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Original article

COSMETIC OUTCOME OF HYPOFRACTIONATED WHOLE-BREAST IRRADIATION WITH CONCOMITANT BOOST IN BREAST CANCER

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ABSTRACT

Background: Breast cancer is the most common cancer in women worldwide, second most common malignancy in Egypt.

Methods: 60 early-stage breast cancer patients who underwent breast-conserving surgery were clusterized into 2 groups: Arm A hypofractionation with concomitant boost and Arm B conventional fractionation, each compromising 30 early stage breast cancer patients. Assessment of cosmetic outcome after breast irradiation was recorded in both groups in 4 intervals to correlate cosmesis in relation to different irradiation schedules and boost dosage and timing. The study was conducted from April 2016 till December 2018, 32 months were obtained to assure that all patients completed their irradiation schedule and 12 months follow-up period.

Results: Lowest cosmetic outcome was recorded immediately after completion of breast irradiation with excellent/good in 66.7% and 73.3% of patients and fair/poor in 33.3% and 26.7% in Arm A and B, respectively. Improvement in cosmesis after 12 months of breast irradiation reaching excellent/good in 83.4% and fair/poor in 16.7% in both Arm A and B.

Conclusion: An abbreviated 4-week hypofractionated schedule with a concomitant boost is as effective as conventional irradiation with comparable cosmesis and may be a reasonable alternative following breast conserving surgery.

Keywords: Breast cancer, Hypofractionation, Boost, Cosmesis.

INTRODUCTION

Breast cancer is the most common cancer in women worldwide with an incidence of 1.67 million new cases and 521,900 deaths and the second most common cancer overall (1, 2). The five-year relative survival rate for women diagnosed with localized, node-negative breast cancer is 98.5 percent.

In Egypt, breast cancer ranked second after liver cancer, which with bladder cancer contributed to approximately 46% of all cancers. Among females, the proportion of breast cancer was highest in upper Egypt (38.7%), less in lower Egypt and lowest in middle Egypt (33.2%, 26.8% respectively). Incidence of breast cancer in Egypt per 100,000 population was 35.8/100,000 in females and 0.6/100,000 in males (3).

Adjuvant whole-breast radiation (WBRT) after breast conserving surgery (BCS) is a standard option for early breast cancer (EBC), as it decreases local recurrence, with

a benefit on overall survival (4, 5). Adding a boost dose to the tumour bed (TB) further raises local control (LC) (6, 7).

Traditionally, WBRT has been delivered over 5 weeks with conventional fractionation (1.8–2 Gy daily) to a total dose of 50 Gy, followed by a sequential 10–16 Gy boost dose to the tumour bed for an overall treatment time (OTT) of 6-7 weeks (5). However, mainly due to resource constraints, altered schedules employing larger dose per fraction delivered in fewer treatment sessions over a shorter overall treatment time were introduced (8, 9).

Hypofractionation represents a safe and effective approach, as a convenient option both for patients and health care providers' convenience as it allows for reduction in hospital visits and increase in patients turnover, globally decreasing treatment costs (35) (36).

Radiobiologically, since in breast cancer the α/β ratio values for tumour and surrounding normal tissue substantially merge, a larger fraction size, with a concomitant slender total dose decrease, is likely to give a comparable tumour control probability with the same rate of expected late effects, compared to conventional fractionation (10, 11).

Treatment acceleration (through hypofractionation), with OTT reduction below 6–7 weeks, might ameliorate cure rates narrowing the time for proliferation and repopulation (12, 13). The concomitant delivery of the TB boost along with WBRT further reduces OTT, with an eventual ulterior gain (7, 14).

The results of retrospective studies of hypofractionated radiotherapy in early breast cancer suggest satisfactory outcomes in terms of tumour control and late adverse effects (15-17), this applies when modest increases in fraction size are combined with consequent and appropriate downward adjustments of the total dose (18-21).

More consistently, the prospective setting of randomized controlled trials also seems to adjunct confirmatory evidence upon the equivalence between hypofractionation and conventional fractionation as an adjuvant approach for early breast cancer (22-26).

