

Toxicity and Cosmetic Outcomes Following Treatment with a Novel Form of Breast IORT

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Objectives: Intraoperative radiation therapy (IORT), a form of accelerated partial breast irradiation (APBI), is an appealing alternative to postoperative whole breast irradiation for early-stage breast cancer. The purpose of this study was to examine the toxicity and cosmetic outcomes of patients treated with a novel form of breast IORT (Precision-Breast-IORT; PB-IORT), that delivers a targeted, higher dose of radiation than conventional IORT.

Methods: The first 204 patients treated with PB-IORT in a phase II clinical trial (NCT02400658) were included. Inclusion criteria were age ≥ 45 with invasive or in situ breast cancer, tumor size < 3 cm, and node negative. Toxicity and cosmetic scoring were performed at 6 and 12 months.

Results: 98 patients (48%) experienced a toxicity. Seven grade-3 toxicities occurred (3.4%, 95% CI 1.4-6.9) (Table). The majority of patients (95%) had excellent or good cosmetic outcomes (95% CI 91-98) at 12 months. The majority of patients (94%) had little or no pigmentation change (95% CI 90-97), 88% little to no size change (95% CI 82-92), and 87% experienced minimal shape change (95% CI 82-92).

Conclusions: Overall, the rate of severe toxicity was low and cosmetic outcomes were excellent. Toxicity with PB-IORT is higher than reported in the TARGIT trial (0.2%) but lower than APBI in the NSABP-39 trial (10.1% grade-3/4 toxicities). We propose that the toxicity of PB-IORT as compared to TARGIT and NSABP-39 is related to the radiation dose and delivery schedule. PB-IORT offers a low toxicity profile and good cosmetic outcomes when compared to other forms of APBI.

Table. Frequency of adverse effects and toxicities in patients undergoing PB-IORT.

Category	Adverse effect	Total n=204				
		G1	G2	G3	G4	G5
Overall maximum toxicity		66 (32.4%)	27 (13.2%)	5 (2.5%)		
General	Fatigue	9 (4.4%)	3 (1.5%)			
	Fever	1 (0.5%)	1 (0.5%)			
	Localized edema	5 (2.5%)				
	Pain	2 (1.0%)	1 (0.5%)			
Infection	Urinary tract infection		1 (0.5%)			
	Breast infection		8 (3.9%)	2 (1.0%)		
	Wound infection		2 (1.0%)	1 (0.5%)		
Procedural	Radiation dermatitis	13 (6.4%)	3 (1.5%)			
	Radiation reaction	2 (1.0%)				
	Seroma	29 (14.2)	5 (2.5%)			
	Wound dehiscence		1 (0.5%)			
	Other	2 (1.0%)				
Hematologic	Lymphocytopenia			1 (0.5%)		
Metabolic	Hyperglycemia	1 (0.5%)				
Musculoskeletal	Fibrosis (deep)	1 (0.5%)				
	Fibrosis (superficial)	8 (3.9%)	1 (0.5%)			
	Generalized muscle weakness			1 (0.5%)		
	Extremity pain		1 (0.5%)			
Reproductive/breast	Breast pain	18 (8.8%)	2 (1.0%)			
	Other	6 (2.9%)	1 (0.5%)			
Respiratory	Cough	1 (0.5%)				
Skin	Erythema multiforme	7 (3.4%)	1 (0.5%)			
	Pruritus	4 (2.0%)				
	Rash maculopapular	3 (1.5%)				
	Skin hyperpigmentation	8 (3.9%)				
	Skin induration	1 (0.5%)	1 (0.5%)			
	Other	14 (6.9%)	5 (2.5%)			
Vascular	Lymphedema	2 (1.0%)				
	Superficial thrombophlebitis	1 (0.5%)	2 (1.0%)			
	Thromboembolic event			1 (0.5%)		
	Other	1 (0.5%)				
Unspecified			1 (0.5%)			

Categorical variables listed as n (%). G = Grade. *Overall maximum toxicity denotes the number of patients that experienced a maximum toxicity of that grade.