A Retrospective Study Comparing Hypofractionated Radiotherapy and Conventional Radiotherapy in Postmastectomy Breast Cancer

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Background: *The conventional radiotherapy (CRT) in postmastectomy breast cancer is 1.8-2.0 Gy daily for 25 fractions, while hypofractionated radiotherapy (HFRT) delivered dose in fewer fractions with larger radiation intensity. The present study compares the efficacy of HFRT and CRT.*
Material and Method: *From 2004 to 2006, 215 patients were retrospectively reviewed. Sixty seven patients received CRT and 148 patients received HFRT (2.65 Gy in 16-18 fractions). Five-year locoregional control (LRC), disease free survival (DFS), overall survival (OS) and toxicities were analyzed.*
Results: *Median follow-up was 39 months. Five-year LRC was 86.6% in CRT and 85.8% in HFRT (p = 0.852). Five-year DFS was 62.7% and 69.6% (p = 0.136) in CRT and HFRT, respectively. Patients who received HFRT had significant increase in 5-year OS (62.7% and 73.0% (p = 0.048). No difference of toxicities including changes in chest wall appearance, skin fibrosis, brachial plexopathy, arm edema, pulmonary fibrosis, rib fractures and cardiovascular events was found between two groups.*
Conclusion: *HFRT is as effective as CRT in postmastectomy breast cancer.*

Keywords*: Breast cancer, Hypofractionation, Radiotherapy, Postmastectomy*

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Breast cancer is the most common female malignancy in Thailand[1]. In the past decade, management of breast cancer dramatically improved. Radiotherapy has been chosen as the part of treatment. Several randomized studies confirm that it could effectively reduce locoregional recurrence and overall mortality rate[2-4].

According to linear quadratic theory[5-7], a radiotherapy schedule for breast cancer with 1.8-2.0 Gy per fraction, five times per week to a total dose of 45-50 Gy, is commonly used to maximize benefit in killing tumor cells and minimize normal tissue damage.

Recently, the alpha/beta ratio of breast cancer cells have proved to be low (approximately 4.6 Gy)[8,9] and randomized studies reveal that hypofractionated radiotherapy did not compromise treatment outcomes when compare with conventional radiotherapy[10-13]. However, those studies enrolled patients with early stages of breast cancer and most underwent breast conserving surgery. The present study reviews hypofractionation radiotherapy comparing with conventional radiotherapy in locally advanced postmastectomy breast cancer patients.

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Material and Method

Patient eligibility

From 2004 to 2006, hypofractionated radiotherapy was used at Therapeutic Radiology and Oncology Division, Chiang Mai University, for treatment of breast cancer due to a long waiting list.

The authors retrospectively analyzed the data of 831 breast cancer patients who were treated at the

center. Patients included in the present study were required to have histologically proven invasive ductal carcinoma, and received adjuvant postmastectomy radiotherapy. Patients were also required to have at least 2 years of follow-up.

Patients were ineligible if there was evidence of positive surgical margin from mastectomy specimen, history of the underlying diseases: systemic lupus erythematosus, scleroderma, and previous breast or chest irradiation. This study was approved by the institutional review board and ethical committee.

Radiation techniques and schedules

Patients were immobilized by breast board. All of them were simulated with 2D technique. Target volumes include chest wall and ipsilateral supraclavicular node with medial and lateral tangential chest wall fields and anteroposterior ipsilateral supraclavicular field, respectively. Axillary boost was allowed if there were clinical N2 disease, inadequate node excision (less than 10 nodes), or perinodal invasion. Chest wall and supraclavicular fields were treated with cobolt-60. A five-millimeter gap was used between field junctions. Planning was approved with maximum lung distance less than 3 centimeters.

The schedule of postmastectomy radiotherapy was divided into two groups during that period. Sixty seven patients received 2.0 Gy daily fractions for 25 fractions to a total dose of 50 Gy, designated as conventional group. One hundred and forty eight patients received 2.65 Gy daily or every other day fraction for 16-18 fractions to a total dose of 42.4- 47.7 Gy, designated as hypofractionated group (Fig. 1).

