Original Article

Breast-conserving therapy and modified radical mastectomy for primary breast carcinoma: a matched comparative study

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Background: To compare two types of therapy for primary breast carcinoma, breast-conserving therapy (BCT) and modified radical mastectomy (MRM), in a matched cohort study.

Methods: A series of 1,746 patients with primary breast cancer treated with BCT or MRM in a single Chinese institute between January 2000 and February 2009 were analyzed retrospectively to compare their outcomes with respect to the incidence of local recurrence (LR), distant metastasis, and survival. The patients were matched with regard to age at diagnosis, spreading to axillary lymph nodes, hormone receptor status, the use of neoadjuvant chemotherapy and maximal tumor diameter. The match ratio was 1:1, and each arm included 873 patients.

Results: The median follow-up period was 71 months. The 6-year disease-free survival (DFS) and 6-year distant disease-free survival (DDFS) rates differed significantly between two groups. The 6-year local recurrence-free survival (LRFS) rates were 98.2% [95% confidence interval (CI): 0.973-0.989] in the BCT group and 98.7% (95% CI: 0.980-0.994) in the MRM group (P=0.182), respectively. DFS rates in BCT and MRM groups were 91.3% (95% CI: 0.894-0.932) and 86.3% (95% CI: 0.840-0.886) (P<0.001), respectively, whereas the DDFS rates in BCT and MRM groups were 93.6% (95% CI: 0.922-0.950) and 87.7% (95% CI: 0.854-0.900) (P<0.001), respectively.

Conclusions: BCT in eligible patients is as effective as MRM with respect to local tumor control, DFS and DDFS, and may result in a better outcome than MRM in Chinese primary breast cancer patients.

Keywords: Breast carcinoma; breast-conserving therapy (BCT); mastectomy; recurrence; survival

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Introduction

In 1990, the National Institutes of Health (NIH) released a consensus statement recommending the use of breast-conserving surgery (BCS) with adjuvant radiotherapy instead of mastectomy for the treatment of early-stage (stage I or II) breast cancer, whenever possible (1). For women diagnosed with early-stage breast cancer, survival with breast-conserving therapy (BCT) is comparable to that achieved with mastectomy following initial treatment (2), and BCT may afford better body image and sexual function (3). BCT is becoming a widely used therapy for breast cancer, as seven prospectively randomized studies involving thousands of patients with follow-up periods of more than 2 decades have demonstrated that local tumor control and disease-free survival (DFS) are comparable to that with radical mastectomy (4-10). In China, however, BCT was not used routinely until 2000, and far fewer patients choose it compared to those in Western countries. Thus, reports regarding its efficacy for Chinese women are few. We present here a large matched research of BCT compared to modified radical mastectomy (MRM) performed in China, and summarize the long-term follow-up results of BCT and MRM for breast cancer from a single unit, focusing on local recurrence (LR), DFS, and distant disease-free survival

(DDFS) in the two groups.

Patients and methods

Study design

A consecutive series of women with primary breast cancer treated with BCT or MRM were derived from a database created and managed by Peking University Cancer Hospital & Institute. A total of 3,109 women were eligible for this study, of whom, 1,746 with stage I and II primary breast cancer were analyzed, and patients with stage III or IV breast cancer were excluded. BCS followed by radiotherapy to the intact breast was performed in 873 cases and MRM was performed in 873 cases between January 2000 and February 2009. These patients were matched according to 5 baseline variables which are thought to possibly have a significant association with LR, distant metastasis, and survival. These were age at diagnosis, axillary lymph node status, hormone receptor status, maximal diameter of the primary tumor, and the use of neoadjuvant chemotherapy (*Table 1*).

The match ratio was 1:1. The median patient age was 47 and 49 years in the BCT and MRM groups, respectively, and the median follow-up periods were 71 and 71 months, respectively. Neoadjuvant chemotherapy was administered to 521 patients (59.7%) in each group.

A cut-off date in February 2009 was chosen to give a minimum evaluable follow-up period of 41 months. Patients were clinically staged in accordance with American Joint Committee on Cancer (AJCC) guidelines (11).

