

with IDC and therefore a lower possibility of breast conserving surgeries. The impact of these results in terms of progressive free and overall survival for patients with ILC will be presented.

355

POSTER

Does placement technique affect the early complications of mammosite™ brachytherapy? Magee-Womens Hospital experience

A. Soran, J. Falk, S. Beriwal, D.K.J. Keenan, M. Balkan, A. Harlak, M. Bonaventura, R. Johnson. *Magee-Womens Hospital, Surgery, Pittsburgh, USA*

Brachytherapy has been used as an alternative to whole breast radiation for adjuvant treatment of early breast cancer following breast-conserving surgery. Open cavity (time of lumpectomy) and closed cavity (ultrasound guided) techniques have been described for placement of Mammosite™-catheter to deliver accelerated partial breast brachytherapy (APBB). Herein, we retrospectively analyzed our registry data and report early complications of both techniques.

Eighty-four early stage breast cancer patients have undergone APBB since 2002. An open technique was utilized in 70 patients (mean age is 64 (range 45–89) years) and closed technique was used in 14 patients (mean age is 62 (range 49–78) years). A dose of 34 Gy was prescribed to 1 cm from the balloon surface using ¹⁹²Ir high-dose rate brachytherapy and was delivered in total of 10 fractions, given twice daily for 5 days. CT was used to confirm that the balloon surface was adherent to lumpectomy cavity and to measure the balloon surface to skin surface. The median minimum distance between balloon surface to skin was 1.4 (0.5 to 4.5) cm in the open technique and it was 1.8 (0.7 to 2.5) cm in the closed technique. Average skin dose was 273 cGy in the open group and it was 255 cGy in the closed group. More than 50% of tumors were in upper outer quadrant in both groups. Average gross specimen size was 75.8 cm³ in open group and 88.2 cm³ in closed group. Re-excision rate prior to placement was 20% (14/70) in the open group and it was 29% (4/14) in the closed group. All patients received antibiotic treatment (7 to 10 days) during the Mammosite™ course. Median follow-up was 12 (4–40) months for open technique and 5 (3–28) months for closed technique.

Table 1: Acute complications of Mammosite™ brachytherapy

	Open technique (n = 70)	Closed technique (n = 14)
Leakage/drainage	2 (3%)	3 (21%)
Abscess	2 (3%)	
Wound infection	2 (3%)	1 (7%)
Balloon rupture	4 (6%)	1 (7%)
Acute skin toxicity grade 2	3 (4%)	1 (7%)

The incidence of persistent seroma (more than 6 months) was 31% (22/70) and aspiration was performed 13 times in 7 patients (10%; 7/70) in the open group. Because the median follow-up for closed group was 5 months it is early to reach any conclusion for persistent and symptomatic seroma differences. Forty-one patients have reached an average of 12 months follow-up since beginning our accelerated partial breast radiation therapy program. The overall cosmesis is excellent in 56% of patients, good in 37% of patients and fair 7% of patients based on the Harvard scale of assessing cosmesis. Despite the short follow-up and small sample size in the study, it seems that the Mammosite™ brachytherapy was well tolerated in patients with early stage breast cancer in both techniques, and overall cosmesis was excellent or good in 93% of patients.

356

POSTER

Different CMF regimens as adjuvant treatment for early breast cancer (EBC) in older patients (pts.): results from the NORA study

G. Mustacchi¹, M.E. Cazzaniga², P. Pronzato³, F. Di Costanzo⁴, A. De Matteis⁵, L. Porcu⁶, Z. Coccorullo⁷. ¹University of Trieste, Medical Oncology, Trieste, Italy; ²Treviglio Hospital, Medical Oncology, Treviglio, Italy; ³La Spezia Hospital, Medical Oncology, La Spezia, Italy; ⁴Careggi Hospital, Medical Oncology, Firenze, Italy; ⁵Pascale Institute, Medical Oncology, Napoli, Italy; ⁶Mario Negri Institute, Oncology Unit, Milano, Italy; ⁷Pietra Ligure Hospital, Medical Oncology, Pietra Ligure, Italy

NORA study aimed at investigating modalities of treatment and patterns of relapse in 3500 EBC pts, radically treated with surgery in 77 Italian Hospitals.

