PP-3-19 Axil 95

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AXIL 95 trial is a multicentric randomized phase III study, which describes the role of axillary node dissection among ≥ 50 years and menopaused women with localized breast cancer of under ≤ 10 mm.

The question is: is it possible to avoid axillary node dissection without impairing survival during the first treatment of small diameter breast cancer among menopaused women?

The treatment consists of phase III study comparing 2 approaches:

- Arm A: standard treatment of infiltrating breast tumors (tumorectomy + axillary node dissection + radiotherapy ± medical adjuvant treatment according to histopronostic factors and local strategies).
- Arm B: same locoregional treatment but without axillary node dissection. They systematically receive adjuvant hormonotherapy with Tamoxifen (20 mg per day over 3 years).

The evaluating criteria are: 1) overall survival; 2) number of axillary nodal relapses; 3) functional evaluation.

Statistical study: because of the small number of cancer related events in these patients, a population of 1612 patients are required (806 per arm) in order to assess the equivalence of both approaches, with a power of 90% and an error risk (type 1) of under 10%.

Trial starting on 1st October 1995.

Organizing center: Institut Bergonié, Bordeaux. Fax: 56 33 33 30 (A Avril, MD, L Mauriac, MD, F Bonichon, MD).

PP-3-20 Local Excision with a 10 mm Margin as Sole Treatment for Ductal Carcinoma in Situ (DCIS) of the Breast

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It has been suggested that radiotherapy to the breast is necessary to reduce the risk of local recurrence after excision of DCIS (NSABP B-17 Trial). In this study patients with localised DCIS (≤ 4 cm) underwent wide local excision. A complete cylinder of tissue was excised from directly beneath the skin down to pectoral fascia aiming surgically for a 1–2 cm circumferential margin. The circumferential margins were examined histologically to ensure at least a 10 mm margin of normal breast tissue from the tumour edges. Between 1988 and 1993, 59 of the 136 patients undergoing surgical treatment for DCIS at this unit were suitable for and chose wide local excision. In 18 of these patients the required excision margin was not achieved at the first operation and further surgery was advised. Subsequently, 11 patients underwent conversion to mastectomy, while in 7 the margins were re-excised to ensure the required 10 mm margin. The 48 patients with complete local excision did not receive post-operative radiotherapy. At a median follow up of 58 months, 3 (6%) of the 48 patients have developed a local recurrence in the treated breast. Although follow up in this study is still relatively short, the results compare favourably with the published results of the NSABP B-17 Trial, where at 43 months the local recurrence rates were 16.4% and 7% in the 'no radiotherapy' and 'radiotherapy' arms respectively. The results of this study suggest that if adequate excision of DCIS is ensured radiotherapy may be unnecessary.

PP-3-21 Loco-Regional Recurrences After Mastectomy in Breast Cancer

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Potential risk factors including flow cytometric derived parameters predicting loco-regional recurrence (LRR) in early breast cancer were investigated. This study included 608 patients treated by modified radical mastectomy between 1982 and 1987. Recommendations regarding local treatment as well as adjuvant systemic therapy did not change during this period. Patients treated by adjuvant chemotherapy were randomized to receive additional hormonal (MPA) treatment. Only 59 (10%) patients received postoperative irradiation (XRT) to the chest wall and/or axillary lymph nodes; another 121 (20%) patients received XRT to the intermammary nodes because of centro-medially located tumours.

The rate of LRR after a median period of 7.5 years was 15% (n = 93), either with (n = 30) or without (n = 63) concurrent distant metastases. The chest wall, regional lymph nodes or both were involved in 41 (44%), 38 (41%) and 12 (13%) patients respectively. At 10 years the estimated overall survival, disease free survival, distant metastasis free survival and loco-regional free survival was 55%, 50%, 57% and 80% respectively. Cox analysis revealed 4 factors associated with LRR: age ($p = 0.04$), pT ($p = 0.04$), nodal status ($p < 0.01$) and pathology ($p = 0.04$). Extracapsular tumour extension and a positive axillary node at the highest level, DNA ploidy and S-phase fraction, did not contribute to the risk independently. In univariate analysis no difference was found whether or not MPA was given.

PP-3-22 Hypofractionated Radiotherapy of Breast Cancer in Elderly

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The breast cancer is the most frequent cancer in elderly patients (over 65 years), because more women have real chance to live much longer and experience very old age. Chemotherapy and radical surgery are often contraindicated because these patients are considered to be more vulnerable due to presence of so called "concurrent" disease (cardiology, respiratory etc.). In one year period at the Institute of oncology and radiology in Belgrade two groups of elderly breast cancer patients were treated. Group A (48 pts.) were treated with concentrated radiotherapy (hypofractionation with split course) TD: 24–26 Gy on breast and 19 Gy on lymphatics, in 8 days (60-Co). The same treatment was repeated after 28 days rest period. 40 patients (group B) were treated with conventional radiotherapy in that period with TD 60 Gy and 20 Gy boost (breast) and 45 Gy lymphatics (with 15 Gy boost dose to the axila). There were no statistical difference between these two groups (age, clinical stage, type of surgery, patohistology). For group A median follow up was 30 months and for group B 26 months. The relapse incidence for group A was 35% with median relapse free interval 11.3 months and for group B 50% with relapse free interval of 16.2 months. There was no significant statistical difference between two group according to standard statistical methods (Hi quadrate test = 7.72 DF = 4 $p > 0.05$). The consensus about treatment of the breast cancer in elderly women is still not clearly established. Our data suggests that radical radiotherapy (– hypofractionated schedule) is an effective and suitable therapeutic approach in the management of breast cancer in elderly women.

PP-3-23 Risk Factors of Local Recurrence after Breast Conserving Therapy

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Since the beginning of the 1980's 1482 stage I and II breast carcinomas were treated with breast conserving therapy. Within this group 99 local recurrences (LR) occurred, with a 5-year local recurrence rate (LRR) of 8%, and a ten-year LRR of 12%. We were able to collect tumor samples of 71 cases with LR, matched each with two controls without LR but similar in follow-up time, menopausal and lymphnode status. The tumors of these 213 patients were histologically reviewed. In addition using immunohistochemistry expression of the following proteins were studied: estrogen and progesteron expression, neu/c-erbB2, Ki-67, cyclin D1, p53, E-cadherin, bcl-2, CD31, EGF receptor. The importance of these factors in relation with LR will be discussed.