A Comparison of Clinical Outcomes for Breast-conserving Treatment and Mastectomy for Early Breast Cancer

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Purpose: To compare the treatment outcomes and to analyze prognostic factors between the use of a breast-conserving treatment (BCT) and a mastectomy for early stage breast cancer.
Materials and Methods: We retrospectively reviewed 1,200 patients with pathological stage T1-2N0 breast cancer who received surgery between September 1994 and December 2002 at Samsung Medical Center. We compared the patient characteristics and treatment outcomes between the two treatment groups.
Results: Among the 1,174 eligible patients, 601 (51.2%) patients received a BCT and the remaining 573 (48.8%) patients received a mastectomy. The mastectomy group of patients had significantly more cases with a larger tumor size, multicentricity, extensive intraductal component, and estrogen- and progesterone-receptor negativity. The ten-year overall survival rates (OS) of the BCT and mastectomy groups were 91.96% and 91.01%, respectively (p=0.1274). The ten-year disease-free survival rates (DFS) were 80.48% for the BCT group of patients and 84.95% for the mastectomy group of patients, respectively (p=0.8795).
Conclusion: Our study shows some differences in patient characteristics between the two treatment groups. However, these differences did not result in significant survival differences.

Key Words: Breast cancer, Breast-conserving surgery, Mastectomy

Introduction

Breast cancer is the most common malignancy in female patients in Korea.[1,2] The incidence has been rapidly increasing and reached 40.5 per 100,000 women in 2004.[3] For breast cancer treatment, about forty-two percent of patients receive breast-conserving surgery (BCS). This represents a two-fold increase since 1996.[4]

The surgical approach to the primary breast cancer involves excision of all invasive cancer with clear resection margins. There have been several surgical methods from radical mastectomy to conservation surgery such as wide local excision, segmentectomy or quadrantectomy.[5~7] But conser-

vation surgery only developed local recurrence from 24% to 40%.[8~11] After breast conserving surgery (BCS), postoperative irradiation reduced the local recurrence rate about 70%.[10,11] Several prospective randomized trials compared treatment outcomes between BCS followed by radiotherapy (BCT) and mastectomy in early stage breast cancer. The survival rates were similar, but local recurrence was more apparent in BCT group.[10,12~16] Given these study results, BCT has become an accepted treatment for early breast cancer patients.[17,18] In this study, we retrospectively analyzed the treatment outcomes of pathologic stage T1-2N0 breast cancer patients between a mastectomy and BCT.

Materials and Methods

From September 1994 to December 2002, 1,200 patients were diagnosed with pathological stage T1-2N0 breast cancer at Samsung Medical Center in Korea. Among the patients, 21 patients who received neoadjuvant chemotherapy and 5

patients who did not receive breast irradiation after BCS were excluded from the analysis. The remaining 1,174 patients were eligible for the retrospective review.

Patients ranged in age from 23 to 82 years with a median age of 46 years. Six hundred one patients (51.2%) received BCS followed by breast irradiation, and the remaining 573 patients (48.8%) received mastectomy. After BCS, whole breast irradiation with the tangential technique was administered with 45~50.4 Gy with a daily fraction size of 1.8~2 Gy. Then, a local boost to the tumor bed was provided with 9~14 Gy in 549 patients (91.3%). After a mastectomy, 13 patients received chest wall irradiation because of positive or close surgical margins. No patient received radiation of the supraclavicular fossa. Adjuvant chemotherapy was given to 356 (59.2%) of the BCT group and 399 (69.6%) of the mastectomy group. Most of the chemotherapeutic regimens included combinations of cyclophosphamide, methotrexate and fluorouracil (99.2% for the BCT group and 97.2% for the

mastectomy group). Adjuvant hormonal therapy was given to 322 patients (53.6%) in the BCT group and 287 patients (50.1%) in the mastectomy group, most used tamoxifen.

