women receiving an AI for non-metastatic breast cancer are analyzed in order to define whether chronic diuretic therapy could affect the impact of arthralgia on those patients.

Results: 42/288 patients were receiving chronic diuretic therapy for heart disease or hypertension (Group A), while 246/288 patients had never received any diuretic medication (Group B). At 43.03 months of mean follow up, in Group A arthralgia was developed in 3/42 patients (6.97%) as opposed to 39/246 patients in Group B (15.85%) – p value: 0.01. Other parameters that could affect the impact of arthralgia in both Groups are also analyzed and taken under consideration.

Conclusion: Reviewing our material, it appears that benefits arising from chronic diuretic therapy as far as Al-associated arthralgia is concerned are not statistically significant. Nevertheless, more research needs to be done in order to investigate the possibility of administering a diuretic agent as an alternative treatment to Al-associated syndrome.

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Stellate ganglion block induced by low level laser therapy to reduce adverse reactions of endocrine therapy in breast cancer patients

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Background: Endocrine therapy is an effect and safe standard treatment for breast cancer, however many patients develop menopausal symptoms due to a low estrogenic state. In many patients, quality of life deteriorates, particularly due to hot flashes and sweating. Generally these symptoms can be treated with various methods such as Chinese herbal medicine, SSRIs, isoflavone, yoga, etc., but the results is insufficient. In 2008, Lipov etal. reported that stellate ganglion block is an effective treatment for hot flashes and night awakenings in breast cancer patients.

We report a case of a treatment using a stellate ganglion block induced low level laser therapy (LLLT) which is a non-invasive and safe method.

Material and Methods: We treated 20 patients with LLLT. All patients had received endocrine therapy, such as LH-RH agonist + TAM or TAM or Als, and the average age was 44.1. A previous treatment for menopause-like symptoms such as hot flashes, sweating and insomnia was included in an untreated patient, but as is common, Chinese herbal medicine and SSRIs were given.

Written informed consent was obtained prior to the start of therapy. We used two machines: one was a low-level diode laser device and the other was a near-infrared laser device. The laser photoradiation site was the sixth and seventh cervical transverse process vertebrae.

Treatment time was approximately 10 minutes. We evaluated the therapeutic effects and according to symptom frequency using a hot flash score

Results: No adverse effects of treatment were recognized, and the hot flash score mean decreased from 63.2 points before treatment to 28.0 points after treatment. In addition, we were able to confirm a decrease in the frequency of hot flashes and sweating in 85% of all patients.

Conclusions: Stellate ganglion block by LLLT is effective on hot flashes and sweating in breast cancer patients. We believe that the introduction of a safe, non-invasive procedure which is extremely simple, for treatment of the adverse reactions of breast cancer endocrine therapy could be significant.

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The effect of exemestane and anastrozole on bone mineral density and bone turnover markers in postmenopausal early breast cancer patients: final results of 3 years after randomization of N-SAS (national surgical adjuvant study) BC04, the TEAM Japan sub-study

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Background and Aims: Postmenopausal women treated with aromatase inhibitors/inactivators (Als) are known to be at risk for bone loss. In preclinical studies, a steroidal Al has a different effect compared with non-steroidal Als. We aimed to investigate the difference among exemestane and anastrozole in the effect on bone mineral density (BMD) and bone turnover markers in patients with postmenopausal primary breast cancer treated with those agents as adjuvant endocrine therapy.

Patients and Methods: Of the 247 postmenopausal patients randomized in the N-SAS BC04 trial, the number of the patients included in the present study for exemestane (25 mg/day) arm was 27, anastrozole (1 mg/day) arm was 23 and tamoxifen (20 mg/day) arm was 26. In Tamoxifen arm, treatment changed from tamoxifen to exemestane at

2.75 years after randomization and, therefore, tamoxifen group was excluded in the present analysis. BMD was measured by dual-energy x-ray absorptiometry at baseline, 12, 24 and 36 months after treatment initiation. Urinary type I collagen cross-linked N-telopeptide (NTX) and serum bone specific alkaline phosphatase (BAP) were measured as bone turnover marker at baseline and 3, 6, 12, 24 and 36 months after treatment initiation. All patients are within normal limit in BMD at radomization.

