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Radical versus modified radical mastectomy for breast cancer

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Summary

A prospective randomised trial (534 patients, 1969–76) was designed to determine whether radical mastectomy conferred advantages over modified radical mastectomy for breast cancer in terms of total survival, local recurrence, distant metastasis, and disease-free interval. The results showed no significant difference in outcome as regards these variables between the two treatments.

Introduction

> 'The general trend of surgery in the treatment of cancer is away from the very extensive operations formerly in vogue, and I believe that this may be found to be true of the future treatment of cancer of the breast.'
>
> GEOFFREY KEYNES *(1)*

Ralston Paterson's pioneer clinical trial *(2)* showed that routine postoperative radiotherapy conferred no advantage in terms of survival on patients whose early breast cancer had been treated by radical mastectomy. Since Paterson's paper was published numerous clinical trials have compared the results of combinations of surgery, radiotherapy, and chemotherapy, but no trial involving surgery alone has compared radical mastectomy with modified radical mastectomy. Two purely surgical trials have been reported: one comparing radical with simple mastectomy was abandoned after less than 3 years (95 patients) *(3)* and the other compared radical mastectomy with radical mastectomy plus internal mammary dissection (1580 patients) *(4)*. It has been argued that the radical (Halsted) operation may be unnecessarily extensive in early cases. In order to see whether this assertion is valid we have carried out a prospective randomised trial comparing radical mastectomy with a modified operation in which the whole breast and ipsilateral axillary nodes were removed in continuity and both pectoral muscles preserved.

Patients and methods

A total of 606 patients were admitted to the trial between October 1969 and September 1976 by the five participating surgeons. The statistical arrangements were initiated by Dr M R Alderson and supervised by him until October 1970 and by Dr Ian Leck from that time until the trial closed.

New cases of breast carcinoma were entered in the trial if they were in clinical Stage I ($T_{1,2}$, N_0, M_0) or Stage II ($T_{1,2}$, N_1, M_0) as defined in the original TNM classification *(5)*. Pregnant women, patients more than 70 years old, those unfit for radical surgery, and those in whom malignant disease of any site had been diagnosed in the past were excluded. Apart from a chest X-ray to exclude pulmonary metastases the initial staging was by clinical

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TABLE I *Distribution of patients between treatment groups according to clinical and pathological stage. (The mean age of each group in years ±1SD is given in parentheses)*

Staging at entry	*Allotted mastectomy*	
	Radical	*Modified*
Clinical Stage I	173 (54±11)	159 (54±10)
Pathological Stage I	119 (55±11)	108 (55±11)
Stage II	52 (54±11)	49 (53±10)
Not known	2	2
Clinical Stage II	105 (54±12)	97 (57±10)
Pathological Stage I	41 (55±12)	38 (58±10)
Stage II	64 (54±11)	59 (56±11)
Not known	0	0

examination alone. Patients were entered by telephone call to the Regional Cancer Epidemiology Unit at the Christie Hospital and Holt Radium Institute, Manchester. The patient's name, clinical record number, and clinical stage were given and the surgical treatment to be given was read off from previously prepared lists on which the two methods of treatment (radical and modified radical mastectomy) appeared an equal number of times in a random sequence.

Two such lists, one for Stage-I and one for Stage-II patients, had been prepared for each surgeon in the trial and these lists were kept at the Epidemiology Unit and were not seen by the surgeons. Apart from the primary surgery allocated, no other treatment was given initially, but when follow-up examination disclosed recurrent or metastatic disease appropriate treatment was arranged in consultation with our radiotherapy colleagues. A record of the initial findings was made in each case and was completed as soon as the histological report was available. These records were assembled at the Epidemiology Unit, as were follow-up forms, the latter completed for each patient 2 years after entry to the trial and annually thereafter. The data presented here are those assembled before May 1980, when the median follow-up period was 5 years (range 1–128 months).

In the early stages of the trial a number of patients were randomised before histological confirmation of the diagnosis had been obtained, some of whom later proved to have a benign tumour (such as a giant-cell adenoma), fat necrosis, or sarcoma; inspection of the completed proformas showed that in some cases the size of the primary lesion exceeded, usually by a small margin, the criteria laid down; and one patient whose biopsy was positive refused operation. For these reasons 72 patients were withdrawn. Of the 534 patients remaining 278 were allocated to radical mastectomy and 256 to modified radical operation. These numbers are unequal because, of the patients withdrawn, more had been allocated to the modified than to the radical operation. Owing to errors in communication 8 of the 534 patients did not receive the treatment they were allocated (5 to radical mastectomy and 3 to modified radical mastectomy) and the figures presented include them in the groups to which they were originally allocated.

