## P64 Initial versus delayed radiotherapy combined with continuous 5-fluorouracile (F), cyclophosphamide (C) and doxorubicine (A) in inflammatory breast cancer (IBC)

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The prognostic significance of an early response to chemotherapy has been reported in IBC. The timing of radiation to concurrent chemotherapy could improve the local control and may influence distant recurrence and survival.

Ninety nine patients were randomly allocated to receive initial radiation therapy (IRT: n = 47) or 12 weeks delayed radiation therapy (DRT: n = 52). Both group received 8 cycles of A (50 mg/m2) + Vindesine (V: 3 mg/m2) + C (1200 mg/m2) + F (2500 mg/m2). A was omitted during irradiation. The median survival time was 61 months in IRT as compared with 53 months in patients treated with DRT (p = 6) The five year survival rate was respectively 50% and 43% (p = 0.6). No difference was found between the IRT group and the DRT group, regarding the local control 66% versus 78% (p = 0.2), the breast conservation 70% in both group, and the distant recurrence rate 64% versus 61% (p = 0.6).

No severe and life threatening side effects occurred.

Timing of concurrent RT to chemotherapy with continuous 5FU did not influence the local control, the distant recurrence and overall survival.

## P65 Radiotherapy and concomitant chemo or ormonotherapy in early stage breast cancer: Acute and late local toxicity

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From 1 august 1990 to 31 december 1993 we treated with adjuvant radiotherapy ± ormono or chemotherapy 276 consequently women, submitted to quadrantectomy plus axillary dissection for stage I or II breast cancer.

The mean age of the patients was 54 ± 10 years (28–78).

The whole breast was irradiated with 2 tangential fields of 60 Cobalt or 6 MV X rays and the booster dose was given with Roentgentherapy or direct field of electrons.

The mean dose to the breast was 50.6 ± 2.7 Gy Supraclavicular and internal mammary nodes, when treated, received respectively 45.6 ± 2 Gy and 46.2 ± 3.4 Gy. The mean booster dose was 9.8 ± 1 Gy.

The mean dimensions of the breast fields were 9.2 ± 2.2 cm (x) and 15.8 ± 2.1 cm (y); the ones of the boost were 8.2 ± 1.9 cm (x) and 9.5 ± 2.9 cm (y).

173 patients didn't receive adjuvant medical therapy and 54 patients were treated with concomitant adjuvant Tamoxifen 20 mg/d (Group A = 227 patients). 49 patients (Group B) were treated with concomitant chemotherapy: 41 women with 6 cycles of CMF and 8 women with 4 cycles of EPI-ADM followed by 6 CMF, dependently on the axillary lymph nodes status.

The mean follow-up was 1120 ± 408.4 days.

The mean overall RT treatment time was 43.9 ± 4.7 days; it was 44 ± 4.4 days in Group A and 45.6 ± 6 days in Group B.

We evaluated the *acute local toxicity* (EORTC-RTOG Scale) according to the treatment: a significant enhancement in grade 2 and 3 cutaneous and mucosal toxicity was observed in Group B (p 0.005 and 0.05 respectively), while no significant difference was observed in the incidence of grade 1 toxicity.

The *late local toxicity* was reported in our charts using the EORTC-RTOG scale and we didn't registered any significant difference between the two groups. We translated the objective and subjective late toxicity parameters in the new SOMA-LENT toxicity scale (in validation) and also with this extremely punctual method there were no differences between the two groups.

*Conclusions:* adjuvant concomitant radiotherapy and chemotherapy is a well tolerated schedule, radiotherapy and chemotherapy can be delivered without delay and the cosmetic results don't seem worse than the ones obtained with the two treatments administered sequentially.