Overall, CMF was used in 928 pts (26.4%). We analyzed the main characteristics of the 246 pts (26% of all CMF) aged over 65 yrs (median

70, range 65–82) who received this regimen, as well typology and dose-intensity. The most frequent typology was iv 1.8–28 CMF (65.85%), followed by 1–21 regimen (30.89%), while classical (oral CTX) regimen was chosen only in 3.25% of the pts. In 68% of the cases CMF was followed by endocrine treatment (mainly tamoxifen).

Any CMF was administered mainly in Stage II tumors (70%) and in Node positive pts (56%: 1–21; 64%: 1.8–28). Curiously, 26% of the oncologists choose the 1–21 iv CMF considering it a standard guideline, as for 1.8–28 CMF. The planned treatment was suspended in 40% of classical CMF, in 5.5% of 1–21 CMF and in only 3.5% of the 1.8–28 regimen. Furthermore, treatment was modified (dose reduction or delay) in 11% (1–21) and 26% (1.8–28) of cases, mainly because of myelotoxicity. The administered median dose-intensity of all the drugs, as compared to the planned one, was reduced by 24.1% with classic regimen, by 20% with 1–21 and by 21.6% with 1.8–28 CMF. No substantial difference was noted between the different drugs.

In older breast cancer patients, CMF is widely used and in one third of cases the regimen of choice is the "1–21 iv", in spite of the lack of evidence from clinical trials. Actually drop outs for toxicity and dose-intensity reduction are similar to the better studied 1.8–28 CMF. The Classical "oral" CMF is not easy to manage in older patients.

357

POSTER

Local control, cosmesis and late sequelae following breast conserving therapy: influence of type of tumour bed boost and adjuvant chemotherapy

A. Budrukkar¹, R. Sarin¹, S. Shrivastava¹, D. Deshpande², K. Dinshaw¹.

¹Tata Memorial Hospital, Radiation Oncology, Mumbai, India; ²Tata Memorial Hospital, Medical Physics, Mumbai, India

Purpose: The aim of this report is to study the influence of type of tumour bed boost and adjuvant chemotherapy on local control, cosmesis and late sequelae in a large cohort of Indian women treated with Breast Conserving Therapy (BCT).

Materials and Methods: During 1980–2000, 1022 pathological stage I/II breast cancer patients (median age 43 years) underwent BCT. This consisted of wide excision, complete axillary clearance, whole breast radiotherapy (45 Gy in 25 fractions) with 6 MV photons plus tumour bed boost either with Low dose rate brachytherapy (LDR) of 15–20 Gy (n = 383), High dose rate brachytherapy (HDR) 10 Gy in single fraction (n = 153) or Electrons 15 Gy in 6 fractions (n = 460); ± systemic adjuvant therapy (SAT). Adjuvant chemotherapy (mostly CMF regimen) was given to 570 women. Median pathological tumour size was 3 cm (1–5 cm). Axillary node metastases were found in 39% women.

Results: The 5 and 10 year actuarial overall survival was 87% and 77% and disease free survival was 76% and 68% respectively. Actuarial 5 year local control rate was 91%. There were no significant differences in the local control between the 3 boost groups. Cosmesis was good or excellent in 78% women. At last follow-up, post radiation worsening of cosmesis over the pre radiotherapy score was observed in 10% women and was similar in the 3 boost groups. Late breast sequelae were observed in 25% women receiving single fraction HDR boost as compared to 13% in LDR (p = 0.0003) and 10% in electron group (p = 0.00009). In women receiving chemotherapy there was significant worsening in the cosmetic outcome (p = 0.02) while the local control and late breast sequelae were comparable.

Conclusion: The late breast sequelae were significantly more in women treated with single fraction HDR implants but the worsening of the post radiation cosmetic score between the 3 boost groups was comparable. Chemotherapy had an adverse impact on the cosmetic outcome but the late breast sequelae and local control rates were however comparable

358

POSTER

A Phase II trial of ultrasound-guided radiofrequency ablation of small invasive breast carcinomas

V. Khatri¹, J. McGahan², R. Ramsamooj³, S. Griffey⁴, J. Brock², M. Cronan², S. Wilkendorf². ¹University of California, Davis, Department of Surgery, Sacramento, USA; ²University of California, Davis, Department of Radiology, Sacramento, USA; ³University of California, Davis, Department of Pathology, Sacramento, USA; ⁴University of California, Davis, Department of Comparative Pathology, Sacramento, USA

Background: Local ablative therapy of breast cancer represents the next frontier in the evolution of minimally-invasive breast conservation therapy. The purpose of this Phase II trial was to determine the efficacy and safety of Radiofrequency (RF) ablation of small (≤1.5 cm) invasive breast carcinomas.

