Methods: 228 pts with HER2-positive LABC randomly received neoadjuvant chemotherapy [CT] (3 cycles of doxorubicin–paclitaxel [AT], A 60 mg/m^2, T 150 mg/m^2 q3w, 4 cycles of T [175 mg/m^2 q3w], and 3 cycles of cyclophosphamide/methotrexate/5 fluoracil [CMF]: C 600 mg/m^2, M 40 mg/m^2, F 600 mg/m^2 q4w on days 1 and 8) plus concomitant Herceptin®; H (8 mg/kg loading dose then 6 mg/kg q3w for 1 year) before surgery [115 pts] or the same chemotherapy only [113 pts]. In parallel 99 pts with HER2-negative LABC received the same CT. The primary end point is event-free survival (data maturing); secondary end points included overall response rate (ORR), pathological complete response (pCR) and overall survival. We report here updated ORR and the percentage of pts in whom breast conserving surgery (BCS) became feasible after primary neoadjuvant treatment.

Results: Improvement of pCR with H (43% vs 23%) in NOAH trial was already reported (ASCO 2007, abstr. 532). In the intent-to-treat population the updated ORR was 89% for the trastuzumab+CT group vs 76% for the CT alone group ($p = 0.012$). After 10 cycles of neoadjuvant therapy, 96 pts (83.4%) from H+AT/T/CMF group and 88 (77.8%) from CT-alone group underwent surgery. Adding H to AT/T/CMF improved rate of BCS (23% vs 12.5%, $p = 0.07$). Furthermore, in the subgroup of patients who achieved a clinical response (>50% tumour size reduction), this improvement was significant (24.7% vs 10.8%, $p = 0.02$).

Conclusion: Addition of H to neoadjuvant CT significantly increased ORR, led to downsizing of HER-positive LABC, thus allowing for more surgical options, and doubled the rate of BCS compared with CT alone.

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External validation of a piecewise effect model of axillary lymph node involvement in elderly breast cancer patients

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Background: Conflicting data exist on the correlation between the presence of axillary lymph node metastasis (LN+) and increasing age in breast cancer. In a large database of a single center of 2227 consecutively treated patients with early breast cancer, a piecewise effect of age on lymph node involvement was found with an increase in lymph node involvement after age 70 mainly in smaller tumors (St-Gallen 2007). The statistical model was now prospectively investigated in an external database.

Patients and Methods: The population-based Eindhoven Cancer Registry was used to validate the prediction model. It contains data from 11061 women with early breast cancer diagnose between 1-1-2000 and 1-1-2006, and for 3448 pts data on age, tumor size and lymph node status were available.

Results: The piecewise effect and tumor size dependence was confirmed. Lymph node involvement decreases up to age 70 (OR per decade increase in age = 0.764, 95% CI = 0.732−0.797) while for age $\geqslant$70, there is an increase with increasing age (OR 1.554, 95% CI = 1.371−1.761). There was a significant interaction with tumor size ($p = 0.0182$) where this increase in lymph node involvement after age 70 was only seen in smaller tumors ($\leqslant$20 mm).

Conclusion: Axillary lymph node involvement decreases with increasing age until the age of 70y, but then increases again. This increase after age 70 is only seen in the smaller tumors and suggests a different behavior of small breast cancers in elderly patients.

We hypothesize that on the one hand, breast tumors may metastasize less frequently to lymph nodes with increasing age due to the decreased biological aggressiveness in these tumors. On the other hand, if the tumors have the potential to metastasize to lymph nodes in elderly, this occurs more rapidly in smaller tumors and this may be related to decreased immune defense mechanisms in elderly patients.

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Elderly breast cancer patients treated by conservative surgery alone and adjuvant tamoxifen: 15 years results of a prospective study

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Background: In elderly patients with early breast cancer and clinically clear axilla, axillary surgery, sentinel node biopsy and post operative radiotherapy to the residual breast may not be necessary because of reduced life expectancy, effectiveness of hormone therapy in achieving long-term disease control and generally favourable biological behaviour of breast cancer in elderly patients.