Assessment of treatment outcomes and toxicities

The primary endpoint was locoregional recurrence, defined as time from the end of radiotherapy treatment to in-field recurrence (mastectomy scar, chest wall, ipsilateral axillary node, ipsilateral internal mammary node and ipsilateral supraclavicular nodes). Secondary endpoints were overall survival, disease free survival, and late radiation toxicities. Overall survival was defined as time from the end of radiotherapy treatment to any death. Disease free survival was defined as time from the end of radiotherapy treatment to any breast cancer related event (locoregional recurrence, distant metastasis, breast cancer mortality) or death.

Each patient underwent a full history review and complete physical examination when visited during the years encompassing this study. Skin fibrosis, brachial plexopathy and lymphedema were assessed using common terminology criteria for adverse event (CTCAE) version 3.0. Their mastectomy scar and chest wall were photographed at the same period. The photograph was scored as 1, 2 and 3 points for minimal, moderate and marked change in chest wall appearance, respectively (see appendix). The change was given score by two clinicians who were blinded from treatment groups and the score was averaged in each patient. Chest radiography was also taken. The radiographic results of pulmonary fibrosis and rib fracture were verified by chest radiologist who was also blinded from treatment groups. Cardiovascular events were reviewed from their medical record.

Statistical analysis

Actuarial 5-year rates of locoregional recurrence, disease free survival and overall survival were computed using Kaplan-Meier method and compared between the conventional and hypo-fractionated groups by the log-rank test.

The Photographic score were described as median with interquartile range (IQR) and were compared using the Mann-Whitney U test. The remaining variables were described as percentage and

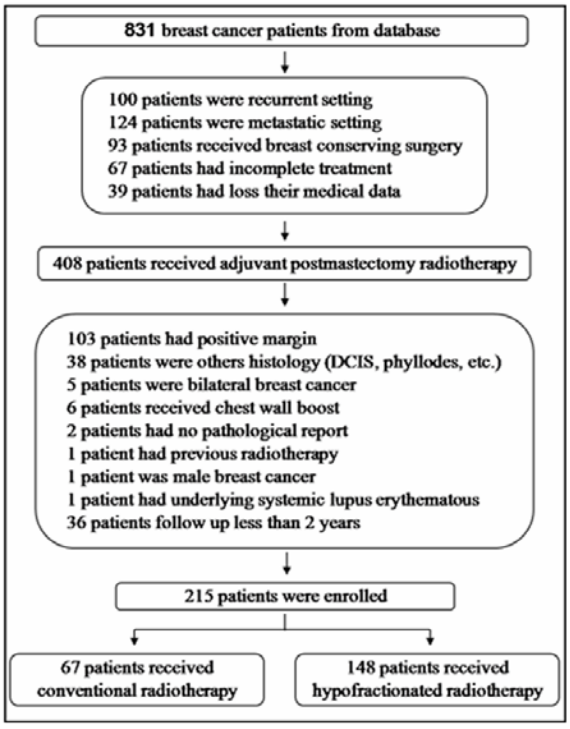

Fig. 1 Trial profile

were compared using the Chi-square or Fisher's exact test. The p-value reports are two-tailed and an alpha level of 0.05 was used to assess statistical significance. All analyses were conducted using SPSS software version 17.0.

Results

Patient and treatment characteristics

Patient and treatment characteristics of conventional and hypofractionated group are summarized in Table 1. Distribution of age, T stage, pathological nodal status, number of excised nodes, estrogen receptor status and CerbB2 receptor status were similar in two groups. There was no different in treatment characteristics including hormonal therapy regimen, sequence of chemotherapy and axillary irradiation. In the hypofractionated group, more proportion of patients had unknown margin status and received CMF chemotherapy regimens.

Treatment outcomes

The median of follow-up time was 39 months (IQR 29-50 months). At the time of analysis, 137 patients (63.7%) were alive without disease recurrence, 4 patients (1.9%) were alive with locoregional recurrence, 6 patients (2.8%) were alive with distant metastatic disease, 3 patients (1.4%) were alive with both locoregional recurrence and distant metastatic disease and 65 patients (30.2%) had died. The distribution of patient status in each group is presented in Table 2.

For endpoint analysis, 5 year locoregional control rate was 86.6% in conventional group and 85.8% in hypofractionated group. The log-rank test showed no statistical difference (p = 0.852). Five-year disease free survival rate was similar in two groups, that was 62.7% in conventional group and 69.6% in hypofractionated group (p = 0.136). Five-year overall survival rate was significantly higher in the patients of hypofractionated group (62.7% versus 73.0% p = 0.048). The Kaplan-Meier survival plots are shown in Fig. 2.