Surgical procedures and other treatments

The surgical procedure included resection of the primary tumor with a surrounding margin of at least 1 cm of normal tissue, which was confirmed to be cancer-free through frozen pathological examination during the operation. Prior to 2004, all patients underwent axillary lymph node dissection (ALND). The surgical approach included level I, II, and partial level III ALND. At least 11 nodes were removed in each case. Sentinel lymph node biopsy (SLNB) was introduced in 2005. Patients with positive sentinel lymph nodes during this procedure went on to have a complete ALND. SLNB without complete dissection was performed in 578 patients with pathologically negative sentinel lymph nodes assessed by conventional and immunocytochemical staining.

After BCS, all patients were treated with radiotherapy using tangential fields directed at the intact breast. Radiotherapy was administered using standard techniques with 4-6 MeV linear accelerators. Patients received treatment to the whole breast at a standard fractionation of 2 Gy daily to a total median dose of 46 Gy (range, 40-60 Gy), followed by electron beam boost to the tumor bed to a total median dose of 60 Gy (range, 50-66 Gy) over a period of 6-8 weeks. Patients undergoing ALND received treatment to the breast alone if they had no more than 3 positive nodes pathologically or to the breast and supraclavicular and internal mammary nodes if there were ≥4 nodes positive pathologically. Patients undergoing SLNB were in general treated with tangents only if they were found to have pathologically negative sentinel nodes. Patients with positive sentinel nodes underwent complete ALND. The treatment policy for these patients was the same as that for those who had ALND initially. The principle of adjuvant (or neoadjuvant) chemotherapy and adjuvant hormonal therapy was in accordance with National Comprehensive Cancer Network/St. Gallen guidelines.

Hormone receptor and human epidermal growth factor receptor 2 expression

Data on estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER-2/*neu*) were obtained through standard clinical testing. ER and PR status were determined using immunohistochemistry (IHC) staining, and tumors were considered to be receptor-positive if more than 10% of cells stained positive. Tumors were considered HER-2-positive only if they had a +++ IHC score or a ++ IHC score and positive *Her-2* gene amplification based on fluorescence *in situ* hybridization (FISH).

Definition of recurrence

The patients underwent annually mammography. Ultrasonography of bilateral breasts (or the remaining breast in cases of total mastectomy) and lymphatic regions were routinely performed every 3-6 months. Other diagnostic studies were performed at the discretion of the referring physician. Treatment failure was defined as histologically confirmed reappearance of cancer in the ipsilateral breast or chest wall. Regional nodal relapses were defined as clinical failure in the ipsilateral axilla, supraclavicular fossa, infraclavicular fossa, or internal mammary chain as the first site of failure. Patients with recurring breast carcinoma who

Table 1 Patient characteristics

Characteristics	n (%)		P*
	BCT (N=873)	MRM (N=873)	
Age (year)			–
≤35	56 (6.4)	56 (6.4)	
>35, ≤60	713 (81.7)	713 (81.7)	
>60	104 (11.9)	104 (11.9)	
Median follow-up time (month)	71	71	–
Tumor dimension on ultrasonography (cm)			–
≤1	39 (4.5)	39 (4.5)	
>1, ≤2	409 (46.8)	409 (46.8)	
>2, <5	425 (48.7)	425 (48.7)	
Hormone receptor			–
Negative	228 (26.1)	228 (26.1)	
Positive	645 (73.9)	645 (73.9)	
Axillary lymph node status			–
Negative	565 (64.7)	565 (64.7)	
Positive	308 (35.3)	308 (35.3)	
Pathological type			0.017
DCIS	35 (4.0)	42 (4.8)	
IDC	722 (82.7)	729 (83.5)	
ILC	45 (5.2)	60 (6.9)	
Other	71 (8.1)	42 (4.8)	
Neoadjuvant chemotherapy	521 (59.7)	521 (59.7)	–
SLNB	345 (39.5)	233 (26.7)	–

BCT, breast-conserving therapy; MRM, modified radical mastectomy; *, Chi-square test; DCIS, ductal carcinoma *in situ*; IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; SLNB, sentinel lymph node biopsy.

also had positive nodes at the time of failure but no clinical signs of regional nodal failure were not considered to have experienced nodal relapse. Distant failure was defined as any clinical and/or radiographic evidence of metastatic disease.

