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Purpose or Objective: To assess the safety, feasibility and efficacy of free-hand intra-operative multi-catheter breast implant and peri-operative high-dose rate brachytherapy (FHIOMBI-PHDRBT program) in early breast cancer treated by breast conservative surgery (BCS).

Material and Methods: Patients with early breast cancer who were candidates for BCS and potential accelerated partial breast irradiation (APBI) were prospectively enrolled for the FHIOMBI-PHDRBT program. Patients suitable for APBI received PHDRBT (3.4 Gy BID for 10 in five days). Patients not suitable for APBI received PHDRBT as anticipatory boost (3.4 Gy BID for 4 in two days) followed by whole breast irradiation (WBI).

Results: From November 2008 to January 2015, a total of 119 patients were treated and 122 FHIOMBI procedures were performed. Median duration of FHIOMBI was 25 minutes. A median of 8 catheters (range 4-14) were employed. No intraoperative complications were observed. Severe early postoperative complications (bleeding) were documented in 2 patients (1.6%), wound healing complications in 3 (2.4%), and infection (mastitis or abscess) in 2 (1.6%). Late mammogram follow-up revealed oil cysts in 56% of patients but symptomatic fat necrosis in only 2 patients (1.6%). PHDRBT was delivered as APBI in 88 patients (74%) and as a boost in 31 (26%). The median CTV-T was 40.8 cc (range 12.3-160.5), median D90 of 3.32 Gy (range 3.11-3.85), median DHI 0.72 (range 0.48-0.82) median D10 in high-risk skin zone 1.94 Gy (range 0.92-3.37). With a median follow-up of 35 months (range 5.9-80.9) in the whole group and 37.7 months (range 7.6-80.9) in APBI patients, no local, elsewhere or regional failures were observed, only one distant failure in PHDRBT boost was documented. Cosmetic outcomes were evaluated in APBI patients as excellent (42.0%), very good (46.0%), fair (10.0%) or poor (2.0%).

Conclusion: The FHIOMBI-PHDRBT program does not add complications to conservative surgery, it adapts to breast size and location of the tumor, fulfilling at the same time prescription requirements and constraints. It allows an exquisite selection of APBI patients and offers excellent results in disease control and cosmetics. It also offers logistic advantages as it dramatically shortens the time of local treatment and avoids further invasive procedures.

PO-0954

Early results of a multi-center trial of IORT using electronic brachytherapy for breast cancer

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Purpose or Objective: To describe early observations of a multi-center study utilizing a single fraction of intra-operative radiation therapy (IORT) using the Xoft® Axxent® Electronic Brachytherapy System® (eBx®) immediately following surgical resection of early stage breast cancer.

Material and Methods: 727 subjects have been treated at 25 hospitals. Upon meeting entry criteria, patients underwent partial mastectomy. While in the operating room a balloon applicator was placed in the lumpectomy cavity and inflated with saline (30–75 cc). The skin was closed over the balloon, a balloon surface-to-skin distance of >1.0 cm was confirmed, and a single fraction of IORT was delivered to the lumpectomy cavity. The prescribed dose was 20 Gy at the balloon applicator surface; the mean treatment time was 10.3 minutes. After treatment, the balloon was deflated and removed, and skin sutured.

Results: 726 subjects received the prescribed dose of 20 Gy; one received 21 Gy. 56 are removed from the primary analysis post-IORT due to subsequent whole breast irradiation (N=37), positive lymph nodes (N=7), positive surgical margins (N=4), re-excision (N=4), inadequate skin bridge (N=2), inadequate balloon conformance (N=1), and other (N=4). These subjects will be followed for the duration of the study. An additional 60 subjects have withdrawn, leaving 667 active subjects. The mean patient age is 65 years (44-88). 148 subjects (20%) had ductal carcinoma in situ, 550 (75%) had invasive ductal carcinoma, 28 (5%) were unknown. DCIS nuclear grade was high (N=55), intermediate (N=64) and low (N=27); 2 were unknown. Invasive cancer was Grade 1-2 in 465/550 cases. 93% (N=676) had T1 lesions, 7% (N=51) had T2 lesions. Mean tumor size is 10.53 mm ± 8.3 mm. Mean follow-up is 336 days (4-1096). Only 125/926 (13.5%) of the reported adverse events were Grade 2 or higher. The most frequent AEs are seroma (15.4%), breast pain (14.1%), erythema (10.7%), and induration (8.5%). Cosmesis was excellent-to-good in over half (65%) of the cases. There have been six (6) deaths (aortic aneurysm; heart attack; pneumonia; liver cancer; 2 unknown causes) and only one (1) recurrence reported to-date.

Conclusion: IORT using the Xoft System as part of the conservative treatment of breast cancer is safe, with low morbidity. Early results from this multi-center trial demonstrate this short, convenient course of radiation therapy for select patients with early stage breast cancer has excellent-to-good cosmetic results and a low rate of low-grade adverse events.

PO-0955

PBI with interstitial HDR brachytherapy: acute and late toxicities & cosmetic results.

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Purpose or Objective: Purpose: The study we report is for early stage breast cancer and is a multicentre clinical investigation of PBI achieved by interstitial HDR brachytherapy with intraoperative placement of catheters.