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Results: Although there was no significant difference in BMD level at 12 and 24 months among 2 arms, there was a significantly lower in anastrozole arm compared with exemestane arm at 36 months. NTX level did not change during 36 months period in exemestane and anastrozole arm. BAP level also constantly increased in exemestane as well as anastrozole arm.

Conclusion: Although there were no significant differences in the bone turnover marker levels between exemestane and anastrozole arms, a favorable effect of exemestane in bone mineral density profile was observed at 36 months after randomization. There might be some differences between steroidal and non-steroidal AI. Further clinical studies are mandatory to confirm these phenomena.

| BMD | Entry | 1 year | 2 years | 3 years |
|---------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| ANA | | | | |
| mean(SD) | 84.49 (13.90) | 80.55 (10.91) | 79.87 (9.41) | 79.99 (8.84) |
| min-max (median) | 47.0-106.3 (80.4) | 59.1-98.4 (78.4) | 63.8-97.3 (78.4) | 70.1-96.1 (78.9) |
| Q1-Q3 | 76.1-95.4 | 73.5-90.0 | 72.5-88.5 | 72.2-87.7 |
| EXE | | | | |
| mean(SD) | 85.77 (13.02) | 86.33 (13.56) | 85.67 (12.32) | 86.47 (11.71) |
| min-max (median) Q1-Q3 | 65.6-118.0 (83.8) 75.7-93.8 | 63.6-114.8 (83.4) 74.6-94.1 | 65.4-107.2 (84.0) 74.2-95.3 | 73.4-105.8 (80.9) 75.0-95.1 |

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Bone effects of anastrozole in Japanese postmenopausal
breast cancer patients: results of a two year follow-up multicenter
prospective study (SBCCSG-06)

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Background: Anastrozole is superior to tamoxifen in terms of efficacy and safety for adjuvant treatment in postmenopausal patients with hormone-responsive early breast cancer. Based on therapeutic guidelines, anastrozole is widely used for adjuvant treatment in Japan. However, there are only a few reports on the safety of anastrozole in Japanese patients, especially the long-term effects on bone mineral density (BMD). The aim of this study is to evaluate the frequency of bone fracture and impact on BMD during the course of adjuvant treatment with anastrozole in Japanese patients. This is a report on the updated two year follow-up data after the first year of analysis.

Patients and Methods: The SBCCSG-06 trial included 350 post-menopausal patients with confirmed the hormone-sensitive stage I to IIIA breast cancer (oestrogen or progesterone receptor positive). All patients received anastrozole (1 mg/day) for five years as adjuvant treatment. Patients underwent clinical examination for any bone fractures and annual check-up for BMD (YAM %: young-adult-mean) during the course of treatment. The oral bisphosphonates were used concomitantly with anastrozole for patients diagnosed with osteoporosis (YAM < 70%).

Results: After a median follow-up of 29 months (ranging from 1 to 47 months), 330 women were analyzed at the time of data cutoff. Bone fractures occurred in five cases, and annual fracture rates were 0.6% (2/330) at 12 and 24 months. The overall median BMD were 85%, 82% and 81% at the time of pre-treatment, at 12 and 24 months, respectively. Paired t-test revealed that BMD significantly decreased in each period of 12 months.

Conclusions: In this multicenter prospective study, there was a significant reduction of BMD in Japanese patients after two years of treatment with anastrozole. We recommend that annual monitoring of BMD be mandatory in treated patients. Moreover, long-term follow-up data is necessary to elucidate the racial disparities of the safety profile of anastrozole.

