Results: Comparing the optimal treatment position to our standard treatment position, the reduction in mean cardiac dose was 60% ($p < 0.001$), and in maximum dose was 32% ($p < 0.001$). The volume of cardiac tissue irradiated was also reduced for all patients. The mean NTCP with the standard technique was 7.4 ± 5.6% (range 0.6–17%) and for the new technique the mean NTCP was 0.3 ± 0.6% (range 0–2%), $p < 0.003$ for the difference between the 2 techniques.

Conclusion: The comparison between the two techniques has shown how simple variation in radiotherapy planning can result in substantial variations in NTCP, with a predicted reduction in late cardiac complications of 23 fold, not clearly evident from cardiac DVH raw data.

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Non-invasive follow-up of the viscoelasticity of the breast skin following radiation therapy

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Post-lumpectomy external-beam irradiation may be associated with early and Late radiation effects to the skin of the preserved breast. We have introduced a new method for the measurement of skin viscoelasticity following different protocols of radiotherapy. For the objective assay of skin condition we used our novel non-invasive viscoelasticity skin analyzer (VESA) which records accurately the speed of propagation of elastic mechanical surface waves on the skin. The VESA readings are inversely proportional to the viscoelasticity. A high correlation between the VESA measurements in contralateral areas of the breasts of healthy women was recorded with similar anisotropy. For the evaluation of late effects of radiotherapy, skin viscoelasticity of the breasts in 110 breast cancer patients from 3 medical centers was measured. In patients irradiated with 45–50 Gy in 1.8 Gy per fraction no significant late changes in the skin viscoelasticity were recorded in the treated relative to the untreated breast. Skin viscoelasticity seemed to be reduced with the increase in the dose of radiation per fraction rather then by the increase in the total accumulated dose given.

We have initiated a follow-up of early radiation effects in the skin with VESA and other dedicated devices that can evaluate other skin physiological parameters. The attenuation of radiation effects induced by high dose radiotherapy by daily application of Zn-based dermal regeneration cream is now being tested. Non-invasive analysis of metals in the skin with our unique Diagnostic-x-ray spectrometry (DXS) device have shown that the Zn in the cream tested (Triple Care, Smith & Nephew) is absorbed in the skin and its elevated concentration stay relatively constant along the continuous treatment. The radio-protective effect of this treatment is being now evaluated in breast cancer patients treated by radiotherapy following lumpectomy.

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Effect of radiotherapy in addition to 6 cycles CMF in node positive breast cancer patients

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Purpose: In 1984 the GBSG started a multicenter randomized trial to compare 6 cycles CMF with 6 cycles CMF plus radiotherapy as adjuvant treatment in node positive breast cancer patients treated with mastectomy.

Methods: During 5 years, 199 patients were randomized from 17 institutions. After a median follow up time of 8 years, the treatment groups (6 × CMF: 101 patients, 6 × CMF + Rad.: 98 patients) are compared with respect to time to recurrence and death.

Results: As first event of failure we observed in 22 patients a locoregional recurrence (LR) and in 80 patients distant metastases and/or death (DIST). With respect to disease free survival (DFS) no significant difference was observed (relative risk radiotherapy vs. control RR = 0.82 with 95% CI [0.55, 1.21]). An event specific analysis showed a significant benefit of radiotherapy with respect to LR (RR = 0.35, 95% CI [0.14, 0.91]) and no benefit with respect to DIST (RR = 1.01, 95% CI [0.65, 1.57]). With respect to overall survival (94 deaths) no treatment effect can be demonstrated (RR = 0.93, 95% CI [0.62, 1.40]).

Conclusion: There is a beneficial effect of radiotherapy on LR. Concerning DFS a tendency in favor of radiotherapy is observed, but this is not significant.

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Neo-adjuvant chemo-radiotherapy for operable breast cancer. Preliminary results of an ongoing phase II study

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Purpose: Primary chemotherapy (CT) is a widely adopted method to reduce the tumor diameter in operable breast cancer (BC) patients (pts) not suitable of conservative surgery (CS). Preoperative radiotherapy (RT) has shown, mainly in the treatment of locally advanced BC, to be at least as effective as CT in determining a significant tumor shrinkage. The aim of this study was to evaluate if the concurrent administration of preoperative CT and RT was a safe and effective method as primary treatment of operable BC.

Methods: From December 1994 to September 1997 52 pts entered the study. 31 are evaluable for results and toxicity. Age ranged from 32 to 70 years (median: 50 years). All patients had been considered not eligible for CS by the surgeon. Clinical tumor diameter ranged from 3 cm. to 6 cm. 26 pts were classified as T2 and 5 as T3. Treatment consisted of CMF (CTX 600 mg/sqm, MTX 40 mg/sqm, 5Fu 600 mg/sqm iv) on day 1 and 8. RT started on day 11 and 36 Gy were delivered to the whole breast in 2 weeks (5 days/week: 1.8 Gy b.i.d.). A second cycle of CMF started on day 28. Re-evaluation and surgery occurred about 3 weeks after the completion of the second course of CT. Postoperative chemotherapy consisted of 4 courses of CMF or EC according to the nodal status (negative or positive). Tamoxifen was given to all the ER+ pts.

Results: 28 (90.3%) pts were submitted to CS. In 3 cases a pathological complete response was achieved. 4 pts submitted to CS had focal involvement of the specimen margins. After the completion of postoperative CT 1 was submitted to mastectomy and 3 to re-excision of the tumor bed. Pathological examination revealed no residual tumor in the case submitted to mastectomy and in 2 out of the 3 submitted to re-excision. A total of 4 (12.9%) pts were, at the end, submitted to mastectomy. Local control was obtained and maintained up to date. Toxicity was mild and only a transient redness of the skin was observed after RT.

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Breast cancer in premenopausal women / should mastectomy be recommended?

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Purpose: To evaluate the role of age at diagnosis, as well as of local treatment on breast cancer outcome.

Methods: We retrospectively reviewed 3476 premenopausal women treated between 1981 and 1990 for stage I–III breast cancer. Median follow-up was 10 years. 1853 were treated by limited surgery and RT, 876 by RT, and 747 by mastectomy. We analyzed 3 groups of patients according age at diagnosis: Age 18–35 (335 patients), Age 36–40 (560 patients), Age 41–55 (2581 patients).

Results: 10-year rates of local and distant relapses according to age were 39%, 33% versus 19% ($p < 0.0001$) and 46%, 44% versus 30% ($p < 0.0001$), respectively. Multivariate analyses showed that: 1. The risk of local as well as of distant relapses was independently increased by young age; 2. The risk of distant relapse was strongly correlated to the time to local failure: the earlier the local failure, the stronger the risk or distant failure. The model was no more significant for a local failure which occurred >5 years following treatment; 3. The risk of distant failure was not influenced by the type of local treatment.

Conclusion: This study confirms, with a 10-year median follow-up time, that age at diagnosis (£40) is a strong independent predictor both for local and distant relapses, whatever the local treatment. In this study, local treatment was performed on the basis of clinical presentation. The higher risk of distant relapses associated with early local failure may reflect tumor aggressiveness rather than inadequate local procedure. So far, mastectomy does not seem to be able to improve the poor outcome of this particular age group.