

## Breast Conserving Operation and Radiation Therapy in Early Breast Cancer : Interim Analysis

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**Purpose** : To evaluate interim results in terms of failure, cosmetic results and survival after breast conserving operation and radiation therapy in early breast cancer.

**Material and Methods** : From January 1992 through December 1997, seventy two patients with early stage 0, I and II breast cancer were treated with conservative surgery plus radiotherapy at Keimyung University Dongsan Medical Center. Age distribution was 25 to 77 years old with median age of 43. According to TNM stage, five patients had stage 0, thirty three were stage I, twenty five were IIa, and nine were IIb. Most patients underwent excision of all gross tumor and ipsilateral axillary dissection. Breast was irradiated through medial and lateral tangential fields of 6 MV photons to 50.4 Gy in 28 fractions over 5.5 weeks. We delivered a boost irradiation dose of 10 to 16 Gy in 1 to 2 weeks to excision site. Adjuvant chemotherapy was administered in forty one patients with CMF (cyclophosphamide, methotrexate, 5-fluorouracil) regimens of 6 cycles concurrently or before radiation. Cosmetic results were assessed by questionnaire to patients grading of excellent, good, fair, poor. Follow-up periods were 22 to 91 months with median 40 months.

**Results** : Five year disease free survival rate (5YDFS) was 95.8%. According to stage, 5YDFS was 100%, 96.9%, 96% and 88.9% in stage 0, I, IIa and IIb, respectively. Two patients had distant metastasis and one had local and distant failure. One patient with distant failure had bone and liver metastasis at 14 months after treatment and the other had lung and both supraclavicular metastasis at 21 months after treatment. Patient with local and distant failure had local recurrence on other quadrant in same breast and then salvaged with total mastectomy and chemotherapy but she died due to brain metastasis at 55 months. Complications were radiation pneumonitis in five patients (four patients of asymptomatic, one patients of symptomatic) and hand or arm edema (4 patients). Fifty nine patients answered our cosmetic result questionnaire and cosmetic results were good to excellent in fifty one patients (86%).

**Conclusion** : We considered that conservative surgery and radiation for the treatment of early stage invasive breast cancer was safe and had excellent survival and cosmetic results. We need to assess about prognostic factors with longer follow up and with large number of patients.

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**Key Words** : Breast cancer, Conservative surgery, Radiation therapy

### INTRODUCTION

Many prospective randomized trials have established the equivalence of conservative surgery and radiation with mastectomy for the treatment of early stage invasive breast cancer.<sup>1-3)</sup> In 1992, the Journal of the National Cancer Insti-

tute published a monograph stating that breast conservation treatment is an appropriate method of primary therapy for most women with stage I or II breast cancer and is preferable because it provides survival equivalent to that of total mastectomy and axillary dissection while preserving the breast.<sup>4)</sup> Our institution started team approach for breast conservation treatment since 1992. We will present our early experiences with failure, complications, cosmetic results, and survival.

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METHODS AND MATERIALS

From January 1992 through December 1997, seventy two patients with early stage 0, I, II breast cancer were treated with conservative surgery plus radiotherapy at Keimyung University Dongsan Medical Center. Patients characteristics were presented in Table 1. Age distribution was 25 to 77 years old with median age of 43. In 5 patients pathologic diagnosis was ductal carcinoma in situ. Sixty seven patients were invasive ductal carcinomas except one lobular carcinoma. There were five patients of Tis, one of T1a, nine of T1b (N+1), thirty nine of T1c (N+13) and eighteen of T2 (N+6). According to TNM stage, five patients were stage 0, thirty three were stage I, twenty five were IIa, and nine were IIb. In forty one patients (57%), the lesions were located in left breast. Most commonly involved site was upper outer quadrant (UOQ, 33 patients) followed by upper inner quadrant (UIQ, 11), lower outer quadrant (LOQ, 11), central area (10), lower inner quadrant (LIQ, 8). All patients underwent excision of all gross tumors in the procedure that attempted to achieve histologically negative surgical margins. Several patients were referred from local surgeons after biopsy and removal of the most of the tumor. In these patients, a re-excision was performed when feasible if surgical margins were involved or if they could not be assessed. One patient with positive surgical resection margin didn't receive re-excision. In addition, Level I-II axillary lymph node dissection for staging was done in all patients. In some cases, radiopaque hemoclips were placed at the margin of resection to assist the radiotherapist in treatment planning of boost fields to the tumor bed. Radiation therapy

