of bisphosphonates in early breast cancer versus non use for the overall number of deaths (summary OR: 0.708, 95% CI: 0.482 to 1.041, *P*-value = 0.079), disease recurrences (summary OR: 0.843, 95% CI: 0.602 to 1.181, *P*-value = 0.321), and bone metastases (summary OR: 0.925, 95% CI: 0.768 to 1.114, *P*-value = 0.413). Conversely, adjuvant treatment with bisphosphonates was not associated with any statistical significant difference for type of recurrences: distant metastases (OR = 0.896, 95% CI 0.674−1.192, p = 0.453), visceral recurrences (OR = 1.051, 95% CI 0.686−1.609, p = 0.820) and local relapses (OR = 1.056, 95% CI 0.750−1.487, p = 0.756).
**Conclusion:** Current available randomized evidence do not support the hypothesis that use of bisphosphonates in adjuvant treatment of early breast cancer is likely to alter the natural course of the disease. Nonetheless there seems to be a non significant trend for better outcomes in patients receiving treatment. Until further evidence from new trials will become available adjuvant bisphosphonates should not be routinely recommended as agents that may potentially alter the course of disease in breast cancer adjuvant setting.

**5147** POSTER

**Taste and smell changes in patients receiving chemotheraphy for breast cancer**

N. Karaman[1,2], H. Vardar[1], L. Dogan[1], C. Atalay[1], C. Ozaslan[1]. *[1]Ankara Oncology Teaching and Research Hospital, Surgery, Ankara, Turkey; [2]Ankara Oncology Teaching and Research Hospital, Pediaetric Oncology, Ankara, Turkey*

**Background:** Taste and smell changes are much more prevalent in patients undergoing chemotheraph. The literature yields little information on taste and smell changes. In this study, the frequency and features of these changes were evaluated in patients receiving chemotheraphy for breast cancer.
**Patients and Methods:** Seventy-four women receiving chemotheraphy in out-patient chemotheraphy unit were evaluated with quastionnaire about taste and smell changes.
**Results:** The mean age was 49.76 (33−74). The most frequently administired chemotheraphy regimens were antracyclines (50 patients), taxanes (13 patients single drug, 4 patients in combinations) and platinum containing regimens (7 patients). Taste and smell dysfunction was reported by 65 (90.2%) and 61 (82.4%) patients, respectively. Forty-eight patients (96%) treated with antracyclines reported taste changes, while 45 patients (90%) were reported smell changes. These rates for single agent taxanes were 10 (76.9%) and 9 (69.2%) patients, respectively. Six patients (85.7%) treated with platinum containing regimens reported both taste and smell changes. Increased sensitivity to odors was reported by 45 patients (73.7%) and 16 patients reported decreased sensitivity. Taste changes were described as bitter (26 patients), metallic (25 patients), sour (10 patients) and salty (4 patients). Forty-five patients (69.2%) informed their families and health professionals about these changes. Meat and fish products were the most common undesired foods for 31 patients, followed by dairy products for 13 patients. Forty-one (63%) patients had not taken any measures against these changes. But 24 patients had taken some measures like increased water intake, some spices and souces.
Forty-four patients (65.2%) reported that taste and smell changes were the most severe during chemotheraphy administration.
**Conclusions:** Much more research is needed to understand the nature, frequency, severity and duration of taste and smell alterations and their significance for the quality of life of cancer patients. Interventions to alter taste and smell changes may improve the outcome of cancer therapy, reduce the cost of care, and improve the quality of life of these patients.

**5148** POSTER

**Emerging recommendations for the prevention of cancer treatment-induced bone loss in women with breast cancer**

L. Costa[1], T. Guise[2]. *[1]Hospital de Santa Maria – University of Lisbon, Oncology, Lisbon, Portugal; [2]University of Virginia, Oncology, Charlottesville, USA*

