Results: Among 3323 women, 179 (5.4%) were classified at high familial risk and 2168 (65.2%) with no familial risk. Compared with women with no familial risk, women at high familial risk were younger and more likely to be diagnosed in recent years. They received less often sub-optimal locoregional treatments (adjusted Odds Ratio 0.6, 95% Confidence Intervals [CI]: 03−1.0). There were no significant differences in tumor characteristics and in use of systemic therapy between the two groups. Five-year breast cancer specific survival was 86% and 85% respectively for women at high and no familial risk. In the multiadjusted Cox analysis, breast cancer mortality risk was significantly associated to age, stage, grade, estrogen receptor status, locoregional therapy, but not family history (Hazard Ratio for high familial risk 0.6, 95% CI: 0.2−1.3).

Discussion: In postmenopausal women a strong family history is associated with better use of standard treatment but is not linked to tumor characteristics or prognosis.

72   Poster

Male breast cancer – a ten year overview

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Background: Male breast cancer is a rare disease accounting for less than 1% of all breast cancers with an annual prevalence in Europe of 1 in 100,000 and mainly affects men over the age of 70. Multiple risk factors have been reported including genetic factors, lifestyle (obesity, alcohol and oestrogen intake), occupation and other diseases (testicular and liver damage).

The aim of this study was to identify the incidence of breast cancer in men referred to our unit with a breast lump over a ten year period.

Methods: All patients referred to clinic with a breast lump between 1/8/1997 and 31/7/2007 were included in the study. Histology results were reviewed and patients with a diagnosis of malignancy were identified. Patient demographics, diagnostic methods used (Fine needle aspiration cytology (FNAC) or Core biopsy (CB)) and final histology was recorded. Data was analysed using Microsoft Access 2000.

Results: During the ten year study period a total of 519 men were referred to our clinic with a breast lump. Of these patients 29 patients (6%) were found to have a malignancy with a median age of 72 (range 27−92). Diagnosis was initially made by FNAC, CB or both in 23 of the cases. Histological type included invasive ductal carcinoma (23), non Hodgkins lymphoma (1), intracystic papillary carcinoma (1), anaplastic small cell carcinoma (1), leiomyoma (1) and invasive mucinous carcinoma (1). There was also one case of ductal carcinoma in-situ (DCIS) in a 27 year old man who underwent unilateral surgery for what was thought to benign gynaecomastia with no prior tissue diagnosis.

In addition one case of atypical ductal hyperplasia was found in a 24 year old male following bilateral gynaecomastia surgery with no prior tissue diagnosis.

All patients were treated in accordance with current practice guidelines.

Conclusion: Male breast cancer remains a rare disease and accounts for a small number of referrals to breast clinics. In our series only 6% of all men referred for assessment were found to have a malignancy. One issue that remains unclear from this study is whether there has been a change the aetiology of male breast cancer and age incidence. Should we consider CB for all male breast lumps with no suspicious features? which is outside the scope of this study.

73   Poster

Timing and severity of prominent side effects of anastrozole and tamoxifen

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Background: Side effect profiles of tamoxifen in the prevention/adjuvant setting and anastrozole in the adjuvant setting are well known. However, little data is available on severity and specifically on timing of these events. It is believed that the more participants of clinical trials know about occurrence and severity of side effects, the fewer and milder of these will the participant experience.

Methods: Women participating in the International Breast cancer Inter-vention Study (IBIS-I) and Arimidex, Tamoxifen Alone or in Combination Study (ATAC) gave detailed information of specific side effects at each 6 monthly follow-up visit. Side effects were defined as mild, moderate, or severe. Prominent side effects of tamoxifen and anastrozole have been analysed according to severity and the occurrence of these events. Here,

we will present new data specifically on timing and severity of side effects reported during the active treatment periods of the IBIS-I and ATAC studies.

Results: For both studies, results are presented for the active treatment period. In the IBIS-I study, highest rates for all severities were seen for hot flushes in both treatment arms, followed by headaches and nausea/vomiting. Gynaecological side effects were mostly of mild severities, with only slightly higher rates of moderate severities in the tamoxifen group compared to the placebo group. Overall, the majority of side effects were of mild severity in both treatment arms. In the ATAC study, a very similar picture was seen where most side effects reported were of mild severity. Highest rates were found for mild and moderate hot flushes in both treatment arms. The rate of severe hot flushes was much smaller but somewhat more related to tamoxifen usage. Other pre-defined side effects were mostly of mild severity and not reported as often as hot flushes. The timing of side effects was very similar in both studies with the majority of events being reported at the beginning of both studies (0−24 months). Detailed timing patterns of side effects and differences between side effects will be available for presentation.