Toxicity-treatment related complication

One hundred and eight patients (50.2%) underwent complete physical examination including toxicity assessment and photography of their chest wall. One hundred nineteen patients (55.3%) underwent chest radiography. Nearly half of the patients had incomplete protocol's procedures because of death, locoregional recurrence or loss to follow-up.

Thirty one patients (46.3%) in conventional group and 77 patients (52.0%) in hypofractionated group had their chest wall photographed. The median score of changes in chest wall appearance was 1.5 and 1.0 in conventional and hypofractionated group, respectively. No statistical difference was found between the two groups (p = 0.242). The distribution of scores is presented in Table 3.

Table 4 presents comparison of radiation toxicities between conventional and hypofractionated group. The most common toxicities were skin fibrosis (30.3% and 47.4%, respectively) and pulmonary fibrosis (23.3% and 32.5%, respectively). Incidence of other toxicities including brachial plexopathy, arm edema and rib fracture was low. None of patients had severe late toxicities (grade 3-5).

Cardiovascular events were reviewed in 112 patients (52.1%), including 33 patients from conventional group and 79 patients from hypofractionated group. The incidence of cardiovascular events was comparable between two groups, with 1 patient (3.0%) in conventional group and 3 patients (3.8%) in hypofractionated group (p = 0.66).

Discussion

Most eligible breast cancer patients in the present study had locally advanced stage of disease and underwent postmastectomy surgery. The results indicate that the outcomes of hypofractionated radiotherapy are comparable with those of conventional radiotherapy including locoregional control, disease free survival and cosmetic outcome. In Canadian[10] and UK START trial[12,13] the criteria for enrollment are difference from the present study. Most patients have early stage of disease and underwent breast conserving surgery. These trials showed no difference in results between hypofractionated radiotherapy and conventional radiotherapy, similar to the present study. The estimate of alpha/beta value for breast cancer is approximately 4.6 Gy. Hypofractionated regimen seemed to be as effective as conventional regimen regardless of the stage of disease or breast surgery procedure. This may result from the same radiosensitivity of breast cancer cells as late responding tissues. Surprisingly, the 5-year overall survival in present study is significant higher in hypofractionated regimen, and similar to the results in START B trial; although the improvement of overall survival is unexplainable. Most of patient characteristics and treatment factors between two groups are similar except for status margin and chemotherapy regimen. Possibly, unknown margin status in the hypofractionated group had much higher

Table 1. Patient and treatment characteristics

Characteristics	Conventional group n = 67	Hypofractionated group n = 148	p-value
Age (years)			0.960[+]
Median (IQR)	48 (44-55)	50 (44-56)	
< 40	6 (8.9)	13 (8.8)	
≥ 40	61 (91.1)	135 (91.2)	
T stage			0.055[++]
T1-2	40 (59.7)	67 (45.3)	
T3-4	27 (40.3)	80 (54.0)	
Unknown	0 (0)	1 (0.7)	
Margin status			0.010*
Negative	54 (80.6)	137 (92.6)	
Unknown	13 (19.4)	11 (7.4)	
Pathologic nodal status			0.198
Negative node	13 (19.4)	30 (20.3)	
1-3 nodes	27 (40.3)	42 (28.4)	
≥ 4 nodes	27 (40.3)	76 (51.3)	
No. of excise nodes			0.128[+++]
Median (IQR)	12 (7-16)	14 (9-19)	
< 10 nodes	24 (35.8)	38 (25.7)	
≥ 10 nodes	43 (64.2)	110 (74.3)	
Estrogen receptor status			0.460
Negative	31 (46.3)	60 (40.6)	
Positive	31 (46.3)	69 (46.6)	
Unknown	5 (7.4)	19 (12.8)	
CerbB2 status			0.104
Negative	39 (58.2)	67 (45.3)	
Positive	16 (23.9)	35 (23.6)	
Unknown	12 (17.9)	46 (31.1)	
Hormonal therapy regimen			0.181[++++]
None	29 (43.3)	50 (33.8)	
Tamoxifen	33 (49.3)	87 (58.8)	
Aromatase inhibitor (AI)	1 (1.5)	5 (3.4)	
Switching Tamoxifen/AI	4 (5.9)	6 (4.0)	
Chemotherapy regimen			0.016*[+++++]
None	2 (3.0)	2 (1.3)	
CMF	11 (16.4)	43 (29.1)	
Antracycline based	42 (62.7)	93 (62.8)	
Taxane based	11 (16.4)	9 (6.1)	
Unknown	1 (1.5)	1 (0.7)	
Chemotherapy sequence			0.621
Neoadjuvant	44 (65.7)	92 (62.2)	
Adjuvant	23 (34.3)	56 (37.8)	
Axillary irradiation			0.798
Yes	22 (32.8)	46 (31.1)	
No	45 (67.2)	102 (68.9)	

