Late Effects and Cosmetic Results of Simultaneous Integrated Boost Versus Sequential Boost after Conventional Irradiation in Breast-Conserving Therapy; Out Come of 7 Months Follow-Up

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Objective: *To compare simultaneous integrated boost and sequential boost after conventional irradiation in breast-conserving therapy in aspect of late effects and cosmetic results.*
Material and Method: *Between August 2006 and June 2007, 60 breasts were treated in this prospective non-randomized study, designed to compare simultaneous integrated boost (additional 10Gy/25F) and sequential boost (15Gy/5F) to the tumor bed in terms of late effects and cosmetic results at 7-month and 3-year follow-up. Pearson Chi-square test was used, with an α-value of 0.05.*
Results: *Hyper/hypopigmentation and induration/fibrosis were commonly seen at 7-months follow-up ($p = 0.84$ and 0.83, respectively). The cosmetic results were good or excellent.*
Conclusion: *Although the present study included a small number of patients and short follow-up time, the preliminary results were comparable between the study groups.*

Keywords: *Breast neoplasms, Radiation dosage, Radiotherapy dosage, Radiation, Radiation injuries*

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The treatment of early-stage breast cancer (stage I-II) with breast-conserving surgery plus post-operative radiation is equivalent to mastectomy, in terms of local control and survival[1-3]. Randomized control trial emphasized the additional radiation boost to the tumor bed to achieve better local control compared to no boost[4]. However, long radiation treatment time and living far from treatment centers result in lesser use of breast-conserving therapy.

A schedule that is commonly used today in clinical practice, is 50 Gy in 25 fractions to the whole breast, administered daily, Monday to Friday, over 35 days, with or without additional boost to the tumor bed[2-4]. There are many possibilities to reduce radiation treatment time and save health-care resources by altering radiation treatment schedules, which have no significant differences in disease-free survival and overall survival. First is hypofractionated irradiation with total doses of 40 to 55 Gy in 16 to 22 fractions[5-8]. Another is to treat only the tumor bed for low-risk patients in a week by using brachytherapy[9]. The last is to boost the tumor bed simultaneously with whole breast radiation.

Simultaneous integrated boost using intensity-modulated radiotherapy (SIB-IMRT) for the breast cancer was reported by Smitt[10]. Guerrero proposed the radiobiological and treatment planning study of SIB-IMRT, using biologically effective dose (BED) and equivalent uniform dose (EUD) to compare among treatment schedules[11]. SIB-IMRT improved dose con-formality, reduced total treatment times, and reduced the unwanted excessive dose to normal structures[10-13]. However, BED and EUD are

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physico-biological properties and there is no clinical trial comparing SIB and sequential boost.

An acceptable rate of long-term radiation sequele with satisfactory cosmesis has become an important issue of successful therapy. Late effects depend on fractionation, interfraction interval, total dose, irradiated volume, and individual patient factors.

At King Chulalongkorn Memorial Hospital, radiation treatment schedule comprises of conventional 6-MV irradiation to the whole breast, 50 Gy in 25 fractions, and sequential electron boost to the tumor bed, 15 Gy in 5 fractions, over 42 days. Because of the large number of waiting lists for radiation treatment, this present study was designed to reduce radiation treatment time by using 50-Gy conventional irradiation to the whole breast with 10-Gy SIB using electron beam to the tumor bed, in 25 fractions, over 35 days. The aim of the present study was to compare simultaneous integrated boost and sequential boost after conventional irradiation in breast-conserving therapy in aspect of late effects and cosmetic results.

Material and Method

Patients

Between August 2006 and June 2007, 60 patients with stage I to II breast cancer, except pT3N0M0 by AJCC staging 2002, treated with breast-conserving surgery with axillary lymph node dissection in King Chulalongkorn Memorial Hospital were entered in this prospective non-randomized control trial comparing late effects and cosmetic results of simultaneous integrated boost versus sequential boost after conventional irradiation. Exclusion criteria were 1) presence of bilateral breast cancer; 2) presence of multicentric disease; 3) patient currently pregnant or lactating; 4) presence of collagen vascular disease; 5) large tumor relative to breast size.

All patients received the study information and gave informed consent before assignment to treatment. The study protocol was approved by the Research Ethics Committee of King Chulalongkorn Memorial Hospital.