371 Poster Medical intervention side effects prevention throughout breast cancer treatment

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Background: Breast cancer patients quality of life is negatively affected not only due to functional deficiency caused by the malignome itself, but also due to medical treatment side effects (limited shoulder movement, arm lymphoedema on the operated breast side), which lead to functional handicap and severely affect patient's life quality.

The aim of this research is to show frequency of medical interventions side effects: limited shoulder movement and arm lymphoedema on the operated breast side, along with early education on medical treatment side effects prevention among treated patients.

Material and Methods: 100 members of "Renesansa", association of patients treated from breast cancer in Canton Sarajevo, who underwent breast cancer treatment within the period span of 1 to 10 years, but experienced neither any metastatic illness nor infection, were examined on side effects mentioned above. Subjects of this research answered surveys, questions asked were regarding education provided by health professionals about medical intervention side effects prevention; were they given early rehabilitation treatment about basic illness and were they given instructions about necessary lifestyle alterations (diet, physical activity, smoking, and alcohol consumption).

Results: Among examined 100 patients, 49% manifested lymphoedema of varying stage, 39% experienced limited shoulder movement on the operated breast side, 27% experienced both side effects. Early rehabilitation treatment related to the base illness was provided to 5% of research subjects, 8% were educated about medical intervention side effects prevention measures and treatment options, 3% were educated on life style alterations after breast cancer due treatment.

Conclusion: Inexistence of systematic medical intervention side effects prevention approach for patients treated from breast cancer, along with inadequate and insufficient therapeutical treatment by health professionals, in addition to ignorance shown towards occurring problems among treated patients due to lack of education about treatment possibilities and side effects control, resulted in large number of medical intervention cases (arm lymphoedema 49%, limited shoulder movement 39%, both side effects 27%).

Early education about medical intervention side effects prevention should be made a mandatory part of breast cancer treatment protocol.

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NACLT (Non-ablative CO₂ laser 10600 nm therapy): a new approach to relieve pain in mild to moderate oral mucositis following breast cancer chemotherapy (a pilot study)

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Background: Oral mucositis after breast cancer chemotherapy is a disabling side effect which is sometimes potentially life-threatening. The pain may be so severe that interfere with eating, drinking and even speaking.

Materials and Methods: Six patients with painful oral mucositis following Docetaxole chemotherapy were included. Before laser irradiation, a layer of transparent, non-anesthetic gel with high water content was placed on the lesions. The lesions were irradiated with CO₂ laser 10600 nm through the gel layer. The patients reported their pain on VAS (visual analogue scale) before and immediately after laser and up to 7 days post operatively.

Results: Immediately after CO_2 laser irradiation of the lesions through the gel (NACLT), the severity of pain declined immediately and it was sustained during follow-up periods (P < 0.001). The procedure itself was painless and anesthesia was not required. There was no visible side effect such as ulceration, erosion and even erythema following NACLT.

Conclusion: Our results suggest that single session of low power, non-ablative CO_2 laser therapy (NACLT) reduces pain in oral lesions of mild/moderate post chemotherapy mucositis immediately and dramatically without visible side effects.

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Docetaxel related neutropenic sepsis rate in breast cancer patients during adjuvant and neoadjuvant chemotherapy; a retrospective study

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Background: Docetaxel has been identified as an important chemotherapeutic agent in the treatment of breast cancer (Miguel et al, 2005 & Henri Roché et al, 2006). In published clinical trials grade 3 and 4 neutropenic sepsis rate (NSR) has varied widely from 10 to 40% (Etienne et al, 2005). The aim of this study was to identify the grade 3 and 4 NSR during routine clinical practice and the associated effect of granulocyte colony stimulating factor (GCSF) use.