was performed at 1 22 weeks (median 3.5 weeks) after surgery. All patients were treated for ipsilateral breast with radiation. Radiation therapy of ipsilateral breast was treated through medial and lateral tangential fields of 6 MV photons to 50.4 Gy in 28 fractions over 5.5 weeks. Medial margin was 1 cm over the midline of anterior chest. Upper margin of the portals was placed at the head of the clavicle to include the entire breast. Lateral margin was placed 2 cm beyond all palpable breast tissue, which is usually near the mid-axillary line. Inferior margin was drawn 1 cm below the inframammary fold. Compensating wedge filter was used in twenty four patients. In most of patients, reduced portals were used to deliver a boost dose to excision site after breast irradiation. Margins, in general, were 2 3 cm from the scar, depending on the size of the lesion and the adequacy of the surgical margins. A boost of 10 Gy in 5 days was delivered through reduced fields with electrons of appropriate energy (9 12 MeV). If the margins contained tumor or if the status of the margins were close or unknown, electron beam boost was used to deliver 16 Gy. In eight patients with axillary node involvement (positive node 4), ipsilateral supraclavicular node and level III axillary node was treated with 45 to 50 Gy for five weeks also. Adjuvant chemotherapy was administered in forty one patients with CMF (cyclophosphamide, methotrexate, 5-fluorouracil) regimens of 6 cycles concurrently or before radiation. Cosmetic results (grading of excellent, good, fair, poor) were assessed by questionnaire to patients. Follow-up periods were 22 to 91 months with median 40 months.

Table 1. Patients Characteristics

Age	25 77 yr (median 43)	Resection margin	-	71
T-stage	Tis	5	+	1
	T1a	1	Chemotherapy	- 31
	T1b	9 (N+1)	+	41
	T1c	39 (N+13)	Hormone Tx	- 21
	T2	18 (N+6)	+	51
N-stage	N0	52	ER	- 26
	N+ (1 3)	15	+	26
	N+ ( 4)	5	unknown	20
Stage	0	5	PR	- 26
	I	33	+	30
	IIa	25	unknown	20
	IIb	9		

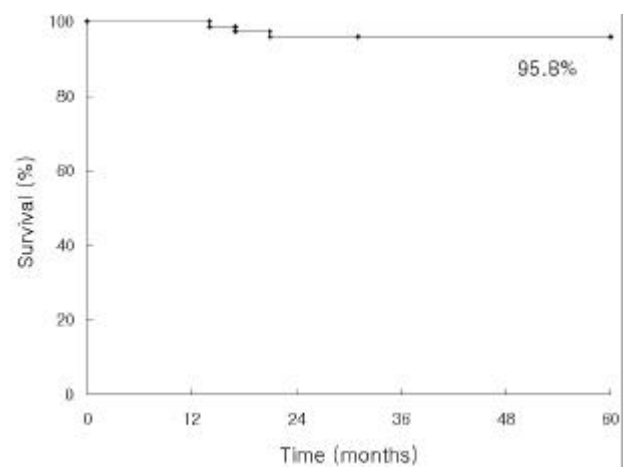


Fig. 1. Five year disease free survival curve.

RESULTS

Five year disease free survival rate (5YDFS) was 95.8% (Fig. 1). According to stage, 5YDFS was 100%, 96.9%, 96% and 88.9% in stage 0, I, IIa and IIb, respectively (Fig. 2). All patients in Tis, T1a, T1b, T2 were alive without disease and 5YDFS in T1c, N0, N1 was 91.4%, 98%, 90%. Two patients had distant metastasis alone and one had local and distant failure (Table 2). One patient with distant failure was medullary carcinoma (T1N0) and had bone and liver metastasis at 14 months after radiation treatment and she was treated with palliative radiotherapy combined with chemotherapy but she died at 31 months after first treatment. The other patient was T1N1 (positive in 3 out of 23). she refused chemotherapy and had lung and both supraclavicular lymph node metastasis at 21 months after treatment. She was treated with CMF (cyclophosphamide, methotrexate, 5-fluorouracil) regimens of 6 cycles and still alive with disease (29 months). One patient with regional and distant failure