Treatment regimens

Radiation therapy was given after completion of chemotherapy. Hormonal therapy or Trastuzumab were allowed to be given concomitantly with radiation therapy.

According to physicians' preferences, patients were assigned to one of two regimens; 1) 50 Gy in 25 fractions to the whole breast with sequential electron boost 15 Gy in 5 fractions to the tumor bed, over 42 days; 2) 50 Gy in 25 fractions to the whole breast with daily additional 0.4 Gy SIB using electron beam to the tumor bed, over 35 days. The appendix shows the radiation biologic effective dose calculations comparing both regimens.

Linear accelerator was used to deliver 6-MV opposing tangential photon beams with 100-cm source-axis-distance, prescribing dose at isocenter. The medial border was located at the midsternal line, the lateral border at the midaxillary line, the superior border at head of the clavicle, and the inferior border at 2 cm below the inframammary fold. Wedges were used to achieve dose homogeneity in the treated breast. Nine to twelve MeV apposing electron beam was prescribed to cover the tumor bed plus 2 cm margin, field size 5 x 5 to 6 x 6 cm^2. In case of positive lymph node, the ipsilateral supraclavicular area was also irradiated. The medial border was located at 1 cm lateral to the midsternal line, the lateral border at the coracoid process, the superior border at the thyroid notch, and the inferior border at the superior border of the opposing tangent fields, field size 10 x 10 cm^2.

Follow-up studies and outcome measures

After completion of radiotherapy, patients were seen at 1 month, then every 3 months for 2 years, then every 6 months for 3 years, then yearly thereafter. At each follow-up visit, each patient provided a medical history and underwent a physical examination.

Late effects and cosmetic results were stable from 2 to 5 years after irradiation[5,6]. The primary endpoints of the present study were late effects (including ulceration, breast edema, breast pain, hyper/hypopigmentation, atrophy, induration or fibrosis, telangiectasia, rib fractures) and cosmetic results, assessed at 7-month and 3-year follow-up by patients and the researcher, using Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 (Table 1) for late side effects[16] and a 4-point scale (Table 2) for cosmetic results, comparing the treated breast with the untreated breast.

Data analysis

Patient records were reviewed and information was collected on patient age, tumor size, nodal status, resection margin, adjuvant systemic treatment, and hormone receptor status. Hormone receptor status was considered to be negative if the level was less than 10%.

Pearson Chi-square test was used for Categorical variable and independent to test for

Table 1. Common Terminology Criteria for Adverse Events version 3.0[16]

	Grade				
	1	2	3	4	5
Rashassociated with radiation	Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation confined to skin folds and creases; moderate edema	Moist desquamation other than skin folds and creases; bleeding induced by minor trauma or abrasion	Skin necrosis; ulceration of full thickness dermis; spontaneous leeding from involved site	Death
Ulceration	-	Superficial ulceration < 2 cm size; local wound care; medical intervention indicated	Ulceration ≥ 2 cm size; operative debridement; primary closure or other invasive intervention	Life-threatening consequences; major invasive intervention	Death
Breast edema	Swelling or obscuration of architecture on close inspection; pitting edema	Readily apparent obscuration of architecture; obliteration of skin folds	Lymphorrhea; interfering with ADL; gross deviation from normal contour	Progression to malignancy (Lymphangio sarcoma); disabling	Death
Breast pain	Mild pain not interfering with function	Moderate pain; pain interfering with function	Severe pain; pain interfering with ADL	Disabling	-
Hyper or hypopigmentation	Slight or localized	Marked or generalized	-	-	-
Atrophy	Detectable	Marked	-	-	-
Induration or fibrosis	Increased density on palpation	Moderate impairment of function; marked density on palpation with or retraction or without minimal retraction	Dysfunction interfering with ADL; very marked density, fixation	-	-
Telangiectasia	Few	Moderate	Many and confluent	-	-
Rib fracture	Asymptomatic with only radiologic findings	Symptomatic but non-displaced; immobilization indicated	Symptomatic and displaced or open wound; operative intervention indicated	Disabling	Death

continuous variables to that the differences between groups, with an α value of 0.05.

Results

Patient characteristics

Table 3 shows the demographic data of the study subjects. The patient characteristics were not significantly different between the study groups.