Material and Methods: A retrospective data was collected from electronic patients' records in the twelve months period from June 2008

until June 2009. A total of 97 patients received either adjuvant 3 weekly 5 flurouracil, epirubucin 100 mg/m² & cyclophosphamide (FEC100) 3 cycles followed by 3weekly docetaxel 100 mg/m² 3 cycles or neoadjuvant 3 weekly epirubicin 90 mg/m² & cyclophosphmide (EC90) 4 cycles followed by 3 weekly docetaxel 100 mg/m² 4 cycles. All patients were chemonaive with no significant co-morbidities. The rate of Grade 3 and 4 neutropenia has been identified and sepsis was defined as a record of temperature of 38° during neutropenia.

Result: Of the 97 patients identified 58% (56/97) received neoadjuvant and 42% (41/97) received adjuvant chemotherapy. Approximately 68% (66/97) of patients had the full intended course of docetaxel 100 mg/m², the remaining patients had either dose reduction or early termination because of other toxicities. Grade 3 and 4 neutropenia was identified in 55% (53/97) of patients, of which 58% (31/53) during the FEC or EC and 42% (22/53) during docetaxel. Secondary GCSF prophylaxis was used in 31% (30/97), 17 patients received it prior starting docetaxel. Total NSR was found to be 30% (29/97), almost 9% (9/97) during FEC or EC and 21% (20/97) during docetaxel. No patient developed neutropenic sepsis while on GCSF. Conclusion: In this study NSR during standard clinical practice of neoadjuvant/adjuvant docetaxel was 21% and 30% overall when using a sequential anthracycline-taxane regimen. Therefore the use of primary GCSF prophylaxis is advisable.

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Patient-reported outcomes in breast cancer patients undergoing endocrine therapy (PRO-BETh): impact of CYP2D6 genotype and side-effects on adherence rates

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Background: Only few studies have investigated the issue of breast cancer patients' adherence to tamoxifen therapy and factors influencing adherence behavior. Especially in the context of different CYP2D6 genotypes adherence to tamoxifen has not been extensively studied yet. Variations in the CYP2D6 genotype, as well as patients taking inhibitors of CYP2D6 (e.g. antidepressants) contribute to different side effects and adherence rates to adjuvant tamoxifen.

Materials and Methods: 106 breast cancer patients who met inclusion criteria were consecutively included in the study at the outpatient unit of the Department of Gynecology, Innsbruck Medical University. Within their routine after care appointment patients completed a comprehensive PRO assessment including the FACT-B/ES, the HADS and a self-report questionnaire on adherence behavior (SMAQ). The multi-method approach comprised the Simplified Medication Adherence Questionnaire, a semi-structured interview, physicians' ratings and blood levels for tamoxifen metabolites. Additionally, the CYP2D6 genotype was determined in all patients participating in this part of the study.

Results: Consistent with from earlier studies we could confirm that patients with CYP2D6*4 genotype (extensive metabolizers) suffered more extensive side effects from tamoxifen therapy than patients with genotypes leading to less extensive metabolism of the pro-drug tamoxifen. The adherence rates of extensive metabolizers were lower than in the poor metabolizer group. In addition anti-depressants were more frequently prescribed in the extensive metabolizer group leading to lower levels of the active metabolite endoxifen.

Conclusion: Adherence rates to adjuvant therapy depend on various factors including the CPY2D6 genotype. Determination of the CPY2D6 status may become a very important tool in the future to improve adherence to endocrine therapy with tamoxifen.

Important to note: final results of analysis are pending and therefore this abstract is preliminary.

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Taxane based regimen as a risk factor for chemotherapy induced amenorrhea (CIA)

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Background: Study design was so to show the impact of chemotherapy on induction of amenorrhea (CIA) in premenopausal women with breast cancer in all ages.

Material and Methods: This is a follow-up study in 226 premenopausal women with breast cancer, median age of 40 yrs (26–56 yrs) who received one of the three groups of chemotherapy regimens: Conventional (CMF), anthracycline based, and anthracycline-taxan based. They were evaluated for CIA in the follow-up clinic of ICBC. Statistically analysis using SPSS