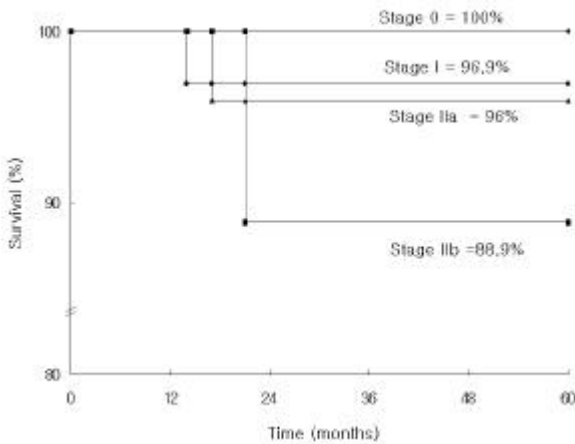


Fig. 2. Five year disease free survival curve by stage.

Table 2 Patterns of Failure

Patient	Failure (post RTx <sup>†</sup> time)	Treatment	Status( <sup>‡</sup> )
1	Bone, Liver (14Mo <sup>†</sup> )	CHT <sup>‡</sup>	DOD <sup>§</sup> (31Mo)
2	Lung both SCL (21Mo)	CHT	DOD (30Mo)
3	Breast (14Mo), Brain (44Mo)	MRM <sup>‡</sup> , CHT CHT	DOD (55Mo)

<sup>†</sup>radiotherapy, <sup>‡</sup> months, <sup>‡</sup> chemotherapy, <sup>§</sup> dead of disease, modified radical mastectomy

had local recurrence on the other quadrant in the same breast at 17 months after primary treatment. She had tumor mass with close resection margin ( 2 mm) and axillary metastasis (four out of twenty five). She was salvaged with total mastectomy and chemotherapy but she had brain metastasis at 44 months which was treated with palliative radiotherapy (30 Gy/10 fr/2 weeks) and combined chemotherapy (Navelbine, Epirubicin 3 cycles) but finally died at 55 months after first treatment. We did not assess about prognostic factors because of few failure and relatively short follow up time. Complications noted were radiation pneumonitis in five patients (asymptomatic in four patients, symptomatic in one patients) and hand or arm edema in 4 patients. The patient with symptomatic radiation pneumonitis was treated with supportive care. Grade II skin reaction (focal moist desquamation) were noted in five patients, two of these patients used compensating wedge filter. Most of skin reactions were noted in anterior axillary folds (Table 3). Fifty nine patients answered our cosmetic questionnaires and cosmetic results were excellent in eighteen patients (30.5%), good in thirty three (55.9%), fair in eight patients (Table 4).

DISCUSSION

Conservative surgery plus radiation therapy is generally accepted as an alternative to mastectomy for many patients with operable breast cancer on the basis of data from several prospective randomized trials.<sup>1 3, 5)</sup> Before the mid 1970s, however, patients were seldom considered for conservation surgery plus radiation unless they refused mastectomy or were considered medically unable to undergo operation under general anesthesia. In our institute, we have performed conservative treatment in early breast cancer since 1992. Many long term results of breast conserving treatment in

Table 3. Complications

Asymptomatic radiation pneumonitis	4 ( 5%)
Symptomatic radiation pneumonitis	1 (1.3%)
Arm edema	4 ( 5%)
Grade II skin reaction	5 (6.9%)

Table 4. Cosmetic Results

Excellent	18 (31%)
Good	33 (56%)
Fair	8 (13%)

early stage breast cancer were reported. Our follow-up time was relatively short. So, we reviewed patient eligibility, radiation therapy, complications and cosmesis.