Material and methods: Sixteen patients with core-needle biopsy-proven invasive breast cancer ≤1.5 cm in diameter were enrolled in this trial.

Under real-time ultrasound guidance, the tumor and a 5mm margin of surrounding breast tissue were treated with RF ablation (Radionics Cool-Tip®, Burlington, MA) followed by immediate surgical resection. Pathologic and immunohistochemical stains (NADH-diaphorase cell viability analysis) were performed to assess tumor viability. We also examined whether there was any loss of ER and PR receptor expression following RF ablation to reflect non-viability.

Results: Fifteen patients completed the treatment: one patient was not treated because the tumor could not be visualized intraoperatively with ultrasound. The mean tumor size was 1.28 cm (range, 1–1.5 cm). The mean ablation time was 21 minutes (range, 9–36 minutes) using a mean power of 35.5 watts (range, 14–53 watts). During ablation, the tumors became progressively echogenic until the tumor margin could not be discerned. The echogenic response corresponded to the region of severe electrocautery injury at pathological examination. In 13 of 14 patients (92.8%), the ablated tumor showed no evidence of viable malignant cells. In one patient, the tumor was difficult to visualize by ultrasound and histological examination showed that non-tumor area had been ablated. Compared to pre-therapy biopsy, 8 patients showed complete loss of ER expression ($p = 0.0006$) and in remaining 6 patients there was a mean 42% reduction in ER expression. For PR expression, complete loss of expression was seen in 7 patients ($p = 0.008$) with a mean 66% reduction in the remaining patients. Following RF ablation, 2 patients developed skin puckering that required a narrow *en bloc* skin excision during lumpectomy but none developed skin necrosis. RF ablation did not interfere with sentinel node mapping. At a median follow-up of 25 months, there have been no adverse events in the ablated area and no evidence of local recurrence.

Conclusions: RF ablation is a promising minimally-invasive treatment of small breast carcinomas, as it can achieve effective cell killing with a low complication rate. Further research is necessary to optimize this image-guided technique and evaluate its future role as the sole local therapy.

359

POSTER

Risk factors for anastrozole-induced bone loss in breast cancer patients pretreated with tamoxifen: results of digital radiogrammetry of clavicle

J. Wojtacki¹, K.W. Zielinski², R. Wiraszka³. ¹Cancer Outpatient Clinic, Gdansk, Poland; ²Medical University, Lodz, Poland; ³Specialistic Voivodeship Hospital, Radom, Poland

Background: Newly developed aromatase inhibitors decrease concentrations of circulating estrogens to nearly undetectable levels. This phenomenon raises the possibility of increased risk of hypoestrogenemia-related diseases, including the bone loss. In two previous studies we stated that non-steroidal aromatase inhibitors such as letrozole (*Breast Cancer Res Treat*, 2003, suppl. 1, abstr. 445) and anastrozole (ANS) (*Eur J Cancer*, 2003, suppl. 1(5), abstr. 393) significantly enhance the radiological features of bone mass loss. The aim of current study is to verify above results on more representative group of patients and identify risk factors for ANS-related osteopathy.

Material and methods: Data for analysis were collected from 48 women (median age: 65, range: 55–80 years) with breast cancer, being postmenopausal for at least 5 years (median: 15, range: 5–27) and pretreated with tamoxifen (TAM; median: 22, range: 6–60 months). To study the influence of ANS on bone, we used radiogrammetrical digital analysis of clavicle based on chest PA X-rays radiograms routinely taken in each patient before and at least 6 months of treatment afterwards (median: 18, range: 7–28) and digitally processed using image analyser. The quantitative analysis was performed in the digital profiles of grey levels plotted perpendicularly to the axis of the bone shadow.

Results: The comparative analysis of the pairs of data taken before and during treatment revealed that the linear spongius/cortical width ratio (S/C) increases significantly in patients being under ANS treatment ($p = 0.001$). Another typical features observed after ANS were the increase of the contrast between cortical and spongius part of bone shadow as well as the coefficient of variance of grey levels profile (differences not significant). The following risk factors of osteoporosis were related to the radiogrammetrical features of bone loss: age at the beginning of anastrozole administration, duration of menopause, initial body mass index (BMI), changes in BMI values during therapy, duration of ANS and TAM therapy, history of cigarette smoking, previous hormone replacement therapy and non-traumatic bone fractures. Only duration of ANS therapy (6–12 vs 12–24 vs >24 months) was significantly ($p = 0.045$) associated with increased risk of radiological signs of bone loss (increase in S/C).