The median follow-up period of surviving patients was 60 months (range 3~136 months) and 65 months (range 2~131 months) for BCT group and mastectomy group, respectively. At the time of analysis, 491 patients (81.7%) out of BCT group and 433 patients (75.6%) out of mastectomy group were under regular follow-up. Fifty-nine patients (9.8%) in BCT group and 73 patients (12.7%) in mastectomy group were lost during follow-up under median follow-up time. We compared the patient characteristics between the treatment groups using the t-test and χ^2-test. The Kaplan-Meier method was used to calculate overall survival and disease free survival. To compare treatment outcomes and analyze prognostic factors, we used the Log-Rank test and the Cox proportional hazard test. Statistical analysis was performed with the SAS® system (SAS 9.0, SAS Institute Inc., Cary,

Table 1. Comparison of Patient Characteristics Enrolled 1,174 Patients according to Treatment Modality

Characteristics		BCT* (%) (n=601)	Mastectomy (%) (n=573)	p-value
Age (years)		27~79 (median 45)	23~82 (median 45)	0.0361
Location	Right	271 (45.1)	273 (47.6)	0.0692
	Left	325 (54.1)	300 (52.4)	
	Bilateral	5 (0.8)	0	
T stage	1	460 (76.5)	286 (49.9)	<0.0001
	2	141 (23.5)	287 (50.1)	
Menopause	Yes	212 (35.2)	213 (37.2)	0.4987
	No	389 (64.8)	360 (62.8)	
Multicentricity	Yes	26 (4.3)	68 (11.9)	<0.0001
	No	575 (95.7)	505 (88.1)	
LVI[†]	Yes	38 (6.3)	48 (8.4)	0.1769
	No	563 (93.7)	525 (91.6)	
EIC[‡]	Yes	128 (21.5)	171 (30.2)	0.0007
	No	468 (78.5)	396 (69.8)	
ER[§]	Positive	341 (65.6)	297 (58.3)	0.0169
	Negative	179 (34.4)	212 (41.7)	
PR[‖]	Positive	267 (51.5)	224 (44.4)	0.0231
	Negative	251 (48.5)	280 (55.6)	
Nuclear grade	Low	70 (13.9)	62 (12.1)	0.6835
	Intermediate	257 (51.2)	269 (52.5)	
	High	175 (34.9)	181 (35.4)	
Histologic grade	Well	74 (17.0)	57 (14.1)	0.4249
	Moderate	183 (42.0)	184 (45.3)	
	Poor	179 (41.0)	165 (40.6)	
Resection margin	≤2 mm	62 (10.3)	67 (11.7)	0.4509
	>2 mm	539 (89.7)	506 (88.3)	

*breast-conserving treatment, [†]lymphovascular space invasion, [‡]extensive intraductal component, [§]estrogen-receptor, [‖]progesteron-receptor
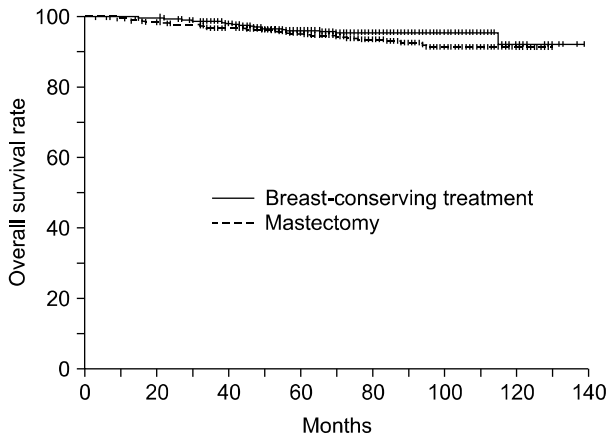
Fig. 1. Overall survival rate according to treatment modality. The ten-year overall survival rate was 91.96% and 91.01% for breast conserving treatment and mastectomy, respectively (p=0.1274).
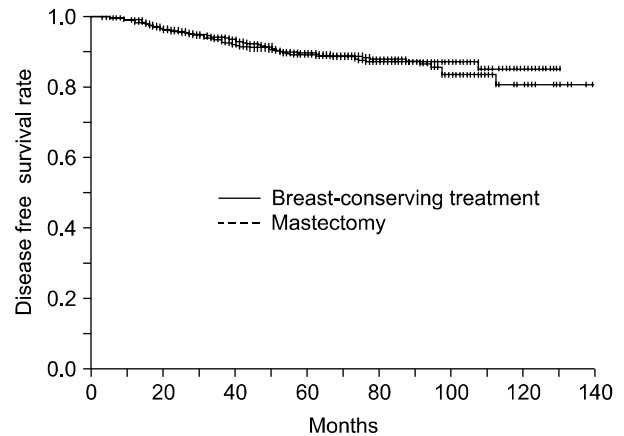

Fig. 2. Disease free survival rate according to treatment modality. The ten-year disease free survival rate was 80.48% and 84.95% in the breast conserving treatment and mastectomy, respectively (p=0.8795).