Late effects

Table 4 demonstrates late effects at 7-month follow-up. Hyper/hypopigmentation, induration or fibrosis, and breast pain were observed in both study groups without significant difference. No other late effects (rash associated with radiation, ulceration, breast edema, atrophy of skin or fat, telangiectasia, and rib fracture) presented in the study at 7-month follow-up.

Cosmetic results

Table 5 shows cosmetic results at 7-month follow-up. Good and excellent results in skin color, breast complexity, breast contour, and nipple displacement were observed in both study groups without significant difference. These results were in accordance with the overall satisfaction rated by the patients.

Table 2. Cosmetic outcome assessment

	Score			
	1 (Poor)	2 (Acceptable)	3 (Good)	4 (Excellent)
Skin color	Marked different in 3-4 quadrants	Marked different in 1-2 quadrants	Slightly different	Comparable color to the other breast
Breast complexity	Marked different in 3-4 quadrants	Marked different in 1-2 quadrants	Slightly different	Comparable density on palpation to the other breast
Breast contour	Marked different in 3-4 quadrants	Marked different in 1-2 quadrants	Slightly different	Comparable contour to the other breast
Nipple displacement	Vertical displacement of nipple > 3 cm	Vertical displacement of nipple ≤ 3 cm, > 2 cm	Vertical displacement of nipple ≤ 2 cm, > 1 cm	Vertical displacement of nipple ≤ 1 cm
Overall satisfaction (by patients)	Poor	Acceptable	Good	Excellent

Table 3. Patient characteristics

Characteristics	SIB (n = 30)	Sequential (n = 30)	p-value
Age (years)			
< 40	8 (27%)	4 (13%)	0.31
40-60	19 (63%)	20 (67%)	
> 60	3 (10%)	6 (20%)	
Mean age (range)	46.4 (28-82)	49.3 (33-74)	0.37
T stage			
T1	12 (40%)	17 (57%)	0.30
T2	18 (60%)	13 (43%)	
Mean dimension (cm) (range)	2.28 (0.5-4.5)	2.21 (0.4-5)	0.80
N stage			
N0	29 (97%)	26 (87%)	0.35
N1	1 (3%)	4 (13%)	
Median node dissection (range)	15 (5-24)	14 (4-28)	0.80
Margin (cm)			
< 2 mm	8 (27%)	11 (37%)	0.58
≤ 2 mm	22 (73%)	19 (63%)	
Mean margin (cm) (range)	0.27 (0.1-0.6)	0.26 (0.1-0.5)	0.78
Chemotherapy			
Yes	25 (83%)	20 (67%)	0.23
No	5 (17%)	10 (33%)	
Hormonal receptor			
ER			
Positive	20 (67%)	25 (83%)	0.23
Negative	10 (33%)	5 (17%)	
PR			
Positive	18 (60%)	23 (77%)	0.27
Negative	12 (40%)	7 (23%)	
Her-2			
Positive	9 (30%)	4 (13%)	0.21
Negative	21 (70%)	26 (87%)	

Table 4. Late effects (7-month follow-up)

Late effects (CTCAE version 3.0)	SIB (n = 30)	Sequential (n = 30)	p-value
Rash associated with radiation			
None	30 (100%)	30 (100%)	1
Ulceration			
None	30 (100%)	30 (100%)	1
Breast edema			
None	30 (100%)	30 (100%)	1
Breast pain			
None	22 (73%)	20 (67%)	0.78
Grade 1	8 (27%)	10 (33%)	
Hyper/hypopigmentation			
None	8 (27%)	8 (27%)	0.84
Grade 1	20 (67%)	21 (70%)	
Grade 2	2 (6%)	1 (3%)	
Atrophy (skin or fat)			
None	30 (100%)	30 (100%)	1
Induration or fibrosis			
None	13 (43%)	12 (40%)	0.83
Grade 1	14 (47%)	16 (53%)	
Grade 2	3 (10%)	2 (7%)	
Telangiectasia			
None	30 (100%)	30 (100%)	1
Rib fracture			
None	30 (100%)	30 (100%)	1

Table 5. Cosmetic results (7-month follow-up)