To define the patients eligibility, we considered several factors such as tumor size, multicentricity, location, patient's age, family history, histology, positive axillary node, surgical resection margin. First, tumor size was considered. Fowble B et al<sup>6)</sup> reported that they have not observed an increased risk of breast recurrence with increasing tumor size for tumors up to 4 to 5 cm in patients in whom excisional biopsy has been performed. We included patients with tumor less than 3 to 4 cm on the basis of data in which tumor size didn't affect local recurrence or survival in breast conservation treatment in most large studies<sup>7, 8)</sup> and the fact that general oriental women's breasts were smaller than western women's. We did not perform conservative operation in multicentric breast cancer. Several series<sup>9, 10)</sup> have reported an increased risk of breast recurrence in patients with clinical evidence of more than one malignancy in a single breast (gross multicentric or multifocal disease). Subareolar tumors are also candidates for conservative surgery and radiation because no significant difference in tumor recurrence according to tumor location provided that an adequate excision is achieved.<sup>11-16)</sup> Young age (<35 or 40 years) has been associated with an increased risk of breast recurrence in a number of series.<sup>8, 17)</sup> Young age was associated with a statistically significant increase in regional node failure and distant metastasis and a statistically significant decrease in cause-specific survival. Young age by itself may be an indication for adjuvant chemotherapy and the addition of chemotherapy may decrease the risk of a breast recurrence in women 35 years or younger treated with conservative surgery and radiation.<sup>17)</sup> Young age itself is not a contra-indication to breast conserving surgery and radiation. In women 65 year or older, their cancer did not have more indolent and the patterns of survival, local control, and distant metastasis are similar to women 50 to 64 years of age. Breast conservation therapy should include radiation until the results of ongoing studies are available.<sup>18)</sup> With appropriate treatment, the probability of death from breast cancer in a women older than 65 years is almost equal to that from intercurrent disease. In women with 65 year or older, breast conservation therapy would be also performed. It has been suggested that women with hereditary breast cancer should undergo mastectomy rather than breast-conservation therapy. By Peterson,<sup>19)</sup> a positive family history was associated with a statistically significant

decreased incidence of positive axillary node. At 5 and 10 years there were no statistically significant difference in breast recurrence rate, overall, or relapse-free survival between positive and negative family history. At the present time, a positive family history should not be a contraindication to conservative surgery and radiation. However, more information is needed in patients with hereditary breast disease. Several studies<sup>6, 20-22)</sup> reported no increased risk of breast recurrence in patients with positive axillary nodes. Though the correlation between the pathological status and the subsequent risk of ipsilateral breast recurrence remains controversial, surgical resection of primary tumor was performed with the goal of achieving microscopic negative margins of resection ( 2 mm). In an earlier analysis,<sup>23)</sup> patients with positive or close margins did not have an increased risk of breast recurrence at 5 years when compared with patients with negative margins. Patients with positive or close resection margins received a somewhat higher dose of radiation to the primary site (60 versus 65 versus 64 Gy). Patient selection and the technical delivery of radiation treatment including a boost may have been important contributing factors to the good outcome in focally positive or close microscopic pathologic margin. However, the ten year actuarial rate of breast recurrence were 8 percents for negative margins, 18 percents for close margins, and 17 percents for positive margins. Therefore we agree with recommendation of re-excision for patients with positive or unknown resection margins or in cases which close margins exist in more than one limited area and in whom post-biopsy mammographic presentation of malignant appearing residual calcification. In this study, one patient had breast recurrence. She had tumor mass with close resection margin ( 2 mm) and received electron beam boost of 16 Gy.

In radiation therapy aspect, radiation clearly plays an important role in the non-mastectomy therapy of breast. The reduction of local breast cancer failures for patients with DCIS treated with radiation after excision versus those treated with excision alone has been detailed. Also the need for radiotherapy after local excision for patients with invasive breast cancer has been subject of several studies and a statistically significant reduction in local breast failure was seen.<sup>7, 28, 36)</sup> Breast radiation therapy has consisted of 46 to 50 Gy to the breast with tangential fields, followed by a boost to the primary site of an additional 10 to 20 Gy. If the margins contained tumor or the status of the margins