NC., USA).

Results

Among the BCT group, 460 (76.5%) patients had pathologic T1 stage and the remaining 141 (23.5%) patients had pathologic T2 stage. Two hundred eighty-six (49.9%) patients of the mastectomy group had pathologic T1 stage (p <0.0001). The mastectomy group had significantly more patients with multicentricity, estrogen- and progesterone-receptor negativity (Table 1).

During the follow-up period, twenty-three patients (3.8%) in the BCT group and twelve patients (2.1%) in the mastectomy group showed local recurrence (p=0.0810). Regional (ipsilateral axilla and supraclavicular) recurrence was detected in 21 patients (3.7%) of the mastectomy group, which was significantly more frequent than 10 patients (1.7%) of the BCT group (p=0.0326). Fifty-eight patients (9.7%) and seventy-one patients (12.4%) in each group had distant recurrence (p=0.1334). The sites of distant metastases were bone, lung, liver and brain in order of frequency with no difference noted between treatment modalities.

The ten-year overall survival rate (OS) and disease free survival rate (DFS) for all patients was 91.73% and 83.29%. The ten-year OS in the BCT group was 91.96%, which was not significantly different from that of the mastectomy group (91.01%, p=0.1274, Fig. 1). There was also no significant

difference in the 10-year DFS between the two groups (80.48% and 84.95%, p=0.8795, Fig. 2).

The multivariate analysis showed that T-stage significantly affected both OS and DFS (p=0.0213 and 0.0164). Lymphovascular space invasion (LVI) and histologic grade affected DFS (p=0.0143 and 0.0038, Table 2). We analyzed the survival outcome according to treatment modalities in same T-stage, OS was not significantly affected by treatment modalities (Table 3). But DFS of BCT group was significantly inferior to that of mastectomy group in T1 patients (p=0.0482). Difference in DFS of T2 patients was not significant between treatment modalities (p=0.6207). We also analyzed the survival difference between treatment modalities according to other characteristics. There was no survival difference in each characteristic except for ER-positive patients OS of mastectomy group was significantly inferior to BCT group (p=0.0220).

Discussion

BCT has become an acceptable alternative treatment modality to mastectomy since the 1990s in Korea.[19] In a nationwide survey of breast cancer treatment in Korea, the use of breast conserving surgery has increased from 18.7% in 1996 to 41.9% in 2004.[3,4] In our hospital, more than half (51.2%) of the patients received BCT, which was higher than the above nationwide survey results. There are several factors

Table 2. Multivariate Analysis for Prognostic Factors Affecting Survival Outcomes[*]

Variables	Overall survival rate		Disease free survival rate	
	10 year rate	p-value	10 year rate	p-value
Treatment				
BCT	92.0%		80.5%	
Mastectomy	91.0%	0.4766	85.0%	0.2708
T-stage				
T1	96.0%		84.9%	
T2	84.1%	0.0213	80.7%	0.0164
LVI				
Yes	80.0%		60.1%	
No	93.3%	0.1656	85.8%	0.0143
Nuclear grade				
Low	98.9%		87.0%	
Intermediate	90.5%		81.3%	
High	86.4%	0.0511	80.9%	0.8968
Histologic grade				
Well	90.9%		86.6%	
Moderate	89.1%		81.5%	
Poor	88.9%	0.7773	81.6%	0.0038
ER				
Positive	94.4%		81.7%	
Negative	90.2%	0.7615	82.3%	0.4368
PR				
Positive	93.2%		80.4%	
Negative	92.1%	0.6645	82.9%	0.2484

*abbreviations were previously introduced in Table 1

affecting surgical procedures in patients with early breast cancer. Several reports evaluating the geometrical difference with BCT have been published.[20~22] BCT was more commonly used in teaching hospitals, in larger hospitals and in hospitals with on-site radiation therapy.[20] Moreover, the physician-to population ratio, education and income levels, and the presence of a cancer center were significant predictors of the type of surgery used.[21] These factors in addition to the location, availability of radiation therapy and surgeon's preference might account for the higher rate of BCT at our hospital.