Conclusion: The majority of side effects reported during IBIS-I and ATAC were of mild severity and occurred early during the treatment period. These results add new information to tamoxifen's and anastrozole's drug profile and are important to incorporate when counseling women to maximise compliance to endocrine treatment.

74   Poster

Young breast cancer patients with small localised disease: the impact of choice of treatment on survival

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Background: Discussion is still ongoing on the value of breast conserving surgery (BCS) in the treatment of young breast cancer patients. In several studies BCS has been associated with increased risk of local recurrence among young women, still there is insufficient evidence that this impairs long term survival. The aim of our study was to determine the effect of type of surgery on survival of young women (<40 year) with small localised breast cancer in a population-based setting.

Materials and Methods: Women diagnosed with breast cancer before age 40, with tumour size ⩽2 cm, without clinically positive lymph nodes, between January 1989 and January 2003, were selected from 3 population based cancer registries in the Netherlands, covering 6.3 million inhabitants. Logistic regression analysis was used to study the choice of treatment. Cox regression survival analysis was used to study the effects of surgical treatment, tumour size, lymph node metastases, age, period of diagnosis, radiotherapy and adjuvant systemic therapy on survival and was performed for lymph node negative and positive patients separately. Variables with $p < 0.1$ were entered in the multivariate analysis.

Results: A total of 1266 patients were included in the study (36% <35 years and 64% 35−39 years of age). In total 63% underwent BCS. In univariate analysis presence of lymph node metastases ($p < 0.001$) and younger age ($p = 0.091$) were associated with radical mastectomy (RM). In multivariate regression presence of lymph node metastases was associated with RM (OR 1.64, $p < 0.001$). Median follow-up was 8.6 years and 266 patients died during follow-up. Overall 5-year and 10-year survival was 88% and 79%, respectively. Patients treated with BCS had a 89% 5-year survival compared to 86% for patients treated with RM. For 10-year survival this was 80% and 76%, respectively. In node negative patients no variables were associated with survival. In node positive patients, survival was worse for patients treated with BCS without RT (HR = 2.79, $p < 0.001$) and patients treated with RM (HR = 1.6, $p = 0.026$), compared to patients treated with BCS with RT. Also, patients diagnosed before 1996 (HR = 1.67, $p = 0.003$) and patients not receiving adjuvant systemic therapy (HR = 2.18, $p = 0.002$) had worse survival.

Conclusions: Patients with positive lymph nodes were more often treated with RM compared to node negative patients. In node positive patients, treatment with BCS with RT had the best survival rate.

75   Poster

Hormone receptor status in breast tumours – An analysis of 11,273 cases

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Background: Breast cancer patients with tumors that are estrogen receptor (ER)-positive and/or progesteron receptor (PR)-positive have lower risk of mortality after their diagnosis compared to women with ER-

and/or PR-negative disease. The results presented in this analysis are from a single centre study on 11,273 partients with primary breast cancer treated in several hospitals in Croatia during the period of 15 years.

Methods: Patients tumour specimens were collected from 1990 and were analysed on ER and PR receptors in the Laboratory of the Department of Medical Oncology, University Hospital Zagreb.

Results: In univariate analysis, the proportion of ER+PR+, ER+PR−, ER−PR+, and ER−PR− tumours among our patients were 34%, 20%, 18% and 28%, respectively. We observed overall increase in proportion of ER+PR+ and ER+PR− tumours from 37% to 38% and 15% to 24%, respectively over 15 years. ER+PR+ tumours increased only among 20- to 49-years-olds and aged 80 and older. The proporton of women diagnosed with PR+ tumours, as well their number, decreased over the study period (56% vs 53%).

Conclusions: In this study we observed ER+ tumours increased with age, continously, with highest percentage in the age group of 70 to 79 years. Similarly, proportion of PR+ tumours was higher in the older age groups, being the highest between 40 and 49 years. During 15 years of the study we detected the trend of increase in frequency and proportion of ER+ tumours (for 10%) and the decrease of PR+ tumours (for 3.5%).

76   Poster

Long term results of breast cancer (BC) treatment (tt) in elderly patients (pts)

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Purpose: To evaluate retrospectively the characteristics and tt of BC in elderly.

Patients and Methods: Analysis of 617 pts $\geqslant$70 yrs treated for non-metastatic BC between 1995 and 1999 with a median follow-up of 91 months (3–146). Clinicopathologic characteristics and locoregional tt were analysed using Khi2 or Kruskal Wallis tests. Cause specific survival (CSS) and distant recurrence free interval (DRFI) were estimated by Kaplan–Meier and compared by Log Rank test; multivariate analysis used Cox regression.