were close or unknown, boost radiation dose was increased. The boost volume was determined by computed tomograph or stereoshift radiograph in surgical bed with or without surgical clips. In comparing between patients with and without clips, ten year risk of true or marginal recurrence rate was 5 percents for patients without clips and 11 percents for patients with clips.<sup>24)</sup> This difference appeared to be related to surgical technique. More precise definition of this region will not compensate for an inadequate surgical excision. We did not irradiate axillary area. In NSABP B-06 and Milan trial, axillary area was not irradiated after axillary dissection even though in axillary node positive patients but regional recurrence rate was from 2.3% to 4.5%.<sup>7, 25)</sup> We irradiated supraclavicular lymph node in cases of four or more positive axillary nodes or one to three positive nodes in women 35 years or younger. There have been reported that increased risk of supraclavicular node failure in case of four or more positive axillary lymph nodes or of one to three positive nodes in women 35 years or younger were noted.<sup>8, 26)</sup> We did not perform irradiation of the internal mammary nodes in axillary-negative or -positive patients with stages I and II breast cancer. Since the incidence of clinical internal mammary node failure is extremely low and this pattern of failure is not significantly diminished by the addition of radiation therapy.<sup>26)</sup>

Our results for 5YDFS were 95.8%, 96.9%, 96% and 88.9% in all, stage I, IIa, and IIb, respectively. All patients in Tis, T1a, T1b, and T2 were alive without disease and 5YDFS in node negative patients (N0) and node positive patients (N1) were 98% and 90% respectively. Veronesi and associates<sup>27)</sup> reported on patients with tumors less than 2 cm in diameter and without palpable axillary nodes who were randomly assigned to treatment with breast conserving treatment (quadrantectomy plus irradiation, 50 Gy in five weeks, 10 Gy boost) or radical mastectomy. Actuarial and disease free survival rates were 83% and 77% in breast conserving treatment. In another trial, four year overall survival rates were about 76%.<sup>28)</sup> The U.S. National Cancer Institute (NCI) has updated results of a randomized study in 247 patients with T1-2N0M0 disease treated with modified radical mastectomy or breast conservation therapy (45 to 50 Gy to breast plus 15 20 Gy boost). After 10 year follow-up, overall survival and disease free survival were 77% and 72% in breast conserving therapy and 75% and 69% in mastectomy.<sup>29)</sup>

Ten years after conservative surgery and radiation for stage I and II breast cancer, 10 to 15 percent of patients will experience recurrence in the treated breast.<sup>6)</sup> Other study reported 5-year local failure rates were 28% with lumpectomy and irradiation and 9% with quadrantectomy an irradiation.<sup>28)</sup> NCI reported locoregional recurrence rate were 10% after mastectomy and 5% after breast conserving therapy.<sup>29)</sup> In Our result was too early to assess recurrent rate but two patients had distant metastasis and one patient had local and distant failure.

Complications after breast conserving therapy were breast or arm edema, breast fibrosis, radiation pneumonitis, and rib fracture.<sup>30)</sup> The incidence of breast and arm edema after conservation therapy varies; it is related to performance and technique of axillary dissection.<sup>31)</sup> Symptomatic pneumonitis was infrequent and the risk of developing radiation pneumonitis may related to the volume of the lung.<sup>32)</sup> Lingos and colleagues<sup>33)</sup> reported 1% of patients developed pneumonitis in review of 1624 patients with breast conserving therapy. Incidence of radiation pneumonitis was correlated with combining chemotherapy and the addition of supraclavicular fields. Our symptomatic pneumonitis patient was irradiated ipsilateral supraclavicular field.

Cosmetic results were reported as good or excellent in more than 80 percent in MD Anderson report but good in 50 percent in european report.<sup>34)</sup> Other series reported excellent cosmetic results of 86% and good to excellent of 93%. Their results were usually physician assessment cosmetic score.<sup>6, 35)</sup> Our cosmetic result was patient's opinion. Eighty six percent of the patients had a good to excellent cosmetic result.

In conclusion, we consider that conservative surgery and radiation for the treatment of early stage invasive breast cancer is safe and has excellent survival and cosmetic results. We need to assess the prognostic factors with longer follow up and with larger numbers of patients.

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