Cosmetic results (4-point scale)	SIB (n = 30)	Sequential (n = 30)	p-value
Skin color			
1 (Poor)	0 (0%)	0 (0%)	0.84
2 (Acceptable)	2 (6%)	1 (3%)	
3 (Good)	20 (67%)	21 (70%)	
4 (Excellent)	8 (27%)	8 (27%)	
Breast complexity			
1 (Poor)	0 (0%)	0 (0%)	0.83
2 (Acceptable)	3 (10%)	2 (7%)	
3 (Good)	14 (47%)	16 (53%)	
4 (Excellent)	13 (43%)	12 (40%)	
Breast contour			
1 (Poor)	0 (0%)	0 (0%)	0.59
2 (Acceptable)	2 (6%)	4 (13%)	
3 (Good)	14 (47%)	15 (50%)	
4 (Excellent)	14 (47%)	11 (37%)	
Nipple displacement			
1 (Poor)	0 (0%)	0 (0%)	0.57
2 (Acceptable)	2 (6%)	4 (13%)	
3 (Good)	16 (54%)	17 (57%)	
4 (Excellent)	12 (40%)	9 (30%)	
Overall satisfaction			
1 (Poor)	0 (0%)	0 (0%)	0.67
2 (Acceptable)	2 (6%)	1 (3%)	
3 (Good)	16 (54%)	14 (47%)	
4 (Excellent)	12 (40%)	15 (50%)	

Discussion

The purpose of radiation treatment following breast-conserving surgery in early-stage breast cancer was to minimize the risk of recurrence[1-4] and toxicity in the treated breast while maximizing cosmetic results. The radiation techniques to shorten radiation treatment time, which is important for patient convenience and efficient use of radiation treatment resources, composed of simultaneous integrated boost, brachytherapy, and hypofrationated irradiation. Different patient, tumor, and surgical variables contribute to the cosmetic and functional outcomes in patients with breast cancer treated with lumpectomy and radiation, in addition to the effects of the radiation dose-fractionation schedule. Induration/fibrosis, breast pain, and breast edema, which improved from prior to start of irradiation to 3-5 years post irradiation[6], are sequele of both radiation and surgery, while hyper/hypopigmentation, rash associated with radiation, ulceration, atrophy of skin or subcutaneous fat, telangiectasia, and rib fracture are late effects of radiation. In the present study, late effects and cosmetic results in SIB group were not significantly different from the sequential group at 7-month follow-up. Good to excellent overall satisfaction was rated by most of the patients. SIB-IMRT planning in breast cancer improved dose conformality, reduced total treatment times, and reduced the unwanted excessive dose to normal structures[10-13]. Acceptable acute skin toxicity at 6-wk follow-up after hypofractionated SIB-IMRT was reported by Freedman[14]. The SIB technique with three-dimensional conformal beams and wedges, which is easier to implement than a sophisticated SIB-IMRT, demonstrated low incidence of acute skin toxicity[15]. Similarly, this current study used SIB to the tumor bed concomitantly with conventional opposing tangential photon beams to the whole breast. This prospective non-randomized study was designed to compare daily additional SIB and sequential boost to the tumor bed in terms of late effects and cosmetic results, which have not been recently reported by any SIB technique.

The partial breast irradiation by brachytherapy is interesting radiation schedule[9] but lack of data from randomized trials showing equivalence to conventional whole breast radiation schedule. Reduction of total treatment time, by means of increasing daily dose, raises concerns about late effects and cosmetic results. A retrospective study showed that 77% of 294 patients were extremely or very satisfied with the overall appearance of the breast at 5-year follow-up after lumpectomy and hypofractionated irradiation[7]. Olivotto also reported that 96% of 186 patients achieved good or excellent cosmetic outcomes at 5-year follow-up[6]. Comparable to the previous studies, the current study demonstrated that 94% of 30 patients in SIB group rated good or excellent overall satisfaction at 7-month follow-up.

Another trial demonstrated worse late toxicities, assessed with the LENT-SOMA criteria, after 55 Gy in 22 fractions (2.5 Gy/F, the equivalent dose of 2-Gy fraction = 62 Gy) than 55 Gy in 28 fractions (2 Gy/F)[8]. A randomized control trial in Canada, comparing 42.5 Gy in 16 fractions (2.66 Gy/F) and 50 Gy in 25 fractions (2 Gy/F), demonstrated comparable 3-year cosmetic results, assessed with the EORTC Cosmetic Rating System[5]. Therefore, radiation dose of 2.5Gy/F with equivalent BED may produce acceptable late effects and cosmetic results. Canadian hypofractionation schedule was not widely acceptable because of absence of a boost, which demonstrated better local control based on data from an EORTC randomized control trial[4].