Values are represented as n (%)

* The p-value less than 0.05 is statistical significance., IQR = Interquartile range , CMF = Cyclophosphamide, Methotrexate and 5-Fluorouracil

[+] The p-value is for the comparison between patients less than 40 years of age and those 40 years of age or older

[++] The p-value is for the comparison between T1-2 and T3-4

[+++] The p-value is for the comparison between excise nodes less than 10 nodes and those 10 nodes or more

[++++] The p-value is for the comparison between no hormonal therapy and received hormonal therapy (Tamoxifen, AI and both)

[+++++] The p-value is for the comparison between CMF, Antracycline and Taxane regimen

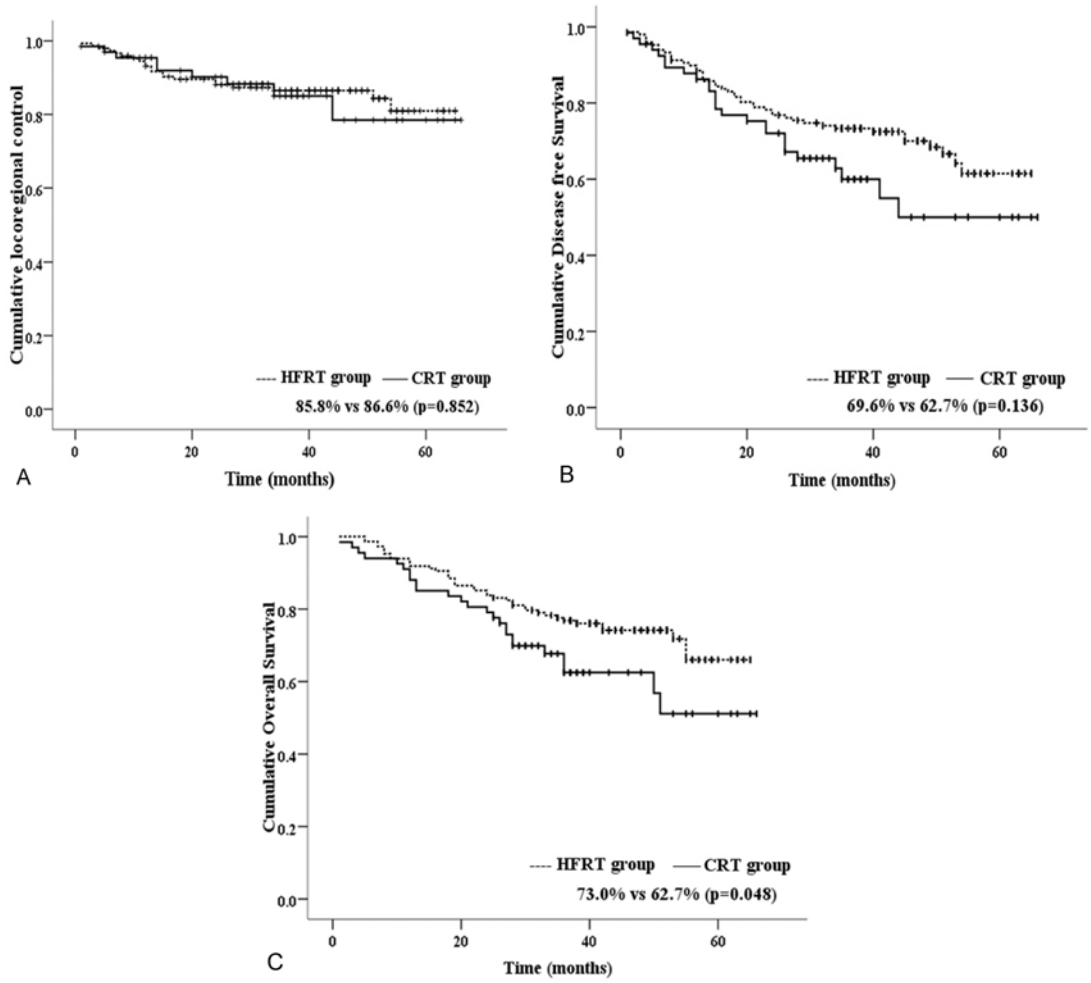

Fig. 2 Kaplan-Meier estimates of locoregional control rate (A), disease free survival rate (B) and overall survival rate (C) between conventional group and hypofractionated group; HFRT Hypofractionated radiotherapy, CRT Conventional radiotherapy

Table 2. Patient status at the time of analysis

Patient status	Conventional group (n = 67)	Hypofractionated group (n = 148)	Total (n = 215)
Alive without disease recurrence	37 (55.2)	100 (67.6)	137 (63.7)
Alive with locoregional recurrence	1 (1.5)	3 (2.0)	4 (1.9)
Alive with distant metastatic disease	3 (4.5)	3 (2.0)	6 (2.8)
Alive with both locoregional recurrence and distant metastatic disease	1 (1.5)	2 (1.4)	3 (1.4)
Dead	25 (37.3)	40 (27.0)	65 (30.2)

Values are represent as n (%)

proportion of the true negative margin than conventional arm but these will be reflected to local control first. Nonetheless, higher proportion of using taxane-based chemotherapy in conventional group give

more benefit than using antracycline-based or CMF chemotherapy in locally advanced breast cancer.