Methods: We followed 354 prospectively recruited women aged 70 years or more with primary operable breast cancer and no palpable axillary nodes treated by conservative surgery and adjuvant tamoxifen, without axillary dissection or postoperative radiotherapy. Cases with resection margins in tumor tissue were excluded.

Endpoints were cumulative incidence of axillary disease, cumulative incidence of ipsilateral breast tumor recurrence (IBTR) and breast cancer mortality.

Results: Pathological stage at presentation showed pT1 size in 274 (77.4%) patients, pT2 ($\leqslant$3 cm) in 59 patients (16.7%) and pT4 b ($\leqslant$2.5 cm) accounted for 6% of cases. Infiltrating ductal carcinoma represented more than 65% of all histological types. ER and PgR receptor status was available for 331 patients; of these, 310 (94%) patients were ER +, 227 (69%) were PgR +, 224 (68%) were ER + and PgR + and 18 (5%) were ER − and PgR −.

After a median follow up of 15 years (interquartile range 14−17) crude cumulative incidences were: 4.2% (4.0% in pT1) for axillary disease, 8.3% (7.3% in pT1) for IBTR, and 17.0% for breast cancer mortality. Of the 268 patients who died during follow up, 222 (83%) died from causes unrelated to breast cancer.

Conclusions: Elderly patients with early breast cancer and no palpable axillary nodes may be safety treated by conservative surgery without axillary dissection and without postoperative radiotherapy, provided that surgical margins are in tumor free tissue and hormonal therapy is administered. Sentinel node biopsy is also unnecessary due to the low cumulative incidence of axillary disease and axillary surgery can be reserved for the small proportion of patients who later develop overt axillary disease.

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China multicenter study of sentinel node biopsy substituting axillary node dissection: CBCSG-01 trial

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Background: China multicenter study of sentinel lymph node biopsy (SLNB) substituting axillary lymph node dissection (ALND) in breast cancer – CBCSG-01 trial was conducted from Jan. 2002 to Jun. 2007, with 1,970 SLNB pts recruitment. The primary objectives were 5ys DFS and complications between SLNB and ALND. The second objectives included 5ys OS, SLN intraoperative diagnosis, micrometastasis detection and prognosis, and radiologic safety.

Materials and Methods: Combined methylene blue dye and 99mTc-sulfur colloid or 99mTc-IT-Rituximab were used as tracers for SLNB. Preoperative lymphscintigraphy was mandatory for all pts. Pts with negative SLN did not receive ALND.

Results: The median age was 46ys. The median number of SLN was 2. Tumor size was less than 5 cm, with mean size as 1.9 cm. With the increase of the size and advance of the histopathology of the primary tumor, the positive rates of the SLN increased significantly ($p = 0.000$, both). The surgical types were as follows: BCS+SNLB 51.4%, Mastectomy+SLNB 26.1%, BCS+ALND 8.9%, and Mastectomy +ALND 13.6%, respectively. Mainly due to the difference of primary tumor sizes, the rates of BCS, SLNB substituting ALND, and the positive rate of SLN were different among different centers. With a median fellow-up of 42 months in one early center – Shandong Cancer Hospital, two cases of axillary relapse (0.82%) were found in 244 SLNB cases ($p > 0.05$), while the complications of SLNB were significantly lower than that of ALND ($p < 0.001$).

Conclusions: 1) First in China to conduct prospective, multicenter study for SLNB substituting ALND for clinically early stage breast cancer, with 1970 cases enrolled; 2) Combined methylene blue dye and 99mTc were used as tracers for SLN, with the successful rate of 99.5%; 3) SLNB technique could avoid ALND for SLN negative pts (77.8% of clinically axillary negative cases in our study); 4) SLN positive rates increased significantly with the increase of the primary tumor size, which indicated that pts with small tumor should be selected first for SLNB substituting ALND in fresh hands; 5) The SLN positive rate was 3.5% in DCIS, which