

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 therapeutic 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 CO<sub>2</sub> 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 CO<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> 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 (G-CSF) 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 fluorouracil, epirubicin 100 mg/m<sup>2</sup> & cyclophosphamide (FEC100) 3 cycles followed by 3weekly docetaxel 100 mg/m<sup>2</sup> 3 cycles or neoadjuvant 3 weekly epirubicin 90 mg/m<sup>2</sup> & cyclophosphamide (EC90) 4 cycles followed by 3 weekly docetaxel 100 mg/m<sup>2</sup> 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/m<sup>2</sup>, 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 G-CSF 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 G-CSF. **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 G-CSF 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 CYP2D6 genotype. Determination of the CYP2D6 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-taxane based. They were evaluated for CIA in the follow-up clinic of ICBC. Statistically analysis using SPSS

software was performed and logistic regression was used to determine the risk factors of CIA.

**Results:** From 226 patients who entered the study, 154 patients (68.1%) were developed CIA, which in 101 patients (65.6%), CIA was established and never resumed. CIA was present in 52.5% of patients treated with conventional regimens (CMF), in 66.7% of patients treated with anthracyclines and in 78.7% of patients treated with anthracycline-taxan ( $p = 0.015$ ). Although a slightly superior incidence of CIA in patients with hormone-insensitive tumors (ER- and PR-) versus hormone-sensitive tumors (ER+/or PR+) treated with combination regimens was observed, no statistically significant difference was found ( $p = 0.629$ ). From all risk factors that evaluated, anthracycline-taxan based regimen (OR: 4.1, CI95%:1.6–10.2) and age >40 yrs (OR: 3.2, CI95%: 1.7–6.1) were the most important factors in developing CIA in the study.

**Conclusion:** Type of chemotherapy and age at the breast cancer diagnosis are the most important risk factors in CIA.

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### Is arthralgia observed in patients treated with adjuvant aromatase inhibitors for breast cancer related to inflammatory rheumatism? Rheumatologic evaluation of a cohort of 36 patients

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**Background:** Arthralgia are frequent side effects in patients treated with aromatase inhibitors (AI). The objective of this study was to determine the rheumatologic pattern of these arthralgia.

**Material and Methods:** An evaluation of patients treated with AI reporting arthralgia was performed, including a clinical examination, biological (inflammatory and immunologic) and morphologic (radiography, ultrasonography and/or MRI) assessments.

**Results:** 36 patients, treated with anastrozole (28), letrozole (6) or exemestane (2), were evaluated. Seven patients had previously received tamoxifen, 15 chemotherapy. The average time of onset's pain was 3 months after starting AI. Patients reported either polyarthralgia of the hands, wrists, knees, ankles, feet (24/36), or isolated pain of the hands and wrists (10), ankle (1) or knees (1). Stiffness (9), myalgia (7), synovitis (2), tenosynovitis (2), carpal tunnel syndrome (7) were also identified on clinical examination. On biological assessments, only 5 patients had moderate elevation of CRP, without any other obvious etiology. CPK were normal. Rheumatoid Factor and Anti-CCP antibodies (specific rheumatoid arthritis antibodies) were negative, Antinuclear antibodies were positive at low levels (1/80 to 1/640) in 7 patients without any specificity or argument for systemic diseases. X rays showed hand, trapezometacarpal or knee osteoarthritis in two thirds (24/36) of the patients. Two patients had chondrocalcinosis, 2 calcaneal enthesopathies, and none had radiographic evidence for rheumatoid arthritis. On the 29 ultrasonographies, synovitis were observed in 55% and tenosynovitis in 41% of the patients. Only 3 patients had erosions associated with osteoarthritis. MRI of the hand, performed in 25 patients, showed synovitis in 76% and tenosynovitis in 60% of the patients, frequently on the ulnar extensor of the carpus (78%) and de Quervain's tenosynovitis (21%). There was no erosion, but a significant incidence of hand osteoarthritis.

**Conclusion:** This study confirms the absence of specific inflammatory rheumatism such as rheumatoid arthritis or Gougerot Sj  gren syndrome associated to arthralgia in patients treated with AI. Synovitis and tenosynovitis associated with osteoarthritis underlines the link between oestrogen deficiency and local inflammation.

