irradiated with CT-based planning. After completetion of Radiotherapy, hormonal agent was continued unless the patient has to be withdrawn earlier owing to progressive disease (as per RECIST criteria).

Results: Tumor response was evaluated by monthly clinical examination till Radiotherapy begins (to asses the response to the hormonal agent alone) and after completion of Radiotherapy (to find the final response to hormone + concurrent Radiotherapy as per RECIST criteria). More than 50% tumor shrinkage was noted prior to Radiotherapy in 48/156 (31%) patients on tamoxifen and 18/65 (27%) on letrozole. Complete remission was achieved in 137/217 (63%) patients at a median interval of 3 months after completion of Radiotherapy i.e. about 7−8 months of commencement of hormonal therapy. Partial response was recorded in 64/217 and Stable disease in remaining 16/217 patients. Median time to progression was found to be a median 13 months for those having overall response and 8 months for those having stable disease. Although 2 year DFS was noted in only 42/217 patients, 2 year OS was recorded in 203/221 patients − 13/17 deaths were of unrelated causes. Surprisingly systemic metastasis was recorded in only 6/217 patients who completed Radiotherapy.

Conclusion: For estrogen receptor positive inoperable locally advanced elderly patients or those who refuse surgery, primary radio-hormone therapy proves to be a non-toxic well-tolerated inexpensive patient-compliant treatment option, which, till date remains nearly untrodden ground in world literature.

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Monthly versus three-monthly goserelin treatment in premenopausal patients with oestrogen receptor-positive early breast cancer

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Background: Goserelin is a luteinising hormone-releasing hormone agonist often used in combination with tamoxifen to treat premenopausal women with oestrogen receptor-positive (ER+) breast cancer. Due to its less-frequent administration schedule, a three-month goserelin 10.8 mg depot may provide a more convenient treatment option versus the current 3.6 mg monthly depot.

Materials and Methods: This multicentre, open-label, randomised study of premenopausal Japanese women with ER+ early breast cancer compared patients receiving goserelin 3.6 mg once every 4 weeks with patients receiving 10.8 mg once every 12 weeks. All patients received concomitant tamoxifen (20 mg/day). The primary endpoint was oestradiol suppression occurring over the first 24 weeks (area under the concentration time curve [AUC]). Secondary endpoints included: oestradiol and follicle-stimulating hormone (FSH) levels; the proportion of patients with oestradiol levels <30 pg/mL; menstruation; disease-free survival (DFS); and safety/tolerability. Treatment continued for 96 weeks or until discontinuation criteria were met.

Results: A total of 170 patients were randomised (84 to the 3.6 mg group; 86 to the 10.8 mg group). The mean AUCs for oestradiol serum concentration were 18.95 pg/mL·week (3.6 mg group) and 18.32 pg/mL·week (10.8 mg group). The baseline adjusted AUC ratio (10.8 mg/3.6 mg) was 0.974 (95% CI: 0.8, 1.19). Oestradiol and FSH levels were suppressed in both treatment groups; $\geqslant$98.8% of patients had oestradiol-serum concentrations <30 pg/mL by Week 4. Menstruation had ceased by Week 16 in both groups. Median follow-up periods for DFS were 675.5 days (3.6 mg group) and 675.0 days (10.8 mg group); a total of four recurrence events were observed during the study (one in the 3.6 mg group and three in the 10.8 mg group, respectively); plus one new cancer (in the 10.8 mg group). The incidence of adverse events (AEs) was similar between treatment groups. The most common AEs were hot flushes, nasopharyngitis and headache. No clinically important differences in the safety and tolerability profiles were found between treatment groups.

Conclusions: In terms of oestradiol suppression, goserelin 10.8 mg is non-inferior to goserelin 3.6 mg in premenopausal patients with ER+ early breast cancer. Both treatments have similar efficacy and similar tolerability profiles.

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Gemcitabine, carboplatin and paclitaxel as neoadjuvant combination chemotherapy in patients with locally advanced (stage III) or inflammatory breast cancer − a non-anthracycline alternative

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Background: The gemcitabine/paclitaxel combination is a highly effective regimen in metastatic breast cancer. Preclinical studies have demonstrated synergistic action, when combining a platin-derivative and paclitaxel. We examined the activity of combining gemcitabine, carboplatin and paclitaxel (GCP) in patients (pts) with locally advanced or inflammatory breast cancer (LABC or IBC).