After BCS in patients with early breast cancer, the remnant breast is a common site of recurrence. The National Surgical Adjuvant Breast and Bowel Project (NSABP) B-06 trial showed a 39.2% cumulative rate of ipsilateral breast cancer recurrence after lumpectomy only.[10] Breast irradiation after lumpectomy reduced the risk of recurrence to about one-third (14.3%). Data from the EBCTCG meta-analysis of randomized trials of BCS with or without breast irradiation showed a 19%

reduction in the 5-year local recurrence risks (7.3% versus 25.9%), and 5.4% reduction in the 15-year breast cancer mortality risk (30.5% versus 35.9%).[11] The reduction rate of local recurrence in BCS with adjuvant breast irradiation was 69% compared with BCS alone (p<0.00001), and the reduction of breast cancer mortality was about one-sixth (p=0.0001).

Several randomized trials demonstrated that survival with BCS plus irradiation is equivalent to that with mastectomy. The Milan I trial randomized 701 breast cancer patients with a tumor of no more than 2 cm in diameter.[15] Their cumulative incidence of local recurrence was 8.8% in the BCT group and 2.3% in mastectomy group (p<0.001). However, the rate of death from breast cancer was 24.3% and 26.1%, respectively (p=0.8). The EBCTCG meta-analysis of nine trials of mastectomy versus BCS plus radiotherapy showed no apparent difference in total mortality (22.9% vs. 22.9%).[23] In our retrospective review, the local recurrence rate of patients with pathologic T1-2N0 was 3.8% and 2.1% in the BCT and

Table 3. Comparison of Survival Difference between Treatment Modalities according to Patients' Characteristics*

Characteristics	10 Y overall survival rate			10 Y disease free survival rate		
	BCT (%)	Mastectomy (%)	p-value	BCT (%)	Mastectomy (%)	p-value
T-stage						
T1	96.5	95.7	0.9075	80.3	89.6	0.0482
T2	78.6	86.2	0.6210	81.3	80.2	0.6207
Multicentricity						
Yes	100	93.6	0.3044	88.5	79.8	0.9530
No	91.2	90.7	0.1467	79.6	85.9	0.7798
LVI						
Yes	68.4	87.0	0.8096	61.7	59.6	0.5340
No	95.7	91.4	0.1414	82.1	87.9	0.9965
EIC						
Yes	46.8	90.8	0.9700	87.4	81.7	0.9083
No	95.7	92.0	0.1426	79.2	86.1	0.6299
ER						
Positive	97.5	90.7	0.0220	75.3	84.3	0.9012
Negative	91.6	89.9	0.9375	79.2	84.5	0.7336
PR						
Positive	97.5	89.3	0.0763	76.4	81.6	0.5739
Negative	92.7	91.4	0.4843	77.7	86.1	0.3619
Nuclear grade						
Low	97.8	100	0.2967	63.7	90.0	0.8848
Intermediate	87.6	91.4	0.0785	75.2	85.3	0.3569
High	90.4	84.0	0.5032	77.6	82.6	0.8536
Histologic grade						
Well	94.9	86.9	0.3442	94.4	84.4	0.7615
Moderate	85.4	90.4	0.1269	73.4	85.4	0.5751
Poor	93.0	86.1	0.3015	82.3	80.9	0.7235

*abbreviations were previously introduced in Table 1

mastectomy group respectively (p=0.0810), the Milan I trial showed a similar tendency. Other randomized trials included patients with tumors that were larger than 2 cm, which provided further evidence of the efficacy of BCT.[13,14,16] About four-fifths of the patients included in the EORTC 10801 trial had clinical tumor size of 2.1~5 cm, while 48.6% of patients had pathologic tumor size of 2.1~5 cm.[14] The ten-year overall survival rates were 66.1% and 65.2% in the mastectomy and BCT groups, respectively (p=0.11). The National Cancer Institute (NCI) randomized trial showed that 52% in the mastectomy group and 57% in the BCT group had a tumor size of 2.1~5 cm, and their twenty-year survival rates were 58% and 54% for each group respectively (p=0.67).[16] Our study included 36.5% of patients with a tumor size larger than 2 cm and showed no significant difference in the OS or DFS between treatment modalities.