Table I shows how all 534 patients were distributed in respect of clinical and pathological stage, the latter being defined as Stage II if tumour deposits in the axillary lymph nodes were demonstrated histologically and as Stage I if not. Clinical and pathological stages were discrepant in one-third of cases. The age distribution of each group is also indicated in Table I to give some indication of how well matched the two treatment groups were. These data suggest that the clinical Stage-I cases were better matched than those in clinical Stage II, for whom there was a difference of nearly 3 years in mean age between the two treatment groups. Follow-up data are complete to May 1980 except for 4 patients whose follow-up was incomplete at that time.

Results

Time-based curves were computed by actuarial methods and compared by the logrank test *(6)* for significant differences in outcome between groups. The graphs (Figs 1–4) show the two groups of patients compared for total survival, local recurrence, distant metastasis, and total disease-free interval. We define local recurrence as recurrence in the skin flaps and related chest wall or the ipsilateral axilla and distant metastasis as secondary disease anywhere else. Table II shows the actuarial percentages for the four outcome variables by clinical and pathological stage for each of the two operations.

FIG. 1 *Total survival rates for each of the two operations, including disease-free, locally recurrent, and metastatic.*

FIG. 2 *Local recurrence rates following each of the two operations regardless of any other outcome.*

FIG. 3 *Distant metastasis rates regardless of any other outcome.*

FIG. 4 *Survival rates free from either local recurrence or distant metastasis.*

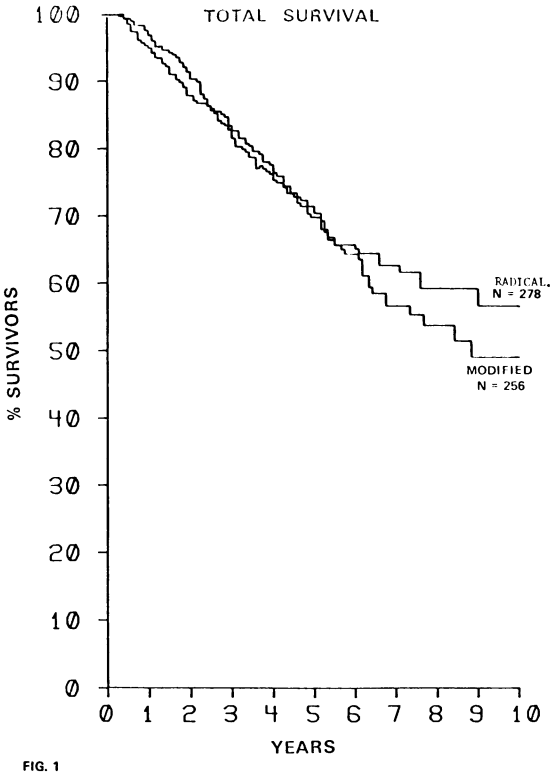

FIG. 1

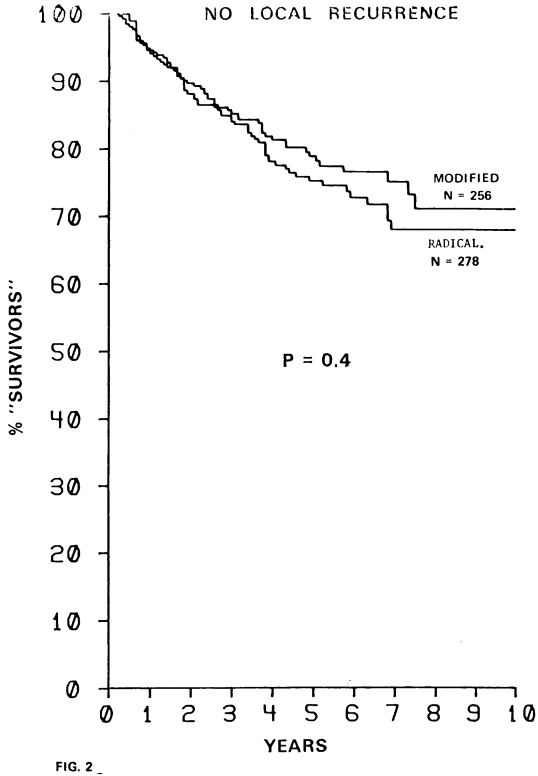

FIG. 2

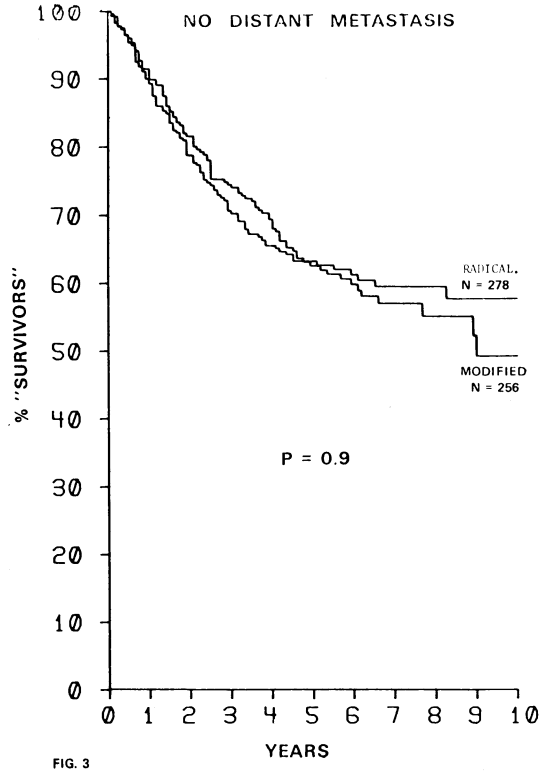

FIG. 3

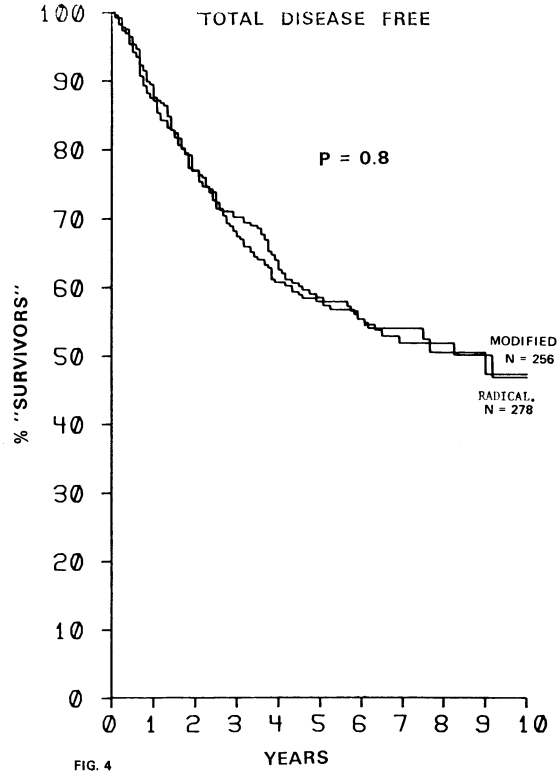

FIG. 4