Material and Methods: In the period 2002−6, 44 consecutive pts with LABC or IBC entered a phase II protocol of neo-adjuvant GCP (G, 800 mg/m^2 d1+8; C, AUC 4.5 d8; P, 175 mg/m^2 d1) every 3 weeks for 4−6 cycles. Median (range) age was 57 (32−76) years and 76% were postmenopausal. Tumor size (median): 80 mm range 7–150 mm; 74% were node positive; 10 had IBC; 85% were hormone receptor positive and 14% were HER2 positive. If there was no sign of response after two cycles of GCP treatment was shifted to CEF (750/60/750 mg/m^2) d1 q3w. After surgery, radiotherapy and adjuvant systemic treatment were given according to standardized guidelines (total of 9 cycles of chemotherapy).

Results: A total of 139 cycles (median 4 cycles (range, 1−6)) were given before surgery; 44 pts was evaluable for toxicity and survival and 39 pts for response. Non-haematological toxicity was mild: no grade 3−4 toxicity was found except that 3% had transient grade 3 increase of transaminases. Most common grade 1−2 toxicities were parestesia (47%) fatigue (36%), myalgia/arthralgia (38%), nausea/vomiting (16%), diarrea (7%) and allergic reactions/hypersensitivity (8%). Grade 1−2 haematological toxicity comprised neutrocytopenia, 21% and thrombocytopenia, 2%; grade 3−4 neutrocytopenia occurred in 12% (one grade 4) and thrombocytopenia in 1%. After two cycles a PR or a minor response (justifying continued GCP) were seen in 64% of the 39 evaluable pts, while NC were observed in 33% of the pts; no complete responses; one patient had progressive disease. A total of 22 pts shifted to CEF before final surgery due to insufficient response (14 pts) or toxicity (8 pts). At surgery 33% obtained a PR and 23% had NC. Radical surgery was possible in all pts. Median follow up time was 48 mos. The 5-year survival was 61% (95CI: 42−80 mos.). In the same period, 47 pts non-eligible to the present protocol or who did not wish to participate in the protocol received CEF (750/60/750 mg/m^2 d, 1q3w x 4−6). The 5-year survival of this (non-randomized) comparable group was 74% (95% CI: 49−89%).

Conclusion: As non-anthracycline drug combinations may be indicated in some clinical settings, we examined the activity of GCP in pts with LABC or IBC. The three drug combination can obtain comparable efficacy and an obvious decreased toxicity compared to traditional anthracyline containing regimens, making this combination an alternative when anthracyclines are not warranted. Updated results in relation to hormone receptor, HER2, P53 and TOP2A status will be presented.

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Locally advanced breast cancer; twelve years results from a single institution

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Background: The management of locally advanced breast cancer (LABC) requires a combined modality treatment approach involving surgery, radiation and systemic therapy. The introduction of new modalities in the adjuvant treatment of primary breast cancer treatment, such as taxanes, aromatase inhibitors and targeted treatments has made a major improvement in recurrence-free and overall-survival. These modalities have been passed on to the locally advanced setting. We now report treatment results for LABC patients treated in a single institution in the county of Funen, Denmark.

Material and Methods: Through a cross check from the national database (Danish Breast Cancer Cooperative Group − DBCG) and the treatment files of our department in the period 1.1.97–31.12.08, 111 patients were identified with LABC. LABC includes any **T3,** any **T4,** any **N2, M0**.

The chemotherapy regimens were mainly anthrycyline based whereas taxanes in the second half-part of the study were used either if no response where observed or in the adjuvant setting. Trastuzumab was used from 2005 in patients with HER-2 positive tumors, either preoperatively with a taxane or in the adjuvant setting.

The patients were analyzed according to treatment period (first vs last half-part) and response to treatment (pCR, PR, NC and PD).

Results: Patient characteristics: age median 58 (27−88), primary treatment chemotherapy 101 vs endocrine therapy only 10. Ninety seven