Statistical analysis

The chi-square test was used to compare the distribution of baseline characteristics among subtypes. The probability of survival (or relapse occurrence), DFS, and DDFS were calculated using the Kaplan-Meier method. Statistical differences among LR, DFS, and DDFS rates were calculated using the log-rank test for univariate analysis. All tests were two-tailed. P<0.05 was considered statistically significant. Statistical tests were performed using SPSS 15.0 software package (SPSS Inc., Chicago, IL, USA).

Results

Local control

As of August 2013, with a minimum evaluable follow-up period of 41 months and a median follow-up period of 71 months, 17 cases of ipsilateral breast tumor recurrence (IBTR) have been noted in the BCT group and 10 cases of LR have been noted in the MRM group. Thus, the 6-year actuarial LR-free survival rates were 98.2% (95% CI: 0.973-0.989) and 98.7% (95% CI: 0.980-0.994), respectively. The incidence of LR was higher in the BCT group than in the MRM group at the 6th year (1.8% *vs.* 1.3%), but this difference was not statistically significant (P=0.182, *Figure 1*). Local regional relapses were noted in the axilla in 14 cases, in the supraclavicular fossa in 13 cases, and in the infraclavicular fossa in 1 case.

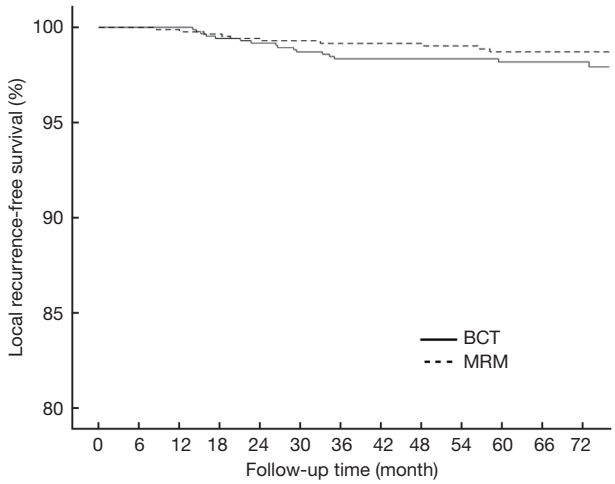

Figure 1 Kaplan-Meier curve of local recurrence-free survival in BCT or MRM groups. BCT, breast-conserving therapy; MRM, modified radical mastectomy.

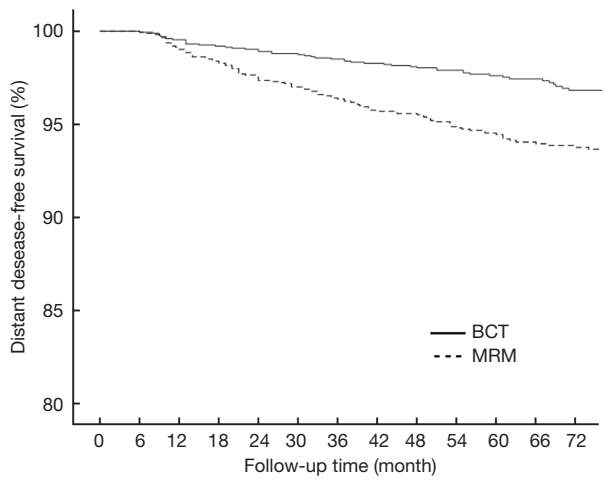

Figure 2 Kaplan-Meier curve of distant disease-free survival in BCT or MRM groups. BCT, breast-conserving therapy; MRM, modified radical mastectomy.

Impact of surgery type on DDFS and DFS

In the BCT and MRM groups, 51 and 109 patients, respectively, were found to have metastasis in distant organs and the 6-year DDFS was 93.6% (95% CI: 0.922-0.950) and 87.7% (95% CI: 0.854-0.900), respectively (P<0.001, *Figure 2*). The 6-year DFS rates in these groups were 91.3% (95% CI: 0.894-0.932) and 86.3% (95% CI: 0.840-0.886), respectively (P<0.001, *Figure 3*).