Several studies operated the concept of hypofractionation to assess the difference in cosmetic outcome. Linares et al implemented 42.4 Gy in 16 daily fractions, 2.65 Gy per fraction to the whole breast plus an additional sequential boost to the tumour bed (34), whereas, Ciammella et al delivered whole breast irradiation dose of 40.05 Gy in 15 daily fractions, 2.67 Gy per fraction and a boost to the tumour bed of 9 Gy in 3 consecutive fractions (30). Cante et al delivered whole breast irradiation of 45 Gy (2.25 Gy/20 fractions) with an additional daily concomitant boost of 0.25 Gy to the surgical cavity (2.5 Gy/20 fractions up to 50 Gy) (21). Collectively, all of the studies showed a high excellent/good cosmetic outcome after hypofractionation.

PATIENTS AND METHODS

The radiation treatment was delivered within 15 days after breast conserving surgery. Patients were clusterized into 2 groups, each compromising 30 patients. The first group (Arm A) received a cumulative nominal dose of 50 Gy with a dose of 45 Gy prescribed to the ICRU reference point dose to whole breast (WB-PTV) using 3D conformal field arrangement of 2 wedged opposing 6 MV tangential fields (2.25 Gy upto 45 Gy/20 fractions) and an additional daily concomitant direct 6 MV field boost to the surgical cavity (CB-PTV) (0.25 Gy upto 5 Gy/20 fractions) with a total treatment time of 4 weeks, whilst, the second group (Arm B) received a cumulative nominal dose of 55 Gy with a dose of 45 Gy to the whole breast (1.8 Gy upto 45 Gy/25 fractions) followed by an additional daily boost to the surgical cavity (2 Gy upto 10

Gy/5 fractions) with a total treatment time of 6 weeks.

For setup, patients were positioned on a wingboard with both arms raised above the head and radiopaque markers along breast borders. Subsequently, the 5-mm slice-thick axial CT images were acquired from the lower mandible aspect to lung bases; an isocenter was found in virtual simulation.

The whole-breast clinical target volume (WB-CTV) encompassed breast palpable tissue, with a superior–inferior border within the extent of the radiopaque catheters. A uniform limit of 5 mm separated the WB-CTV from the skin surface and the thoracic wall. The whole-breast planning target volume (WB-PTV) was generated by adding a 5-mm isotropic margin around the WB-CTV. The definition of the tumour bed was driven by radio-opaque clips placed during surgery. The concomitant boost clinical target volume (CB-CTV) was generated by adding a 5-mm isotropic margin around the tumour bed, the consequent planning target volume (CB-PTV) required a further margin of 5 mm around the CB-CTV. In both arm A and arm B the same isocenter was used for both tangents and boost field. This was also used as the normalization point.

The acceptable levels of coverage for both WB-PTV and CB-PTV were as follows: 95 % of PTV is required to receive a minimum of 95 % dose and 99 % of PTV to receive a minimum of 90 % dose. For setup verification purposes, tangential fields' portal images were compared to digitally reconstructed radiographs (DRRs).

Cosmetic assessment was recorded after completion of radiotherapy and after 3, 6 and 12 months, using the Harvard criteria (4-point Likert scale) **(27-28-29)**. Cosmosis was defined by: excellent, good, fair or poor, differentiating both the treated breast and the unaffected breast.

Cosmesis assessment:

1) Excellent cosmetic score- was assigned when the treated breast looked nearly identical to untreated breast (basically similar)
2) Good cosmetic score- was assigned when the treated breast looked slightly different from untreated breast (little but detectable radiation effects)
3) Fair cosmetic score- was assigned when the treated breast looked clearly different from untreated breast but not seriously distorted (prominent radiation effects were attained)
4) Poor cosmetic score- was assigned when the treated breast looked seriously distorted (tremendous late effects of breast tissue as a result of radiation)

Written informed consent was obtained from all participants and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical methods:

Data were analyzed by Statistical Package of Social Science (SPSS), software version 24.0 (SPSS Inc., 2016).

Continuous data were presented as the Mean±SD if normally distributed and Median (Range) if not normally distributed. Normality was checked by Shapiro-Wilk test.

Categorical data were presented by the count and percentage.

RESULTS

The characteristics of the studied patients were presented in table 1, 2. It was noticed that median age was slightly higher in Arm A, 46 years in comparison to 45 years in Arm B, with 70% of patients ≥40 years. Premenopausal status predominated in both arms, with 70% in Arm B.

