranges (9).

In conclusion, this series demonstrates the value of a breast conserving approach to early breast cancer. Local control and survival data are consistent with the early results of other reported conservation series, which demonstrate the equivalence of this approach to more radical surgical procedures. Limited surgery to the primary and axillary surgery confined to a sampling procedure (≤ 5 nodes) produce good loco-regional control and minimal complications. This series shows that an external beam boost with electrons is effective and relatively complication-free. Elective axillary nodal irradiation will produce a negligible incidence of complications, but has the theoretical disadvantage of not allowing the clinician a rational choice on the question of adjuvant therapy according to currently accepted criteria. This situation may alter if the current generation of node-negative trials indicate that systemic therapy is effective for all patients, without the requirement for axillary surgery, allowing a re-examination of the role of elective axillary irradiation. The real value, if any, of elective nodal irradiation and elective irradiation of the uninvolved quadrant of the ipsilateral breast cannot be answered from present data and awaits confirmation from future trials.

Assuming that the surgical procedure can become little or no more conservative than at present, then our atten-

tion must necessarily be directed to minimising the dose and extent of radiotherapy to maximise local control and minimise complications. The need for effective follow-up protocols to detect local recurrence at an early stage is highlighted by our data, both in terms of survival and the possibility of performing further conservative salvage procedures.

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Request for reprints: Dr Chris S. Hamilton, Newcastle Mater Misericordiae Hospital, Edith Street, Waratah, NSW 2298 Australia.

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