Results: 3 groups (grp) were compared: I (330 pts; $\geqslant$70–<75 yrs), II (173 pts; 75−79 yrs), III (114 pts; $\geqslant$80 yrs). T1 tumors in the 3 grps were resp. 40.3%, 34.7%, 27.2% (p < 0.0001). Histology, hormonal receptors and SBR grading were not significantly different. In the 3 grps respectively, surgery was undergone in 99.1%, 94.2%, 75.4% of pts (p < 0.0001): 15.6%, 7.4%, 22.4% underwent conservative surgery without axillary node dissection (AND); 58.4%, 59.5%, 36.5% with AND, and 25.7%, 33.1%, 41.2% mastectomy and AND (p = 0.004). Neoadjuvant hormonal therapy (HT) was prescribed in 7.3%, 15.6%, 36.8% of pts (p < 0.0001); adjuvant (adj) HT in 46.1%, 59%, 52.8% (p = 0.001); adj. chemotherapy in 4.5%, 2.9%, 0.9% of pts (NS). At 7 yrs: CSS was: 0.91 [0.87−0.94] for grp I, 0.86 [0.81−0.92] and 0.85 [0.77−0.93] for II and III (NS); the DRFI was resp.: 0.88 [0.85−0.92] for I, 0.85 [0.79−0.91] − II; 0.86 [0.78−0.94] − III (NS). At 7 yrs the local control was 91.9%, 91.7% and 90.3% in the 3 grps. In multivariate analysis, the stage, oestrogen receptors and SBR grade remained prognostic for cause specific death risk and the stage, oestrogen receptors and clinical node involvement for distant recurrence risk adjusted on the other prognostic factors.

Conclusions: In our study the long term results of BC in elderly is identical to reported results for younger pts. It can be hypothesised that CSS could be improved by BC screening in elderly pts in order to detect more early T1 tumors.

77   Poster

The GISS Trial: A pilot phase randomized prevention trial of screening plus goserelin plus ibandronate, versus screening alone in premenopausal women at high risk of breast cancer

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Introduction: The availability of genetic testing for inherited mutations in breast cancer genes 1 and 2 provides valuable information on women at increased risk for breast and/or ovarian cancer. However, premenopausal women with increased risk in breast cancer have few clinical management options to reduce their risk without having surgical intervention.

Material: The GISS trial, a randomized, multi-center, open phase II trial assessed the feasibility of a preventive treatment with goserelin and ibandronate for premenopausal women at increased risk for breast cancer. The primary endpoints were the refusal to undergo randomization and the discontinuation of treatment; the secondary endpoints were safety, quality of life, sexual activity, cancer worry scale and changes in bone and breast density.

Results: Between 2001 and 2003, 31 out of 322 eligible women participated in the trial in 11 centers. One woman withdrew her consent after randomization; 15 participants received only screening and 15 received goserelin, ibandronate plus screening. Treatment was planned for 24 months, but after 12 months less than 50% of all randomized women participated. No difference in the agreement to randomization and compliance was assessed between the groups. After 12 months of treatment no significant differences were observed in severe side-effects, excepting hot flushes, headache and vaginal dryness. In breast tissue density, cancer incidence and quality of life evaluation no differences were evaluated between the two groups.

Conclusion: In conclusion, the treatment with GnRH analogues might offer a non-surgical option in the prevention of breast cancer when applied to premenopausal women, if efficacy can be proven in a larger population. To enhance the participation better information about health care is sorely needed.

78   Poster

ONCOPOOL – A European Dataset of 17,600 cases of breast cancer

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Objectives: To assemble a clinical reference database, recording tumour characteristics and pathology/biology, treatments, and follow-up outcomes compared with SEER.

Entry: From 12 European Breast Cancer Units. Primary Invasive, surgery first line, <5 cm, age <70. Consecutive cases diagnosed in each unit in periods in 1990's

Data: Retrieved and analysed for each unit and combined:
1. Size. Mean diameter all cases 18.0 cm (range of means by unit 17.0−20.7)
2. LN status, All Cases: neg 66%, 1−3 pos 24%, 4+pos 10%. Figures consistent across units. Negative rates were in "sampling units" (2 units, 67%) and "clearance units" (10 units, 64%)
3. LN status. v. size. Second order polynomial functions have been fitted (R2's all >0.9)
4. Grade. 87% graded. Average from 7 most consistent units: G1 23%, G2 41%, G3 86%
5. ER + 73%
6. Clinical outcomes and prognosis were reported in a separate paper
   ONCOPOOL is European based, data direct from units with high rates of retrieval, large range of variables, long term follow up, outcomes follow up from modern treatment protocols.
   ONCOPOOL now represents the standard dataset for breast cancer.