Adjuvant chemotherapy is not associated with increased rate of surgical site complications following intraoperative radiation therapy

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BACKGROUND: Single-dose intraoperative radiotherapy (IORT) has emerged as an alternative to standard whole-breast radiotherapy as a component of breast-conserving therapy (BCT) for early stage breast cancer. Because IORT is reserved for patients with biologically favorable tumors, need for adjuvant chemotherapy is uncommon and its impact on frequency of wound complications and radiation recall is uncertain. The aim of this study is to determine if adjuvant chemotherapy is associated with an increased rate of complications in patients treated with IORT.

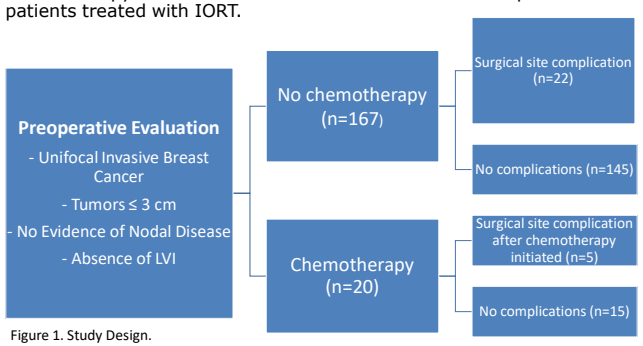


Figure 1. Study Design.

METHODS: This retrospective study used data derived from a prospective database of patients receiving single-dose IORT as a component of BCT between Jan 1, 2012 and Oct 31, 2016. Patients meeting inclusion criteria outlined in Figure 1 were offered partial mastectomy and IORT. Based on final pathology and Oncotype DX score, select patients were offered adjuvant chemotherapy. Patients who received whole breast radiotherapy were excluded. Endocrine therapy was recommended to patients with hormone receptor positive tumors. All surgical site complications were prospectively recorded during post-operative and follow up clinic visits.

METHODS (cont.): Radiation recall was defined as radiation related skin changes during chemotherapy. Major complications were defined by need for hospitalization or reoperation. Minor complications were defined as wounds requiring local wound care or observation.

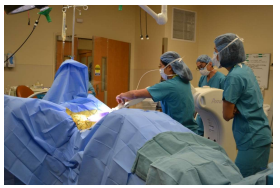
RESULTS: A total of 187 patients were identified, 20 (10.7%) patients were treated with IORT and chemotherapy (chemo group) and 167 patients with IORT alone (IORT group). Clinicopathologic features are summarized in Table 1. Tumor size was significantly larger in the chemo group. More frequent receipt of endocrine therapy in the IORT group paralleled the higher rate of ER+ cancers. No major complications or radiation recall were noted in either group. There was no significant difference in the rate of minor complications, the rate of complications requiring interventions, or types of complication between the two groups (Table 2). All complications in the chemotherapy group occurred after chemotherapy was initiated. One local recurrence was noted in the chemo group (5%) and 4 local recurrences were noted in the IORT group (2.4%) at an average follow up of 49.8 months (p=0.32). There was no incidence of regional nodal or distant recurrences or deaths in either group.

Clinicopathologic Features	IORT alone N=167 (%)	IORT + chemo N=20 (%)	p value
Age (years)	63 ± 8.6	60 ± 7.4	0.06
BMI (kg/m^2)	28.8 ± 7	29.2 ± 6.8	0.76
Tumor size (mm)	12.9 ± 0.7	16.6 ± 1.3	0.02
Histologic type:			
Invasive ductal carcinoma	116 (69.5%)	16 (80.0%)	
Invasive lobular carcinoma	6 (3.6%)	0	0.60
Invasive carcinoma with ductal and lobular features	40 (24.0%)	3 (15.0%)	
Other	5 (3.0%)	1 (5.0%)	
Skin bridge thickness (mm)	11.6 ± 0.3	11.2 ± 0.6	0.53
Receptor Status			
ER Positive	160 (95.8%)	15 (75.0%)	<0.001
PR Positive	143 (85.6%)	12 (60.0%)	0.01
Her 2 Positive	6 (3.6%)	5 (25.0%)	<0.001
Triple Negative	4 (2.4%)	4 (20%)	<0.001

Table 1. Clinicopathologic features of patients treated with IORT alone and those who received IORT plus adjuvant chemotherapy.

Complications and Interventions	IORT alone N=167 (%)	IORT + chemo N=20 (%)	p value
Complication (any)	22 (13.2%)	5 (16.7%)	0.18
Complication type:			
Dehiscence	9 (5.4%)	1 (5.0%)	0.62
Infection	0	1 (5.0%)	0.19
Fat necrosis	2 (1.2%)	0	>0.99
Seroma	4 (2.4%)	1 (5.0%)	>0.99
Skin Necrosis	0	1 (5.0%)	0.19
Multiple	7 (4.2%)	1 (5.0%)	>0.99
Intervention required	11 (6.6%)	2 (10.0%)	>0.99
Intervention performed			
Aspiration	1 (9.1%)	1 (50.0%)	
Oral antibiotics	1 (9.1%)	0	0.15
Local wound care/debridement	6 (54.5%)	1 (50.0%)	
Combination	3 (27.3%)	0	

Table 2. Number and type of complications and interventions performed on patients treated with IORT alone versus those who received IORT plus adjuvant chemotherapy



CONCLUSION: IORT is a safe and effective treatment option for patients with early stage breast cancer. Although the addition of chemotherapy is not associated with an increased rate of surgical site complications, all of the complications in this group occurred after initiation of chemotherapy highlighting the importance of close clinical monitoring and interdisciplinary communication. These findings may also help in the decision making process for patients considering IORT and alleviate concerns regarding use of chemotherapy after IORT.

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