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High-dose rate accelerated partial breast irradiation using MammoSite device in patients >60 years of age with localized breast carcinoma: preliminary report of a phase II study from a single institution experience

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Purpose: After breast-conserving surgery adjuvant postoperative radiation therapy (RT) delivered to the whole breast remind the standard of care. However, a large proportion of patients qualifying for conservative approach still do not actually receive it in some countries because of the difficult access to radiation centers. In an effort to overcome this problem, several teams have attempted an accelerated regimens using intra-operative brachytherapy. Moreover, in some patients older than 60y of age with co-morbidity, the long duration of conventional fractionated RT may significantly alter the quality of life and the treatment observance. The MammoSite [RTS] balloon applicator has been advised for clinical use in per-operative brachytherapy of the breast in USA and Canada.

Material and Methods: In April 2003, we started a phase II pilot study to evaluate the MammoSite performances. Inclusion criteria are: T1N0M0, ⩾60 years of age, DCIS component less than 25%, negative margin ⩾5 mm, skin-balloon surface distance ⩾7 mm, sentinel node negative. Patients are implanted after lumpectomy. CT-Scan is performed 48 h after surgery. Brachytherapy deliver 34 Gy in 10 fractions, twice a day (6h between fractions). As of October 2004, 25 patients have been included. Median age was 70y (62–74). TNM classification is T1a (20%), T1b (40%) and T1c (40%). All patients had ER (+) tumors. After treatment patients received Tamoxifen (50%) or Anastrozole (50%).

Results: Among the 25 included patients, 17 (56%) had completed their treatment. 8 patients were explanted and excluded from the study for: lobular histology (n = 2), sentinel node involvement (n = 5), bifocal lesions (n = 1), Distance cavity edge-skin surface < 7 mm (n = 2). The median fluid volume used was 57 ml (35–70). The skin thickness recovering the balloon measured by CT scan was > 7 mm in all patients (median: 1.9 cm; 0.7–2.6). Device malfunction consisting of slight modification of the catheter straightness was detected during treatment of 1 patient. In the 24h after implantation, hematoma was observed in 2 patients and allergic reaction in 1 case. The skin adverse events were grade 2 or 3 in 6 patients (35%). Moderate inflammation was observed in 6 cases. Severe inflammation and hematoma > grade 3 were observed in 1 and 2 cases respectively. At 6 months all acute side effects have been resolved and 1 patient presented telangiectasia GII. The cosmetic results at 6 months were available in 11 patients, 100% were scored as good to excellent.

Conclusion: Our preliminary results confirmed that the procedure is safe and feasible with high rate of residual seroma. The rate of infection is lower than other US reports (A. Agarwal, ASTRO 2005). Only one patient presented telangiectasia despite a skin spacing >7 mm (as compared to 29% in M. Keish series, ASTRO 2005, abstr. 10). The cosmetic results, the quality of life and economic evaluations are still ongoing, they will be presented during the meeting.

Wednesday, 22 March 2006 16:00–16:45

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Hormone replacement therapy

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Treatment of vasomotor symptoms with tibolone in breast cancer surgery patients – design and baseline data of the LIBERATE trial

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Background/Objectives: Many patients with a history of breast cancer (BC) will suffer from vasomotor symptoms, which can be induced or exacerbated by treatment with tamoxifen or aromatase inhibitors. A pilot study has shown that tibolone, which does not stimulate breast tissue, relieves vasomotor symptoms in patients receiving tamoxifen after BC surgery. LIBERATE was designed as a randomized, double-blind trial to evaluate that tibolone 2.5 mg/day (Livial®) is non-inferior to placebo regarding BC recurrence in women with vasomotor symptoms surgically treated for primary BC within the last 5 years. Secondary objectives are overall survival as well as effects on vasomotor symptoms, BMD and health-related QoL.

Methods: Patients had histologically confirmed and surgically treated BC (T1–3, N0–2, M0) and complained of vasomotor symptoms. In non-hysterectomized women, entry required normal thickness of endometrium as judged by TVUS, defined as absence of endometrial polyps in tamoxifen users and double-layer thickness ⩽4 mm or 4–8 mm (when inactive/atrophic) in non-tamoxifen users. The primary end-point is breast cancer recurrence rate. Frequency and severity of hot flushes and sweating episodes will be recorded regularly. The primary analysis will be performed mid 2007, with a follow-up analysis on all data in 2009.

Baseline data: Enrolment was completed in December 2004, with 3583 patients recruited of whom 3148 were randomized at 245 centers in 31 countries worldwide. Based on the data 11/2005, mean age at randomization was 52.6 years, and the mean time since surgery was 2.1 years. The mean daily number of hot flushes and sweating episodes was 7.3 and 6.1, respectively. For the primary tumour, stage IIA or higher was reported for >70% of the patients. In subjects whose receptor status was known, 79% of the tumours were ER+. Prior to or at study entry, tamoxifen was given to 74% of the patients and aromatase inhibitors to 8%, with other chemotherapeutic agents given in 70%. Regular unblinded safety reviews performed so far by an independent DSMB have led to recommendations to continue without modification.

Discussion: The adjuvant tamoxifen use in LIBERATE allows a comparison with the Stockholm trial (showing no risk of BC recurrence associated with hormone therapy), which was stopped prematurely subsequent to HABITS. The LIBERATE trial remains the largest and only ongoing, well-controlled study for treatment of vasomotor symptoms following BC surgery.

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Compliance and persistence of tamoxifen and aromatase inhibitors in breast cancer patients

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Objectives: For women with estrogen receptor positive tumors, adjuvant therapies that block estrogen or disrupt estrogen synthesis following breast cancer surgical approaches are indicated. There is little known about the utilization patterns of aromatase inhibitors (AIs) and tamoxifen since the introduction of AIs and even less known about adherence and