Although the present study included a relatively small number of patients and only 7-month follow-up, the preliminary results demonstrated comparable late effects and cosmetic results between the study groups. The final results (3-year follow-up) are expected.

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Appendix. Radiation biological effective dose calculations

Biological effective dose (BED) = Total dose x [1 + dose per fraction/(α/β)]

Whole breast : 50 Gy in 25 fractions

Tumor effects : BED_{10} = 50 x (1 + 2/10) = 60 Gy

Late effects : BED_3 = 50 x (1 + 2/3) = 83.33 Gy

Sequential boost : 15 Gy in 5 fractions after 50 Gy in 25 fractions

Tumor effects : BED_{10} = [15 x (1 + 3/10)] + 60 = 79.5 Gy

Late effects : BED_3 = [15 x (1 + 3/3)] + 83.33 = 113.33 Gy

Simultaneous integrated boost : Additional 0.4 Gy in 25 fractions (2.4 Gy in 25 fractions)

Tumor effects : BED_{10} = 60 x (1 + 2.4/10) = 74.4 Gy

Late effects : BED_3 = 60 x (1 + 2.4/3) = 108 Gy

การศึกษาผลข้างเคียงระยะยาวและความสวยงามของเต้านมภายหลังการฉายรังสีเพิ่มเติมบริเวณก้อนมะเร็งทุกวันควบคู่กับการฉายรังสีบริเวณเต้านม เปรียบเทียบกับการฉายรังสีเพิ่มเติมบริเวณก้อนมะเร็งภายหลังจากเสร็จสิ้นการฉายรังสีบริเวณเต้านม ในผู้ป่วยที่ผ่าตัดแบบสงวนเต้านม

ทัศน์พงศ์ รายยวา, ชวลิต เลิศบุษยานุกูล, ประยุทธ์ โรจน์พรประดิษฐ์

วัตถุประสงค์: *การฉายรังสีตามหลังการผ่าตัดแบบสงวนเต้านมในมะเร็งเต้านมระยะแรกเพื่อลดความเสี่ยงที่โรคจะกลับคืนมาบริเวณเต้านม การฉายรังสีเสร็จสิ้นในระยะเวลาอันสั้นทำให้ผู้ป่วยสะดวกและเป็นการใช้ทรัพยากรได้อย่างคุ้มค่า แต่อย่างไรก็ตามจะต้องคำนึงถึงผลข้างเคียงระยะยาวและความสวยงามของเต้านมด้วย*

วัสดุและวิธีการ: *ระหว่างเดือนสิงหาคม พ.ศ. 2549 และเดือนกรกฎาคม พ.ศ. 2550 ผู้ป่วย 60 ราย ได้เข้าร่วมโครงการศึกษานี้ เพื่อเปรียบเทียบการฉายรังสีเพิ่มเติมบริเวณก้อนมะเร็งทุกวันควบคู่กับการฉายรังสีบริเวณเต้านม (10Gy/25F) และการฉายรังสีเพิ่มเติมบริเวณก้อนมะเร็งภายหลังจากเสร็จสิ้นการฉายรังสีบริเวณเต้านม (15Gy/5F) ในด้านผลข้างเคียงระยะยาวและความสวยงามของเต้านม ณ เวลา 7 เดือน และ 3 ปี ภายหลังการรักษาโดยใช้สถิติเพียร์ซันไคสแควร์ในการเปรียบเทียบระหว่างกลุ่มการศึกษา*

ผลการศึกษา: *ผลข้างเคียงระยะยาวที่พบบ่อยที่ระยะเวลา 7 เดือนภายหลังการรักษา คือ สีผิวที่เปลี่ยนแปลง และการหนาตัวขึ้นของเนื้อเยื่อใต้ผิวหนัง แต่ไม่พบความแตกต่างกันอย่างมีนัยสำคัญระหว่างกลุ่มการศึกษา ส่วนผลด้านความสวยงามของเต้านมนั้นดีถึงยอดเยี่ยม*

สรุป: *การศึกษานี้มีจำนวนผู้ป่วยน้อยและระยะเวลาติดตามผลการรักษาค่อนข้างสั้น แต่อย่างไรก็ตามผลการสรุปเบื้องต้นแสดงให้เห็นว่าไม่มีความแตกต่างอย่างมีนัยสำคัญระหว่างกลุ่มการศึกษา*