A median follow-up of 39 months is too short to allow assessment of toxicity. The cardiovascular events may occur after 10 years of follow-up and the incidence are greater over time[14,15]. Higher incidence of late side effects was concerned using hypofractionated radiotherapy to supraclavicular area; those were brachial plexopathy, skin fibrosis, pulmonary fibrosis, arm edema and rib fracture. Powell et al[16] and Johanssson, et al[17] reported that the incidence rate of these side effects is higher and greater over time when compared with conventional radiotherapy. These studies used a large radiation fraction size at almost greater than 3 Gy per fraction, and the radiation technique may be out of date. Furthermore, the alpha/beta ratio value for brachial plexus injury[18] arm edema[19] and rib fracture[20] are the late responding tissues. When calculated to biological effective dose (BED), these tissues have higher BED than conventional fractionation. However, Galecki et al[21] reported that radiation induced brachial plexopathy was smaller than 1% if using regimens with doses per fraction between 2.2 and 2.5 Gy with the total doses between 34 and 40 Gy. In the present study, the incidence rate of brachial plexopathy, fibrosis, arm edema and rib fracture were low and comparable with that of conventional regimen because the radiation fraction size was less than 3 Gy and the total dose was also reduced.

Table 3. The Score of change in chest wall appearance according to the fractionation schedule

Score	Conventional group (n = 31)	Hypofractionated group (n = 77)
1.0	14 (45.2)	47 (61.0)
1.5	6 (19.3)	9 (11.7)
2.0	11 (35.5)	17 (22.1)
2.5	0 (0)	2 (2.6)
3.0	0 (0)	2 (2.6)
Median (IQR)	1.5 (1.0-2.0)	1.0 (1.0-2.0)

Conclusion

In summary, this is the retrospective study based on a hospital-based data registry to demonstrate similar efficacy and toxicity between hypofractionated radiotherapy and conventional radiotherapy in postmastectomy breast cancer. The significantly higher 5-year overall survival in hypofractionated group in our results could not be explained. Therefore, the conclusion must always be done with a caution and future prospective studies with longer follow-up time are clearly warranted to validate the finding.

Potential conflicts of interest

None.

