

PublisherInfo		
PublisherName	:	BioMed Central
PublisherLocation	:	London
PublisherImprintName	:	BioMed Central

## Breast conserving therapy vs mastectomy for larger tumours

ArticleInfo		
ArticleID	:	3727
ArticleDOI	:	10.1186/bcr-2000-66690
ArticleCitationID	:	66690
ArticleSequenceNumber	:	93
ArticleCategory	:	Paper Report
ArticleFirstPage	:	1
ArticleLastPage	:	4
ArticleHistory	:	RegistrationDate : 2000-8-14 OnlineDate : 2000-8-14
ArticleCopyright	:	Current Science Ltd2000
ArticleGrants	:	
ArticleContext	:	1305822

## Keywords

Breast conserving therapy, mastectomy, randomised controlled trial, stage II

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## Introduction

Previous randomised controlled trials have shown that breast conserving therapy is as effective as mastectomy in the treatment of breast cancers measuring 2 cm or smaller. Evidence of the effectiveness of breast conserving therapy in the longer term for women with larger tumours is limited.

## Aims

To compare the effectiveness of breast conserving therapy with that of mastectomy in women with stage I-II tumours, in terms of survival, time to the occurrence of distant metastases and time to locoregional recurrence before the occurrence of distant metastases.

## Comments

The results of this trial form part of the continuing process of clarifying and tailoring appropriate treatment options for women with breast cancers larger than 2 cm (stage II disease). The finding of similar survival rates and time to occurrence of distant metastases in women randomised to breast conserving treatment (compared to those randomised to modified radical mastectomy) is reassuring, although the finding of a substantially and significantly higher risk of locoregional recurrence in the breast conservation arm highlights the need for caution in interpreting these results. The results from this small trial cannot exclude important but moderate differences in survival and time to occurrence distant metastases between the groups (for example, the 95% confidence intervals for the relative hazard include 1.3 for both of these outcomes).

# Methods

This is a multicentre randomised controlled trial of 868 women with clinical stage I or II disease. Of the 868 women, 80% had tumours measuring 2.1-5.0 cm. Women were randomised to modified radical mastectomy or to breast conserving therapy, consisting of lumpectomy (with an attempted margin of 1 cm of healthy tissue) and axillary clearance, followed by radiotherapy to the breast and a supplementary dose to the tumour bed. Patients were stratified by participating centre, stage of cancer (I or II) and by menopausal status. Analysis was by intention to treat. Follow-up continued for a median of 13.4 years.

# Results

There was no significant difference in overall survival between the groups. Ten year survival was 66.1% (95% confidence interval (CI) 61.4%-70.7%) for patients assigned to the mastectomy group and 65.2% (59.7%-70.7%) for women assigned to breast conserving therapy. The hazard ratio (Cox proportional hazards model) was 1.13 (0.92-1.39) following adjustment for tumour size, axillary lymph node status and age. There was no evidence of a significant difference between the groups in terms of time to the occurrence of distant metastases. Distant-metastases-free survival at 10 years was 66.3% (61.6%-70.9%) for women in the mastectomy group and 60.5% (55.8%-65.2%) for women in the breast conserving group ( $P= 0.24$ ). Adjustment for tumour size, lymph node status and age resulted in a hazard ratio of 1.09 (0.88-1.35). Locoregional recurrence before the diagnosis of distant metastases was significantly more common in women assigned to breast conserving therapy compared to those assigned to mastectomy. The locoregional recurrence rate at 10 years was 19.7% (15.4%-24.0%) in the breast conservation group compared to 12.2% (8.7%-15.7%), and this resulted in a hazard ratio of 1.64 (1.12-2.38) following adjustment.

# Discussion

This trial showed no significant difference in survival and time to occurrence of distant metastases in women assigned to breast conserving therapy compared to those assigned to mastectomy. The great majority of women in the trial had stage II breast cancer and this study therefore provided evidence that breast conserving therapy is a feasible option in women with tumours over 2 cm in size. The greater risk of locoregional recurrence in patients assigned to breast conserving therapy should be considered. The small number of patients with locoregional recurrence did not permit a formal analysis of which risk factors were associated with recurrence. The higher risk of locoregional recurrence was not of sufficient magnitude to cause a substantial difference in rates of distant metastases and overall survival. Patients in the trial were enrolled from May 1980 to May 1986 and since then there have been changes to breast cancer treatment. In particular, contemporary practice means that more attention is paid to microscopic completeness of tumour excision.

## References

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