In Korea, there is no prospective randomized trial comparing BCT with mastectomy in early stage breast cancer. Son et al. retrospectively reviewed 3,700 patients accrued from a multi-institution study on operable breast cancer. Among them 2,821 patients (76.2%) received a mastectomy and 860 patients (23.2%) had BCS procedures.[24] Their cumulative incidence of locoregional recurrence at 10-years was 6.5%. Although the incidence was not described according to treatment, the results were consistent with our data, 5.5% for the BCT group and 5.8% for the mastectomy group. The Korean Breast Cancer Society reported on a survival analysis of Korean breast cancer patients diagnosed between 1993 and 2002.[25] The five-year survival rates of stage I patients were 95.8% and 98.8% in the mastectomy and BCS group, respectively. The 5-year survival rates for stage II patients were 91.5% and 94.2% for each group, respectively. There is

limited data comparing survival outcome between the two treatment modalities in Korea. Kim et al. reported retrospective data on 171 patients with stage I-II Breast cancer.[26] Among them, eighty-five patients received BCT. The five-year overall survival rate was 96.4% with BCT and 97.2% with mastectomy, which was not significantly different (p=0.2313). The five-year disease free survival rate was also not significantly different between thetwo groups (93.4% and 95.7%, p=0.1836). Yea et al. retrospectively reviewed 62 patients with stage I-II breast cancer; 22 with BCS and 40 with mastectomy.[27] They reported a 95.5% locoregional control rate and 86.3% were satisfied with their cosmetic results in the BCT group. However, there was no report on the survival outcome. Lee et al. reported 54 patients treated with BCS followed by radiotherapy.[28] In this study, overall survival and disease free survival rates at 10-years was 92.4% and 81%, respectively. The incidence of local recurrence was 7.5%, which was similar to our results. However, these reports have only a small number of patients.

This study was limited due to its retrospective analysis, short follow-up period, and heterogenous patient's characteristics. The mastectomy group had more patients with T2 stage, multicentricity, EIC, ER/PR negativity. But among these different factors between treatment groups, only T-stage significantly affected survival outcome on multivariate analysis. Other significant prognostic factors such as LVI and histologic grade were not different from each treatment group. When we analyzed the survival outcome according to treatment modalities in same T-stage, OS was not significantly affected by treatment modalities (p=0.9075 in T1 patients and 0.6210 in T2 patients). But DFS of BCT group was significantly inferior to that of mastectomy group in T1 patients (p=0.0482). This difference may be due to the tendency ofmore local recurrence in BCT group. Difference in DFS of T2 patients was not significant between treatment modalities (p=0.6207). We also analyzed the survival difference between treatment modalities according to other characteristics. There was no survival difference in each characteristicexcept for ER-positive patients OS of mastectomy group was significantly inferior to BCT group (p=0.0220, Table 3).

In conclusion, our study showed a similar survival rate between BCT and mastectomy while tendency of more local recurrence in BCT group for early breast cancer. Although this study had some limitations, we suggest that BCT can be a feasible alternative to mastectomy in patients with pathologic T1-2N0 breast cancer.

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───── 국문초록 ─────

조기 유방암에서 유방보존치료와 유방절제술 치료성적 비교

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목 적: 조기 유방암에서 유방보존치료와 유방절제술의 치료 성적을 비교하고, 예후 인자를 알아보고자 하였다.

대상 및 방법: 1994년 9월부터 2002년 12월까지 본원에서 근치적 수술을 받은 병리학적 병기 T1~2N0 유방암 환자 1,200명을 후향적으로 분석하여 유방보존치료와 유방절제술을 사이의 차이를 비교해 보았다.

결 과: 분석에 포함된 1,174명의 환자 중 601명이(51.2%) 유방보존치료를 받았고 573명이(48.8%) 유방절제술을 받았다. 유방절제술을 받은 군에서 유의하게 종양의 크기가 컸고, 다발성(multicentricity), 에스트로겐 및 프로게스테론 수용체 음성 등의 인자가 더 많은 경향을 보였다. 유방보존치료 및 유방절제술을 받은 환자의 10년 생존율은 각각 91.96%와 91.01%였고(p=0.1274), 10년 무병생존율은 각각 80.48%와 84.95% (p=0.8795)로 유의한 차이를 보이지 않았다

결 론: 조기 유방암에서 유방보존치료 내지는 유방절제술을 받은 군 사이에 환자 특성의 차이는 일부 있었으나 생존율에서 유의한 차이를 보이지 않았다.

핵심용어: 유방암, 유방보존치료, 유방절제술