**Background:** Cytotoxic chemotherapy, ovarian ablation/suppression, and endocrine therapies reduce estrogen levels, causing rapid bone loss and increasing fracture risk in women with breast cancer. Bisphosphonates have demonstrated efficacy for preventing cancer treatment-induced bone loss (CTIBL). Several independent recommendations for managing CTIBL in women with breast cancer have been published. Although not specifically for women with breast cancer, guidelines for treating postmenopausal osteoporosis (PMO) based on data from large population-based studies provide the foundation for overall fracture risk assessment.
**Material and Methods:** A systematic review was performed to identify recommendations related to CTIBL and PMO in published literature and society guidelines. Diagnosis and treatment recommendations were compared and evaluated for similarities and differences regarding risk assessment and treatment thresholds to identify common trends.
**Results:** In the past, World Health Organization PMO guidelines and American Society of Clinical Oncology CTIBL guidelines relied on bone mineral density (BMD) as the primary indicator of fracture risk and need for therapy. Recently, guidelines have begun to include clinical risk factors as part of fracture risk assessment. For example, the FRAX algorithm for PMO further refines fracture risk assessment using BMD and clinical risk factors to determine the 10-year probabilities of hip and major osteoporotic fractures. In the breast cancer setting, recently published consensus recommendations suggest evaluating clinical risk factors, such as age, aromatase inhibitor use, family fracture history, corticosteroid or alcohol use, and smoking, with or without BMD to determine whom to treat.
**Conclusions:** The emerging consensus is that BMD alone is not sufficient to evaluate patient fracture risk and direct treatment decisions. Although BMD cutoff points vary slightly between guidelines, most recommendations now use overall fracture risk (clinical risk factors with or without BMD) to determine who requires preventive therapy. Therapy options for CTIBL include calcium and vitamin D supplementation, lifestyle advice, and bisphosphonate therapy based on degree of fracture risk. Individualized fracture risk assessment will allow more proactive management of bone health in patients with breast cancer.

**5149** POSTER

**Randomized phase II trial of preoperative chemotherapy plus lapatinib, trastuzumab or both in HER2 positive breast cancer: results of the first step simon's design**

V. Guarneri[1], A. Frassoldati[1], A. Bottini[2], K. Cagossi[3], L. Cavanna[4], A. Ravaioli[5], D. Amadori[6], G. Giardina[7], F. Piacentini[1], P.F. Conte[1]. *[1]Modena University Hospital, Department of Oncology Hematology and Respiratory Diseases, Modena, Italy; [2]Istituti Ospitalieri, Division of Medical Oncology, Cremona, Italy; [3]Ramazzini Hospital, Division of Medical Oncology, Carpi (MO), Italy; [4]Hospital of Piacenza, Division of Medical Oncology, Piacenza, Italy; [5]Ospedale Infermi, Division of Oncology, Rimini, Italy; [6]ISRSCT, Oncology, Meldola (FC), Italy; [7]Ospedale di Circolo e Fondazione Macchi, Division of Oncology, Varese, Italy*

**Introduction:** This is a randomized phase II trial of preoperative chemotherapy (CT) with sequential taxanes-anthracyclines combined with trastuzumab, lapatinib, or both trastuzumab and lapatinib in HER2 positive, stage II-IIIA breast cancer patients. Primary end point of the study is the percentage of pathological complete response (pCR) as defined as complete disappearance of invasive tumor in breast and axillary nodes.
**Methods:** CT consists of sequential paclitaxel 80 mg/m$^2$ weekly $\times$12 followed by $FE_{75}C$ $\times$4 courses every 3 weeks. In arm A CT is combined with weekly trastuzumab; in arm B CT is combined with lapatinib 1500 mg po daily; in arm C CT is combined with weekly trastuzumab+ lapatinib 1000 mg po daily. Both trastuzumab and lapatinib are started concomitantly with the first paclitaxel dose, and are administered throughout the duration of CT. Following the second safety report of the Independent Data Monitoring Committee, the protocol has been amended by reducing lapatinib dose at 1250 mg in arm B and at 750 mg in arm C, due to the occurrence of grade 3 diarrhoea in 20% and in 41% of the patients randomized to arm B and C respectively. The study sample size has been calculated according to the two steps Simon's design. The first stage includes 52 patients: at least 4/17 pCRs in arm A, 4/17 pCRs in arm B and 8/18 pCRs in arm C are needed to proceed to the second step. The overall planned accrual is120 patients.
**Results:** 62 patients have been randomized: 20 in arm A, 19 in arm B, and 23 in arm C. Median age is 49 years (range 27−66). Clinical stage at diagnosis: IIA in 35%, IIB in 49%, and IIIB 16%. Forty-four patients underwent surgery, and are evaluable for response: 67% of the patients received breast conserving surgery. A pCR in breast and axillary nodes has been observed in 17 patients (39%). Left ventricular ejection fraction (LVEF) has been evaluated at baseline, after 12−13 weeks, and at the end of therapy. Mean LVEF% (range) was 61.8% (52%-77%), 61.1% (50%-78%) and 61% (53%-77%) respectively. No clinically relevant cardiac events were observed. One patient in arm A experienced a drop of 24 percentage points from baseline at the end of therapy, still remaining above the limit of normal.
**Conclusions:** The study accrual is ongoing. The results of the first step Simon's design per treatment arm will be presented at the Meeting.