Material and methods: 1420 women (aged 40-80) insured by 4 major Hellenic health insurance companies were included in the study: 505 were insured by the Institute of Social Insurances (IKA), 549 by Agricultural Insurances (OGA), 260 by Public Insurance (DHM), and 106 by Trade and Craftsmanship's Greek fund = (TEBE). Women without health insurance coverage were used as a control group (Contr). The annual screening rates by means of clinical breast examination (CBE) and mammogram (MRX) were analyzed. For the subgroup of women aged 40-49 BCS practice was analyzed within a period of two years.

Results:

Age	Test	Contr	IKA	OGA	DHM	TEBE
40-49	CBE	26,0%	47,2%	38,2%	49,5%	36,1%
50-59	CBE	11,1%	27,9%	13,0%	27,3%	28,5%
60-69	CBE	9,0%	13,1%	10,5%	14,2%	10,3%
70-80	CBE	0%	11,6%	4,7%	6,6%	14,2%
40-49	MRX	20,0%	26,7%	23,4%	34,1%	27%
50-59	MRX	0%	22,0%	11,5%	17,8%	14,2%
60-69	MRX	9%	9,6%	10,0%	16,3%	3,4%
70-80	MRX	0%	13%	4,7%	6,0%	-

Conclusion: Health insurance coverage plays a main role in BCS practice. In all the age-subgroups analyzed women without health insurance showed the lowest rate both for mammography and clinical breast examination. However BCS practice did not exceed the 50% in any of the investigated subgroups.

Breast cancer adjuvant therapy

396 POSTER

Randomized controlled study comparing surgery alone, surgery plus tamoxifen, and surgery plus tegafur-uracil in patients with node-negative breast cancer: 5-year results from the Kanto cooperative study group of adjuvant chemo-endocrine therapy for breast cancer (ACETBC) of Japan

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Background: Development of highly convenient and safe postoperative adjuvant therapy is awaited specially for the patients with breast cancer without lymph node metastasis but with poor prognosis. We performed a randomized controlled study in Japanese women with node-negative breast cancer to compare the outcome of the three groups of patients assigned to surgery alone, or postoperative adjuvant therapy with tamoxifen, or surgery plus the oral 5-fluorouracil derivative tegafur-uracil (UFT). We report the results of 5 year follow-up.

Subjects and Methods: Eligible patients comprised women with breast cancer who had undergone mastectomy, had tumors of 5 cm or less in diameter, and had no histological evidence of lymph node metastasis. Enrolled patients were randomly assigned by the minimization method to receive surgery alone (surgery group) or surgery plus tamoxifen (tamoxifen group, 20 mg/day, orally for 2 years) or surgery plus UFT (300 mg/day, orally for 2 years). Treatment response was analyzed on an intention-to-treat basis.

Results: A total of 671 women (surgery group, 223; tamoxifen group, 224; UFT group, 224) were enrolled from 1992 through 1994. The 5-year survival rate was 93.2% in the surgery group and 95.5% in the tamoxifen group (vs. surgery, P = 0.27), as compared with 97.3% (vs. surgery, P = 0.041) in the UFT group. Subgroup analysis confirmed that UFT was very effective in high-risk patients whose tumors were 2 cm or more in diameter (vs. surgery, P = 0.041) or patients for estrogen negative receptor (vs. surgery, P = 0.037).

Conclusions: Our results suggest that postoperative chemotherapy withUFT is effective in women with node-negative breast cancer.

397 POSTER

Preoperative trastuzumab and vinorelbine (HN) is a well-tolerated, active regimen for Her2 3+/FISH+ stage II/III breast cancer.

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Introduction: The combination of Trastuzumab and Vinorelbine (HN) is well tolerated, with high clinical activity (RR 68-78%) in patients with HER2 overexpressing, metastatic breast cancer. To evaluate this regimen in early stage breast cancer, we conducted a phase II study of preoperative HN, followed by breast surgery, and postoperative doxorubicin/cyclophosphamide (AC).

Study Design: The primary endpoint was pathological complete response, defined as absence of invasive cancer. Eligible patients had HER2 3+ by IHC or FISH+ tumors, clinical stage II or III disease (including inflammatory breast cancer), and normal LVEF. Preoperative therapy consisted of trastuzumab (4 mg/kg x 1, then 2 mg/kg weekly x 11) with vinorelbine (25 mg/m^2 weekly x 12). Adjuvant AC at standard doses of 60/600 mg/m^2 respectively, every 3 weeks x 4, was given postoperatively. Higher risk patients subsequently received trastuzumab/paclitaxel; all patients received a total of 52 weeks of trastuzumab. LVEF was assessed at baseline, following HN, after 4 cycles of AC and every 3 months while on protocol-based therapy.

Results: To date, 39 patients with clinical stage II (12/39=31%) or III (27/39=69%) cancer have completed HN>surgery>AC therapy and are currently evaluable for efficacy and safety. Asymptomatic grade 2 cardiac toxicity was seen in 2 patients, following AC therapy. One patient came off study following AC for tachycardia with palpitations. Full dose HN was delivered on 302/324 HN planned weekly doses. A reduced dose of N was administered on 14/324 weeks and N was omitted 8/324 weeks. One patient had grade III stomatitis, and nausea. No other Grade III/IV toxicities were seen during HN. Clinical response (CR+PR) was observed in 36/39 patients (92%). Pathological complete response was observed in 8 of 39 patients (21%). In patients with residual tumor at the time of surgery, 85% had persistent HER2 by immunostaining (3+) or FISH (>2 copies HER2/cell). Correlative studies on HER2 in circulating tumor cells and tissue will be presented.

Conclusions: Neoadjuvant HN is well tolerated in women with stage II/III HER2+ breast cancer, and has significant clinical activity, warranting further exploration in early stage breast cancer. Residual breast cancer remains HER2 positive, suggesting that selection of non-HER2 expressing clones is not a common mechanism of resistance to Herceptin/vinorelbine.

398 POSTER

Self-reported cognitive function appears unimpaired by adjuvant chemotherapy for breast cancer in post-menopausal women.

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Our purpose was to evaluate the possible impact of adjuvant chemotherapy for breast cancer on cognitive and other functional domains of health-related quality of life (HRQL).

Methods. Sixty-five post-menopausal women completed the EORTC QLQ-C30 core HRQL questionnaire, BR23 breast cancer module, and other measures prior to, during, and at the completion of adjuvant chemotherapy, and 6 months later. All patients received 5-fluorouracil, doxorubicin, cyclophosphamide (FAC). Changes in QLQ-C30 functional scale scores of between 5 and 10 are perceived by patients as small, and changes of between 10 and 20 as moderate.

Results. Mean patient age was 60 years (range 31-80). Mean drug dose intensities ranged from 92-94%. Cognitive function did not change significantly from baseline (84 ± 18, mean ± standard deviation) to completion of chemotherapy (80 ± 20, P=0.11). The mean change in CF was -5 ± 19 (95% confidence interval (c.i.) 10 to 1) and was not related to patient age or drug dose intensity. By contrast, physical function, role function, social function and global health status decreased and fatigue increased during chemotherapy (all P<0.01). Mean changes in physical