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Prone Partial Breast Irradiation (PBI): Prospective Randomized Trial to Compare Five Versus Three Fractions

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Purpose/Objective(s): To report preliminary results of a phase II trial (NCT02755896) of accelerated partial breast irradiation delivered prone in three versus five fractions, after breast-conserving surgery.

Materials/Methods: Postmenopausal women with Stage T1N0 breast cancer and Stage 0 DCIS (low and intermediate grade, <2cm in size) were eligible and randomized to receive either prone PBI with five 6Gy daily fractions (total dose = 30Gy) or three fractions of 8Gy delivered every other day over a 5-day period (total dose = 24Gy). Planning CT in the prone position was performed on a dedicated prone breast board. The postoperative cavity was contoured as the clinical target volume with a 1.5 cm margin added to determine the planning target volume (PTV). Primary endpoints were a comparison of post-treatment radiation fibrosis (grades 2+3), local control, and cosmetic outcomes on the 8Gy x 3 arm versus the 6Gy x 5 arm. Normal tissue constraints for uninvolved breast included a goal of less than 35% of the whole breast receiving prescription dose (Rx) and less than 60% of the whole breast receiving 50% of Rx. Adverse events were reported in case report form and followed for the duration of the trial.

Results: There were 70 patients accrued; 6 patients withdrew and 2 patients failed the screening process. A total of 62 patients were randomized and are currently available for analysis (31 patients in 6Gy x 5 arm and 31 patients in 8Gy x 3 arm). Median age was 66 years (range 53-80 years). The median PTV volume was 99.8cc (range 30.6-383.6cc) and the median breast volume was 795.3cc (range 165.9-2671cc). Normal tissue constraints were met for 100% of patients. Within a median post-treatment follow up time of 6 months, no serious radiation-related adverse event occurred. Maximum adverse event was grade 2 (radiation dermatitis), which occurred in one patient. Grade 1 breast/cutaneous event occurred in 31 additional cases. These events included 13 in the 8Gy x 3 arm and 18 in the 6Gy x 5 arm. At the one-week time point, there were 14 acute skin toxicities (7 events in the 6Gy x 5 arm and 7 events in the 8Gy x 3 arm). These events included radiation dermatitis (10) and hyperpigmentation (2), and mild breast pain (2). All these events were Grade 1. At the one-month time point, 18 total radiation-associated breast/cutaneous events occurred (11 events in the 6Gy x 5 arm and 7 events in the 8Gy x 3 arm). These events included radiation dermatitis (8) pigmentation change (3), edema (2) rash (3) and mild breast pain (2). There was one Grade 2 event of radiation dermatitis, which occurred by the 1 month time-point.

Conclusion: This preliminary data suggest comparable tolerability of the 2 accelerated approaches with only mild acute side effects.

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Outcome and Patterns of Failure in Breast Cancer Patients with FDG-PET Positive Internal Mammary Lymph Nodes: A Multicenter Rare Cancer Network Study

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Purpose/Objective(s): To assess the outcome and patterns of failure in non-metastatic operable breast cancer (NMBC) patients (pts) whose diagnostic work-up included FDG-PET and revealed positive internal mammary lymph nodes (IMLN) (with or without biopsy [bx]).

Materials/Methods: A multicenter retrospective study of 55 pts with NMBC treated between 2003 and 2015, whose diagnostic FDG-PET revealed positive IMLN, was performed in the framework of the Rare Cancer Network (RCN). Inclusion criteria were biopsy-proven NMBC, FDG-PET assessment, hormone receptor status, at least 12 months of follow-up; and exclusion criteria were age <20 or >90 years, or distant metastatic or inoperable disease.

Results: Median age was 47 years (range, 23-70) and all of the pts were female. The histopathological diagnosis was invasive ductal carcinoma in 51 pts (93%). Distribution of pts according to the clinical tumor (T) and lymph nodes (N) was; six pts T1 (11%), 36 pts T2 (65%), seven pts T3 (13%), six pts T4 (11%), 20 pts N2 (36%), and 35 pts N3 (64%). Primary tumor was located in inner quadrant in 30 pts (55%) and in superior in 42 pts (76%). There was FDG involvement in one IMLN in 31 pts, and 20 had multiple IMLN; all were ipsilateral, and IMLN SUVmax values ranged from 1.5-23.2 (median 4.95; 25% quartile 3.09). The median diameter of FDG-avid IMLN was 7 mm (range, 1-60 mm). IMLN were biopsied only in seven pts. Total mastectomy or breast-conserving surgery was performed in 42 (76%) and 13 (24%) pts, respectively, including axillary dissection in 50 (91%). Postoperative radiotherapy (median dose 50 Gy in median 25 fractions) to chest wall or breast and regional lymph nodes including IMLN was given in 53 pts (96.4%). Preoperative or postoperative chemotherapy was given in 20 (36%) and 35 pts (64%), respectively. In a median follow-up period of 104 months (range, 16-274), 48 pts were alive (7 deaths; 5 breast cancer, and 2 intercurrent disease), and 41 alive without disease. There were 13 relapses in 11 pts (2 local, 3 nodal, 8 distant). Five- and 10-year overall survival rates in all pts were 95% (95% confidence interval [CI]: 87-100%) and 93% (95% CI: %85-100); and 5- and 10-year disease-free survival (DFS) rates 83% (95% CI: 72-94%) and 71% (95% CI: 57-85%), respectively. In univariate analyses, IMLN dissection or bx did not influence DFS, while FDG-avid IMNL count (1 vs multiple; 10-year DFS 84% [95% CI: 69-99%] and 54% [95% CI: 28-80%]; p = 0.08), IMLN diameter (≤7 vs >7 mm; 10-year DFS 87% [95% CI: 73-100%] and 58% [95% CI: 30-78%]; p = 0.03), and IMLN SUVmax values (≤3 vs >3; 10-year DFS 100% and 60% [95% CI: 41-79%]; p=0.05) were factors influencing DFS. In multivariate analysis, the only independent factor for DFS was SUVmax value >3 (p = 0.025).

Conclusion: In pts with NMBC, whose diagnostic FDG-PET revealed positive IMLN, outcome does not seem to be different than those without FDG-PET assessment. However, in pts with IMLN SUVmax value >3, outcome is worse than those with SUVmax value ≤3; and prospective studies assessing more intensive treatments are warranted.

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