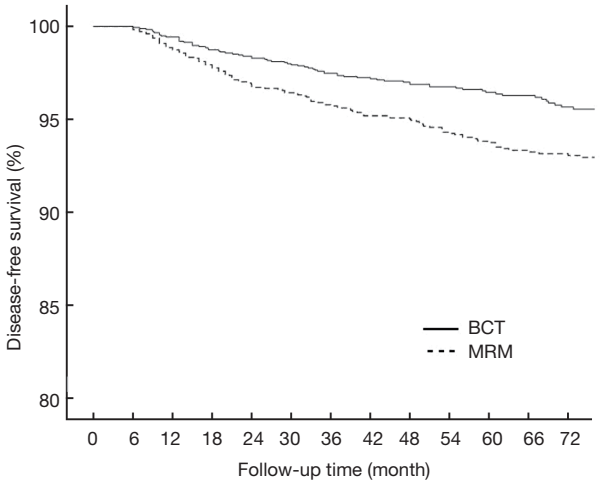

Figure 3 Kaplan-Meier curve of disease-free survival in BCT or MRM groups. BCT, breast-conserving therapy; MRM, modified radical mastectomy.

Subgroup analysis

We performed subgroup analysis to determine the occurrence of LR and distant metastasis in BCT patients according to clinical and pathological parameters (*Table 2*). The LR rate was significantly higher in patients with positive axillary lymph nodes (3.2%, 10 of 308) than in patients with negative axillary lymph nodes (1.2%, 7 of 565; P=0.030). The rates of actuarial breast relapse for T1 and T2 tumors were 1.1% (5 of 448) and 2.8% (12 of 425), respectively (P=0.067), and the incidence of LR was higher among patients who received neoadjuvant chemotherapy (2.7%, 14 of 521) than among those who did not receive neoadjuvant chemotherapy (0.9%, 3 of 352; P=0.062).

Discussion

Several previous retrospective and prospective randomized trials have shown that BCS followed by adjuvant radiotherapy is equivalent to mastectomy in terms of survival for patients with early stage breast cancer, despite of a higher rate of LR (2,12-14). Consequently, BCT has been used routinely in clinical practice for more than 20 years in many Western countries. The comparatively low take-up rate of BCT in China may relate to factors such as social and economic circumstances, although concern over the increased risk of relapse and metastasis seems to have been the primary consideration for both breast cancer patients

Table 2 Subgroup analysis of local recurrence and survival in BCT group

Factors	Survival rate ($\bar{x}\pm s_e$, %)		
	6-year LRFS	6-year DDFS	6-year DFS
Age (year)			
≤35	100	91.8±7.8	91.8±7.8
>35	98.1±1.0	93.8±1.7	91.3±2.1
P	0.965	0.585	0.755
Axillary lymph node status			
Positive	97.3±1.7	89.1±3.7	85.5±4.1
Negative	98.7±1.0	96.1±1.7	94.5±2.1
P	0.030	<0.001	<0.001
Hormone receptor status			
(+)	98.5±1.0	93.5±3.2	91.3±2.3
(–)	97.3±2.1	93.9±3.3	91.3±3.7
P	0.424	0.892	0.741
Tumor stage			
T1	99.1±0.7	94.8±2.3	94.0±2.5
T2	97.2±1.5	92.4±2.7	88.5±3.1
P	0.067	0.148	0.005
Neoadjuvant chemotherapy			
(+)	97.6±1.4	92.9±2.3	90.0±2.7
(–)	99.1±1.0	94.6±2.9	93.1±3.1
P	0.062	0.091	0.025

BCT, breast-conserving therapy; LRFS, local recurrence-free survival; DFS, disease-free survival; DDFS, distant disease-free survival. P values were for the log-rank test.

and their doctors.