## P66 Inflammatory breast cancer: Chemotherapy and concommittant radiotherapy

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We report an ongoing study in 70 inflammatory breast cancer (IBC) treated from 1990. Chemotherapy doses increased from 1993. Induction treatment consists in 3 courses of EPIRUBICINE 50 mg/m$^2$ or 75 mg/m$^2$, CYCLOSPHOSPHAMIDE 300 mg/m$^2$ or 500 mg/m$^2$, VINDESINE 2 mg/m$^2$ D1 and concommittant continuous infusion of CDDP 20 mg/m$^2$ and 5 FU 500 mg/m$^2$ D15 to D20 and bifractionnated RADIOTHERAPY 15 Gy in 5 days. 3 courses every 28 days were administered. PREDISONE and COUMADINE were given oraly during induction then RADIOTHERAPY boost until 65 to 70 Gy was given. 3 courses of MTX (1.5 g/m$^2$) and 6 courses of FEC (5 FU: 500 mg/m$^2$, CYCLOPHOSPHAMIDE 500 mg/m$^2$, EPIRUBICNE 50 mg/m$^2$) were administered. Hormonal treatment was given for 3 years. Median age was 49 y (31–73). 32 pts were premenopausal, 38 menopausal 56 pts were clinically IBC, 14 occult IBC. 15 pts were metastatic with 1 bone, 5 hepatic, 2 node 2 lung sites, 3 were bilateral. Local treatment was biopsy alone in 50 pts, tumorectomy or mastectomy in 20 pts, axillary dissection in 48 pts. In 50 evaluable local reponse, 45 complete clinical reponse were obtained 11 after 2 courses 34 after 3 courses, 3 partial reponse and 1 no reponse. 1 pt was not evaluated because a lung embolism, 6 biopsies by true-cut were performed in 12 pts to confirm complete clinical reponse. Survival evaluation was performed in 58 pts, 17 metastases occurred in 44 non metastatic diseases with a median delay of 19 m, 5 local recurrences: 3 were associated with lung (1) and liver (2), and 2 were the only sites (1 controlateral IBC, 1 ductal: size 1 mn). Median follow up is 30 m. Median survival for all patients was 53 m and is not attained in non metastatic patients.

Toxicity was mainly hematological with 64% neutropenia GIII or IV, 6 to 60% thrombopenia GIII or IV (in function of increased doses), 4 transaminases GIII or IV, 10 phlebitis. 2 deaths were noted during induction with 1 lung embolism and 1 hepatic dysfunction. More than 90% of planned doses of induction drugs were given. The results of this regimen are very enccuraging in these bad prognostic breast cancer.

## P67 Breast cancer: External beam radiotherapy and interstitial implantation – 10-Year clinical results

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The purpose is to present 10-year data of a prospective treatment method and demonstrate the safe use of combined external beam and interstitial Iridium-192 HDR irradiation.

Since 1984 HDR Ir-192 brachytherapy has been used to deliver an interstitial boost to the primary site in conservative breast cancer treatment. Up until December 1993 508 patients with 513 tumours have been treated (T1: 341, T2: 172, N+: 146, N−: 367). Treatment method (after tumourectomy or quadrantectomy) included external beam irradiation of 45 to 50 Gy to the breast followed by an interstitial 10 Gy boost. Mean follow up of survivors: 69 months (range 27 to 137).

5-years actuarial data (10-yr. data in brackets): Overall survival: 88.1% (69.7%), local control: 95.9% (89.7%), disease free survival: 84.5% (75.0%), and disease specific survival: 91.8% (77.1%). There were no severe complications. 412 out of 426 living patients (96.7%) live with their preserved breasts. The reasons for mastectomy were local recurrences in 10 cases, suspected recurrence in 3 patients and multiple abscesses in 1 patient after a glass-splinter accident 3 years after radiotherapy. The cosmetic outcome has been evaluated in the first 212 patients using a 4 grade scoring system: The mean value of cosmetic results after surgery (before radiotherapy) was 1.74, 5 years after radiotherapy 1.96. Normalizing the postoperative value to 1, the 5-year value changed to 1.13. The rate of good to excellent results before radiation therapy was 84%, and after 5 years 75%. Normalizing the 84% to 100% to exclude bad cosmetic results after surgery, the 75% changes to 89% good to excellent results after 5 years, representing exclusively the changes in cosmetic appearance after irradiation (± chemotherapy).

*Conclusion:* The use of a HDR source in boosting the primary tumour site after external beam radiotherapy with a dose of 10 Gy in 1 fraction is a safe procedure and has no negative impact on cosmesis. Our local relapse rate and survival data are very similar to those reported in literature. More than 96% of the patients live with their preserved breast.

## P68 Adjuvant chemotherapy of patients with primary breast cancer (PABC) by fluorouracil (5-FU)

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The goal of this study was to evaluate direct and late effects of 5-FU during radiotherapy of PABC.

*Materials and Methods:* Chemoradiotherapy was used in 366 patients with PABC ($T_{3-4}N_{1-2}M_1$). The patients had undergone $^{60}Co$ radiotherapy by conventional fractionation schedule at total dose 60 Gy to the breast and 40–50 Gy to the same side of axillary and supra/infraclavicular lymph nodes. Then all patients were treated by 4–6 cycles CMF or CAF chemotherapy. Besides, 210 out of 366 patients were administered 5-FU in the dose 1000 mg i.v. once a week for 30–45 min before irradiation during the course of radiotherapy (N = 4–6).

*Results:* Additional 5-FU chemotherapy leads to considerable reduction of primary breast tumour, local pain and decrease of involved skin area of the breast, if compared with patients of control group. The overall 5-year survival rate was 48.8% at the 5-FU group (210 patients) and 31.2% at 156 patients of control group.

*Conclusion:* Adjuvant 5-FU chemotherapy improves the direct and late results of the treatment of patients with PABC $T_{3-4}N_{1-2}M_1$.