UOQ lesions predominated in both groups, with majority IDC histology. T2 tumours showed 63.3% in Arm A with contrast to

53.3% T1 in Arm B. Absence of perineural and lymphovascular invasion predominated in both arms, as well as, grade 2 in 73.3% and 63.3% in Arm A and Arm B, consecutively. Most of the cases were ER+, PR+, Her-2 negative. Chemotherapy was indicated in 90% of patients in Arm A and 76.7% in Arm B, where AC-Taxol regimen predominated.

The dosimetric characteristics (Table 3) of Arm B patients showed larger breast size, with median volume 1400.7 cc in contrast to 1306 cc in Arm A. Since Arm B showed predominance of T1 lesions, size ≤2 cm, thus boost volume was relatively smaller, 35 cc and 20cc in Arm A and Arm B, consecutively.

Cosmetic results (Table 4) were excellent/good in 83.4% and fair/poor in 16.7% in both Arm A and B.

Table (1): Patient characteristics

Variables	Arm A	Arm B
	n=30 (%)	n=30 (%)
Age (years)		
Mean±SD	46.9±10.8	44±9.6
Median(Range)	46(27-70)	45(30-65)
Age groups (years)		
<40	9(30%)	12(40%)
≥40	21(70%)	18(60%)
Menopausal status		
Premenopausal	15(50%)	21(70%)
Perimenopausal	9(30%)	6(20%)
Postmenopausal	6(20%)	3(10%)

Table (2): Tumour characteristics

Variables	Arm A	Arm B
	n=30 (%)	n=30 (%)
BCS		
Lumpectomy	13(43.3%)	17(56.7%)
Quadrantectomy	17(56.7%)	13(43.3%)
Tumour location		
UOQ	19(63.3%)	22(73.3%)
UIQ	3(10%)	7(23.3%)
LOQ	5(16.7%)	1(3.3%)
LIQ	3(10%)	0(0%)
Tumour grade		
Grade 1	0(0%)	2(6.7%)
Grade 2	22(73.3%)	19(63.3%)
Grade 3	8(26.7%)	9(30%)
Tumour size		
T1	11(36.7%)	16(53.3%)
T1a	1(3.3%)	3(10%)
T1b	1(3.3%)	2(6.7%)

T1c	9(30%)	11(36.7%)
T2	19(63.3%)	14(46.7%)
Histology		
IDC	20(66.7%)	28(93.3%)
ILC	5(16.7%)	1(3.3%)
Mixed (ductal and lobular)	5(16.7%)	1(3.3%)
Laterality		
Right	12(40%)	14(46.7%)
Left	18(60%)	16(53.3%)
Nodal status		
N0	15(50%)	16(53.3%)
N1	15(50%)	14(46.7%)
LVI		
Absent	27(90%)	26(86.7%)
Present	3(10%)	4(13.3%)
PNI		
Absent	27(90%)	26(86.7%)
Present	3(10%)	4(13.3%)
ER status		
Negative	5(16.7%)	8(26.7%)
Positive	25(83.3%)	22(73.3%)
PR status		
Negative	6(20%)	10(33.3%)
Positive	24(80%)	20(66.7%)
Her-2 status		
Negative	27(90%)	20(66.7%)
Positive	3(10%)	10(33.3%)
Ki-67		
Low	24(80%)	22(73.3%)
High	6(20%)	8(26.7%)
Chemotherapy		
No	3(10%)	7(23.3%)
Yes	27(90%)	23(76.7%)
Chemotherapy regimen		
FAC	11(40.7%)	5(21.7%)
FEC	3(11.1%)	0(0.0%)
AC-Taxol	13(48.1%)	18(78.3%)
Hormonal treatment		
No	5(16.7%)	8(26.7%)
Yes	25(83.3%)	22(73.3%)
Trastuzumab		
No	27(90%)	20(66.7%)
Yes	3(10%)	10(33.3%)

Table (3): Treatment and dosimetric characteristics

Variables	Arm A n=30	Arm B n=30	Chi-squared for trend	P-value
Breast volume (cc)			Unpaired t-test=0.64	0.52
Mean±SD	1395.1±573.6	1484.4±500		
Median(Range)	1306(535.5-3199.8)	1400.7(810.7-3004.6)		
Boost volume (cc)			Mann-Whitney U test=416.5	0.62
Mean±SD	45.7±32.2	39.0±28.6		
Median(Range)	35(10-103)	20(10-93)		
Maximum Dose (Gy)			Unpaired t-test=1.3	0.19
Mean±SD	105.2±1.5	104.6±2.0		
Median(Range)	105(102-107)	104.5(102-107)		
Mean PTV dose (Gy)			Unpaired t-test=1.0	0.30
Mean±SD	98.5(2.3)	99.2±2.9		
Median(Range)	98(95-104)	98.5(95-104)		