The study we report here has a longer follow-up period than any previous study conducted regarding the relative efficacy of BCT and MRM for primary breast carcinoma in China. In order to minimize the selection bias of patients between these groups, the data were analyzed retrospectively by a matched cohort study method using 5 baseline variables: patient age, axillary lymph node status, hormone receptor status, the use of neoadjuvant chemotherapy and tumor diameter. All these factors were considered likely to be associated with LR, distant metastasis, and survival, based on previous studies.

The ultimate aim of this study was to help patients and physicians in China decide whether BCT or MRM is the better option in any given case. We found that BCS followed by radiotherapy provides comparable results to those of MRM in terms of local control. This is consistent with the findings of earlier, randomized trials (1,2). One possible concern in interpreting these results is that IBTR may actually represent 2 distinct entities: a true recurrence (TR) and a new primary tumor (NPT). Some studies suggest that NPTs are associated with a more favorable outcome than TR (15-17). However, as no standard method for sub-classifying IBTR as either TR or NPT has been established yet, we did not attempt to distinguish these entities in this study.

Breast cancer has a prolonged natural history, and hence competing causes of mortality (for example heart disease and stroke) may potentially skew the DFS and DDFS data. We found that the BCT group had significantly better 6-year DFS and DDFS rates than the MRM group. These results are striking and suggest that BCT is likely to be the superior treatment option in most cases. This is consistent with the findings of several recent studies (18-20). However, because it is retrospective, this study is not sufficient to conclusively prove that BCT is superior to MRM. Unknown biases may

have prevented us from identifying the true differences between the efficacy of BCT and MRM in these patients.

Some studies on the efficacy of BCT have found higher locoregional recurrence rates in younger patients (21-23). There was no such finding in a mastectomy series (24,25), and some investigators postulated that the higher locoregional recurrence rates were due to limited breast resection in younger patients (21). Younger age itself, however, was also shown to be associated with diverse, aggressive pathological features (23-26).

Neoadjuvant chemotherapy is an important method for enabling otherwise ineligible patients to undergo BCT (27,28). In this study, 59.7% of patients in each of the BCT and MRM groups received neoadjuvant chemotherapy. Within the BCT group, the 6-year DFS of patients who received neoadjuvant chemotherapy was significantly lower than that of patients who did not receive this treatment. This may reflect the fact that patients undergoing neoadjuvant chemotherapy did so because on average they had larger tumors and more positive axillary lymph nodes. Our subgroup analysis showed that both tumor size and axillary lymph node status at initial treatment are strongly associated with both the 6-year LRFS rate (lymph node status only) and the 6-year DFS and DDFS rates (lymph node status and tumor size). Tumors insensitive to neoadjuvant chemotherapy generally have more aggressive behavior, resulting in a poor prognosis for patients undergoing MRM.

We found statistical differences in the distribution of pathological types between the BCT and MRM groups in this study (P=0.017), suggesting that this potential selection bias might not be have been completely controlled. Previous studies have shown that invasive lobular carcinomas have similar rates of local control to invasive ductal carcinoma. Furthermore, the survival and local control afforded by BCT in patients with invasive lobular tumors do not differ statistically from those achieved in patients with invasive ductal tumors (29,30), which is consistent with this study.

HER-2 is an important prognostic marker of primary breast cancer. It was not included in this study, however, because HER-2 testing was not routine practice in our center until 2004, and subsequent HER-2 results were not of sufficient quality to allow the analysis. As compared with luminal A-like subtype, HER-2-positive was associated with a worse DFS in node-positive patients. Anti-HER-2 therapy results in a significant survival advantage when given after chemotherapy to early breast cancer patients over observation alone (31-33), and even to metastatic breast cancer patients (34). In the current study, only a few patients could afford trastuzumab treatment, but the inclusion of these few might also have biased the analysis of the results to some degree. The short follow-up period in our study also limits the comparison of BCT and MRM, and we hope that this might be addressed by future studies with an extended follow-up period.

Conclusions

Our matched retrospective study indicates that BCT performed for eligible patients is as effective as MRM with respect to local tumor control, DFS, and DDFS. BCT may be a superior treatment option for most Chinese primary breast cancer patients.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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