9 OPAR: A Multicenter Phase II Randomized Trial of Fractionation Schedules for Once-a-Day Accelerated Partial Breast Irradiation (APBI)

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Presenting Author

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Body

Purpose/Objective(s): APBI is the delivery of radiotherapy (RT) to the tumor bed after breast conserving surgery (BCS) often given over a week or less. An attractive approach to deliver APBI is by external beam 3DCRTor IMRT. Previous studies have suggested that external beam APBI delivered twice-a-day can lead to increased late effects and poor breast cosmesis. The objective of our trial was to determine if two doses for APBI given once-a-day over 1-week result in acceptable long-term morbidity.

Materials/Methods: Eligible patients were >50 years with DCIS or invasive breast cancer <3 cm treated by BCS with negative margins and negative axillary nodes. Consenting patients were planned to receive APBI with 3-5 non-coplanar fields using a 3DCRT or IMRT and randomized to 27.5Gy or 30Gy each given in 5 fractions once-a-day over 5-8 days. Cosmetic evaluation with the EORTC Cosmetic Rating System was performed at baseline and 2 years by: a study nurse directly assessing the breast, and a group of oncologists unaware of RT regimen assessing photographs. Patient assessment of cosmesis was also performed at 3 years. Patients were followed for toxicity using the NCI CTCAE and recurrence. The primary outcome was adverse cosmesis (fair or poor global score) by photographic assessment at 2 years. The rate of adverse cosmesis with standard whole breast irradiation was 17% in our previous trial. Based on this consideration and one-sided α of 5% for each group, the upper bound of a one-sided 95% (two-sided 90%) confidence interval (CI) had to be <23% for the treatment to be acceptable; 140 patients were required for each group. The proportion of patients with adverse cosmesis at 2 years and cosmetic deterioration from baseline to 2 years (excellent/good to fair/poor) with corresponding two-sided 90% CIs were estimated using the Wilson score method. The proportion of patients with any late breast toxicity (edema, induration, and telangiectasia) grades 2-3 at 2 years and local recurrence (LR) were also determined.

Results: Of the 281 patients: 139 were randomized to 27.5Gy and 142 to 30.0Gy. Median follow-up was 3 years. The mean age was 65 years; mean tumor size was 1.2cm. With respect to photographic assessment both schedules met our criteria for acceptability (Table). Adverse cosmesis assessed by nurse or patient and toxicity appeared to be less for 27.5Gy compared to 30Gy. No LRs were observed for 27.5Gy and one LR was observed for 30Gy.

	27.5 Gy	**30 Gy**
	% (90% CIs)	**% (90% CIs)**
Adverse Cosmesis		
Photograph at 2 years	15.2 (10.8, 21.1)	12.1 (8.2, 17.6)
Nurse at 2 years	7.7 (4.7, 12.5)	12.9 (8.8, 18.4)
Patient at 3 years	11.8 (7.2, 18.7)	20.9 (14.7, 28.9)
Cosmetic Deterioration		
Photograph	9.4 (5.9, 14.5)	9.3 (6.3, 16.8)
Nurse	5.6 (3.1, 10.1)	7.6 (4.6, 12.4)
Late Toxicity	1.4 (0.5, 4.3)	4.9 (2.8, 8.9)

Conclusion: According to the study design 27.5Gy and 30Gy resulted in acceptable cosmetic outcomes. In light of recent studies, the lower dose may be preferable in terms of late adverse effects but requires further evaluation.

Sessions

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Sunday, Oct 24 1:45 PM

McCormick Place West, Room W185 a/b/c/d

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