Table (4): Cosmetic Assessment

Variables	Arm A n=30 (%)	Arm B n=30 (%)	Chi-squared for trend	P-value
Assessment after radiotherapy			X^2=0.25	.61
Excellent	11(36.7%)	12(40%)		
Good	9(30%)	10(33.3%)		
Fair	6(20%)	5(16.7%)		
Poor	4(13.3%)	3(10%)		
Assessment after three months			X^2=0.57	.45
Excellent	11(36.7%)	13(43.3%)		
Good	9(30%)	10(33.3%)		
Fair	6(20%)	4(13.3)		
Poor	4(13.3)	3(10%)		
Assessment six months			X^2=0.29	.59
Excellent	14(46.7%)	15(50%)		
Good	9(30%)	10(33.3%)		
Fair	4(13.3%)	3(10%)		
Poor	3(10%)	2(6.7%)		
Assessment 12 months			X^2=0	>.99
Excellent	17(56.7%)	16(53.3%)		
Good	8(26.7%)	9(30%)		
Fair	2(6.7%)	3(10%)		
Poor	3(10%)	2(6.7%)		

DISCUSSION

Cosmetic results scored in both arms after 12 month were excellent/good in 83.4% of patients and fair/poor in 16.7%, whereas superiorly, Cante et al reported cosmetic results were excellent in 69% of patients, good in 22%, fair in 5% and poor in 4% (21). Cante et al, as well in 2017, reported results of excellent/good in 87.8% of patients and fair/poor in 12.2% (7), thus suggesting improved cosmosis after longer follow-up periods. Ciammella et al reported even better results of excellent/good cosmetic outcome in 93% of the women (30) since the majority patients were operated with lumpectomy not quadrantectomy. Reddy et al documented similar to improved cosmetic outcome with hypofractionation in correlation to conventional fractionation 1 year after treatment (31). Good or excellent cosmetic outcomes was found in 91% of patients in the study by Linares et al (34).

Cosmetic assessment done immediately after completion of breast irradiation showed the lowest results with excellent/good in 66.7% and 73.3% of patients and fair/poor in 33.3% and 26.7% in Arm A and B, respectively. Improvement in cosmesis occurred after 6 months to excellent/good in 76.7% and 83.3% of patients and fair/poor in 23.3% and 16.7% in Arm A and B, respectively. Consistently, Fujishiro et al stated that the cosmetic result deteriorated after radiotherapy but gradually improved and stabilized after 1 year (32).

No correlation was observed between any of the patient nor tumour characteristics and cosmesis at any interval. Fujishiro et al stated that tumour size over 2 cm and tumours in the inner or upper quadrants were factors which negatively affected the cosmetic score at 3 years (32), on the other hand, Charfare et al excluded several factors from influencing cosmesis, such as, tumour size in mm, tumour location whether inner or outer quadrant and number of operations (1 vs 2) (33). In addition, the large breast size didn't serve as a hindering factor to cosmesis.

Whole breast volume after conservative surgery in arm A showed a mean of 1395.1±573.6 cc against 1484.4±500 cc in arm B, whereas, the mean boost volume was 45.7±32.2 in arm A and 39.0±28.6 in arm B. A much smaller breast volume was documented with Ciammella et al 813.8 with a range of 89.6 - 1892.1, whereas, the boost volume was 138.75 with a range of 23.07 - 230.02 (30). Median boost volume irradiated in Arm A was 35cc (10-103), whereas, slightly less in Arm B 20cc (10-93). Charfare et al noted that the percentage of breast volume excised can influence the cosmetic result, removal of a larger percentage volume gives a poor cosmetic result and a smaller percentage volume an excellent/good result, 45-65% of patients with <10% estimated breast volume excised had good to excellent cosmetic result compared with 35-50% good to excellent result if >10% breast volume was excised (33).

CONCLUSION

An abbreviated 4-week hypofractionated schedule with a concomitant boost is as effective as conventional irradiation with comparable cosmesis and may be a reasonable alternative following breast conserving surgery.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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