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### Patient-reported outcomes in breast cancer patients undergoing endocrine therapy (PRO-BETH): adherence rates and symptom burden over the disease trajectory

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**Background:** Only few studies have investigated the issue of breast cancer patients' adherence to aromatase inhibitor (AI) therapy and factors influencing adherence behavior. These limited results are inconsistent and vary due to heterogeneous study designs and methodological problems.

The main objective of our study was the comprehensive evaluation of adherence rates over the course of AI therapy in post-menopausal breast cancer patients using a multi-method approach. We focused on the impact of patient-reported physical symptoms and psychosocial burden on patients' adherence behavior.

**Materials and Methods:** 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 patient-reported outcome (PRO) assessment including the FACT-ES, the HADS. In addition, adherence was rated by the treating physician.

**Results:** 169 patients (mean age 64.2 SD 8.7) within AI therapy at least 3 months and no more than 5 years after primary treatment were included in the study. 10 patients (5.9%) were rated as being non-adherent. We found no significant differences between adherent and non-adherent patients with regard to PRO scales. A trend level significance in favour of non-adherent patients was found for endocrine symptoms (effect size 0.69;  $p = 0.08$ ) and depression (effect size 0.75;  $p = 0.09$ ).

**Conclusion:** In contrast to the literature we found very high adherence rates. Our results suggest, that there might be an association between adherence and depression and endocrine symptom burden. Further research is necessary to explore causal relations between these factors which are supposed to be interdependent. Due to the low proportion of patients rated as being non-adherent, group comparisons suffered from a relevant lack of power. As patient recruitment for this study is still ongoing, this might be overcome.

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### A multicentre prospective longitudinal study establishing level II evidence of health related quality of life after types of immediate latissimus dorsi (LD) breast reconstruction

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**Introduction:** NICE recommends that the majority of women recommended to undergo mastectomy should be offered immediate breast reconstruction with its potential benefits to improve health related quality of life (HRQL). A systematic review shows poor and conflicting evidence with a lack of 'hard' data to best inform both clinicians and their patients. Our aim was to evaluate the effects of implant-assisted LD (LDI) versus autologous LD (ALD) breast reconstruction on HRQL over 12 months.

**Methods:** An MREC approved prospective longitudinal cohort study involving 6 centres commenced in early 2007. Serial patient reported outcome measures using the EORTC C30 (global QL, role and social functioning, fatigue, pain), BR-23 (breast and arm symptoms), 10 item Body Image Scale (BIS) and HADS, were completed pre-operatively and at 3, 6, 12 and 24 months after surgery. Longitudinal analyses used GEE models to test for effects of treatment variables, baseline HRQL, age and time on QL domains from 3 to 12 months. A cut-off for significance was set at  $p = 0.01$  to account for multiple testing.

**Results:** 171 patients (93 ALD, 78 LDI) were recruited to the study with a mean age of 50 years (range 22–70). Compliance with questionnaires at all time points was between 85–90%. There were no significant differences in HRQL domains between LDI and ALD or according to whether radiotherapy was given. Chemotherapy patients reported poorer overall HRQL ( $p < 0.001$ ), poorer role ( $p = 0.003$ ) and social ( $p = 0.01$ ) functioning, and greater fatigue ( $p = 0.002$ ) and depression ( $p = 0.01$ ). Levels of body image concerns and anxiety were significantly better in older patients ( $p = 0.01$ ). Significant improvements over time were seen for overall HRQL, role and social functioning, fatigue and pain ( $p < 0.001$ ). Radiotherapy was not associated with significantly more breast symptoms in the ALD group ( $p = 0.06$ ). There were no significant differences between LDI and ALD in terms of patient satisfaction with outcome of their surgery. Good satisfaction with overall breast appearance and with the overall outcome of the surgery was significantly associated with fewer body image concerns. Follow-up is continuing.

**Conclusion:** There is an important need for cumulative clinical evidence in this field on which to base patient informed consent and clinical recommendations.