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Table 4. Adverse effects according to the fractionation schedule

Adverse effect	Conventional group (n)					Hypofractionated group (n)				
	Grade 0	Grade 1	Grade 2	Grade 3-5	Total (n)	Grade 0	Grade 1	Grade 2	Grade 3-5	Total (n)
Skin fibrosis	23	7	3	0	33	41	29	8	0	78
Brachial plexopathy	26	5	1	0	32	64	7	6	0	77
Arm edema	28	1	1	0	30	66	9	3	0	78
Pulmonary fibrosis	23	7	0	0	30	60	29	0	0	89
Rib fracture	30	0	0	0	30	88	1	0	0	89

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Appendix. Three point scale for photographic assessment of chest wall appearance

a) Minimal change (1 point scale)

b) Moderate change (2 point scale)

c) Marked change (3 point scale)

การศึกษาวิเคราะห์แบบย้อนหลังเปรียบเทียบการฉายรังสีแบบสัดส่วนน้อยกว่ามาตรฐานกับการฉายรังสีแบบมาตรฐานในผู้ป่วยมะเร็งเต้านมที่ได้รับการผ่าตัดเต้านมออกทั้งเต้า

อรรถพล พินิจพัชรเลิศ, อิ่มใจ ชิตาพนารักษ์, จันทิมา เอื้อตรงจิตต์, เอกสิทธิ์ ธราวิจิตกุล, วิมล สุขถมยา, วิชาญ หล่อวิทยา

ภูมิหลัง*: การฉายรังสีแบบมาตรฐานในผู้ป่วยมะเร็งเต้านมที่ได้รับการผ่าตัดเต้านมออกทั้งเต้าคือ การใช้รังสีปริมาณ 1.8-2.0 เกรย์ต่อครั้ง, 5 ครั้งต่อสัปดาห์, รวมทั้งหมด 25 ครั้ง การศึกษานี้เป็นการศึกษาประสิทธิภาพการฉายรังสีแบบสัดส่วนน้อยกว่ามาตรฐานเปรียบเทียบกับการฉายรังสีแบบมาตรฐาน*

วัสดุและวิธีการ*: ระหว่างปี พ.ศ. 2547 ถึง พ.ศ. 2549 ผู้ป่วยจำนวน 215 คนได้ถูกนำข้อมูลมาวิเคราะห์ย้อนหลัง ผู้ป่วยจำนวน 67 คน ได้รับการฉายรังสีแบบมาตรฐาน และผู้ป่วยอีก 148 คน ได้รับการฉายรังสีแบบสัดส่วนน้อยกว่ามาตรฐาน (2.65 เกรย์ต่อครั้ง รวม 16-18 ครั้ง) อัตราการควบคุมโรคเฉพาะที่ที่ 5 ปี, อัตราการมีชีวิตรอดโดยปราศจากโรคที่ 5 ปี, อัตราการรอดชีวิตทั้งหมดที่ 5 ปี และผลข้างเคียงถูกนำมาวิเคราะห์*

ผลการศึกษา*: ระยะเวลาติดตามอาการผู้ป่วยมีค่ามัธยฐาน 39 เดือน อัตราการควบคุมโรคเฉพาะที่ที่ 5 ปีเท่ากับ 86.6% ในกลุ่มที่ได้รับการฉายรังสีแบบมาตรฐานและ 85.8% ในกลุ่มที่ได้รับการฉายรังสีแบบสัดส่วนน้อยกว่ามาตรฐาน (p = 0.05) อัตราการมีชีวิตรอดโดยปราศจากโรคที่ 5 ปี เท่ากับ 62.7% และ 69.7% ตามลำดับ (p = 0.14), ผู้ป่วยในกลุ่ม ที่ฉายรังสีแบบสัดส่วนน้อยกว่ามาตรฐานมีอัตราการรอดชีวิตทั้งหมดที่ 5 ปีดีกว่า (62.7% และ 73.0%, p = 0.05) ผลข้างเคียงจากการฉายรังสี ซึ่งประกอบด้วยการเปลี่ยนแปลงของผนังทรวงอก, การเกิดพังผืดที่ผิวหนัง, ความผิดปกติ ของเส้นประสาทแขน, แขนบวม, พังผืดที่ปอด, กระดูกซี่โครงหัก, ความผิดปกติ ของหัวใจและหลอดเลือดพบว่า ไม่มีความแตกต่างกันในทั้งสองกลุ่ม*

สรุป*: การฉายรังสีแบบสัดส่วนน้อยกว่ามาตรฐานมีประสิทธิภาพเทียบเท่ากับการฉายรังสีแบบมาตรฐาน ในผู้ป่วยมะเร็งเต้านมที่ได้รับการผ่าตัดเต้านมออกทั้งเต้า*