TABLE II *Results of radical and modified radical mastectomy (rates %) according to clinical and pathological stage at entry.*

	No of patients followed up	*Total survival*			*No local recurrence**			*No distant metastases**			*No recurrence**		
		1 yr	*3 yr*	*5 yr*	*1 yr*	*3 yr*	*5 yr*	*1 yr*	*3 yr*	*5 yr*	*1 yr*	*3 yr*	*5 yr*
All cases													
Radical	278	97	83	70	95	84	75	89	70	63	87	67	58
Modified	256	95	82	70	94	85	79	90	74	63	88	70	58
Clinical Stage I													
Pathological Stage I													
Radical	119	98	90	80	99	92	85	97	85	79	95	78	69
Modified	108	96	89	79	98	95	90	96	86	78	95	82	71
Pathological Stage II													
Radical	52	98	73	57	92	71	57	87	61	52	79	52	39
Modified	49	94	86	62	96	81	74	92	77	62	88	63	57
Pathological stage not known	4												
Clinical Stage II													
Pathological Stage I													
Radical	41	95	90	85	100	97	91	98	87	79	98	87	79
Modified	38	95	87	78	95	92	88	92	82	71	87	76	70
Pathological Stage II													
Radical	64	94	73	55	84	69	59	83	56	47	72	47	38
Modified	59	93	63	55	84	65	56	81	59	45	75	51	30

*These figures indicate the percentages of patients not experiencing each event regardless of any other outcome.

Discussion

The analyses now recorded show no statistically significant differences between radical and modified radical mastectomy for clinical Stage-I and Stage-II breast cancer *(5)* in any of the four outcome variables. When the proposed trial was being discussed in 1968 the main question that we sought to answer was, 'Does the radical operation confer a measurable advantage over the modified operation in terms of total survival, local recurrence, distant metastasis, or disease-free interval?' The results recorded here indicate clearly that it does not. Follow-up of surviving patients continues and the results of further analyses of the same variables, and of others, will be reported later.

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