Conclusion: Our data confirm preliminary clinical data that ANS administration increases the risk of bone mass loss, particularly in patients under long-term therapy.

360

POSTER

Single duct nipple discharge and underlying breast malignancy

E. Kouskos^{1,2}, C. Markopoulos², D. Mantas², Z. Antonopoulou².

¹"Vostanio" Hospital, 2nd Surgical, Mytilene, Greece; ²"Laiko" Hospital, Breast Unit, 2nd Surgical, Athens, Greece

Background: In the present study we have reviewed all the surgically treated cases referred for single duct nipple discharge to our Breast Clinic during the last twelve years, in order to identify specific discharge factors related to breast malignancy. Nipple discharge is a quite common disorder presented by women attending to breast clinics, and it is reported in up to 3% of breast cancer patients.

Patients and Methods: Single duct nipple discharge was the presenting symptom of 127 patients. Clinical examination and radiologic assessment did not reveal any other significant breast abnormality. The patients' mean age was 47 years, ranging from 23 to 78 years. The discharge was spontaneous in 104 and elicited in 23 patients. In 58 (45.7%) cases the discharge was bloody/serosanguineous, in 48 (37.8%) cases it was serous/watery, and in the remaining 21 (16.5%) cases it was either green or yellow. Cytology of the fluid was performed in all cases.

Results: After surgical intervention (excision of the involved duct) benign breast disease was found in 106 (83.5%) patients. The usual findings were papillomas ($n = 73$), duct ectasia ($n = 19$), and papillomatosis ($n = 14$). The remaining 21 (16.5%) cases were found to have malignancy and underwent additional operation. Ductal in situ, lobular in situ, and early invasive cancer was found in 14, 3 and 4 cases respectively. Among the 58 patients with bloody discharge, 11 (19%) found to have cancer in histology. Papillomatosis and DCIS were observed mainly in older patients. Cytology was positive or suspicious for malignancy in 4 cases with benign histology, and in 13 cases (61.9%) found to have in situ or invasive carcinoma.

Conclusion: Older women with spontaneous, single duct nipple discharge, mainly when it is bloody/serosanguineous, should have cytological examination of the fluid and mammography depending on their age or additional clinical findings. Most of them will require a microdochectomy, as the possibility of finding a carcinoma among them is about 15%. However, single duct papilloma is the most common cause of bloody discharge.

361

POSTER

Semi-automatic setup system for breast irradiation

C. Collen, J. Van de Steen, G. Storme. AZ-VUB, radiotherapy, Jette, Brussels, Belgium

Background: A feasibility study to analyze and correct setup errors by on-line correction using a semi-automatic setup system (SAS) during breast irradiation.

Materials and methods: A graphical user interface, called SAS was in-house developed. This system was added to the free-movable treatment couch (Hercules, Precitron AB, Uppsala, Sweden). It allows viewing a reference (digitally reconstructed radiograph or DRR) and an active image (EPID), drawing a contour on the reference image that is simultaneously visible on the active image, moving the contour in the active image and automatically calculating the required table corrections. Correction factors are expressed in lateral (cross-plane) and longitudinal (in-plane) directions of the treatment field, viewed from the beam axis. The couch is moved by remote control from outside the treatment room. For each patient the systematic error is calculated after 4 sessions, the patient is repositioned and new laserlines are drawn on her skin. Afterwards monitoring can be continued, by verification EPID, to evaluate residual errors.

Results: A total of 108 measurements were performed. The maximum correction was 14 mm in lateral direction and 10 mm in longitudinal direction. The mean systematic error was 3.5 mm (SD = 2.5 mm) in lateral and 1.0 mm (SD = 0.4 mm) in longitudinal direction. The mean SSD value was 99.98 (range 100.5–99.3). Mean treatment time using SAS was 11.6 minutes versus 9.8 minutes without.

Conclusion: The SAS repositioning tool seemed to be a fast and easy to use graphical user interface. The additional time needed per session was acceptable to allow for implementation of this system in routine practice. The corrected errors are small and this can be explained by the fact that to shorten the learning curve all consecutive patients were included. More measurements need to be made to evaluate the hypothesis that on-line daily positioning is useful in "difficult-to-position" patients and that for other patients the SAS system can be used to detect and correct the systematic error. Another interesting application of this system is the routine use of the SAS system to replace treatment portal films.