transformation to accelerated phase or blast crisis and death. A 5-year time horizon was considered. Each 3 months the patient faces a probability of staying in the same health state or moving to a next state. Transition to death is possible from all health states. This model was populated with efficacy data from clinical trials and different times to events were modeled using Weibull regression techniques. **RESULTS:** The Weibull model for the time to response and time to transformation to accelerated phase and blast crisis showed significant differences between treatment groups. The model coefficient indicated that the chance of response was higher in dasatinib patients with a difference of 12.54% versus imatinib. Patients receiving imatinib had 1.57% higher chance of moving to the accelerated phase and blast crisis earlier. Time to death did not differ significantly between treatments. CONCLUSIONS: The analysis showed earlier responses and a lower chance of reaching the accelerated phase and blast crisis faster with dasatinib 100 mg/day over imatinib 400 mg/day. Results were obtained according to the assumptions used but will need to be validated by future patient level data.

TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA (TLN-REGISTRY): A "REAL LIFE" OVERVIEW OF TREATMENT BY OFFICE-BASED ONCOLOGISTS IN

<u>Hartmann H</u>¹, Knauf W², Abenhardt W³, Aldaoud A⁴, Lerchenmüller C⁵, Koska M¹ ¹iOMEDICO AG, Freib urg, Germany, ²Oncology Group Practice, Frankfurt, Germany, ³Munich Oncology Outpatient Centre Elisenhof, München, Germany, ⁴Oncology Group Practice, Leipzig, Germany, ⁵Haematology-Oncology Group Practice, Münster, Germany

OBJECTIVES: The treatment of patients with Multiple Myeloma (MM) has changed significantly over the last years. The clinical registry on Multiple Myeloma (TLN Registry) conducted by the iOMEDICO AG in collaboration with the Arbeitskreis Klinische Studien (AKS) and the Kompetenznetz Maligne Lymphome was established to follow the implementation of new standards into daily practice. Here, we present data regarding the therapy reality of MM patients treated by office-based $\,$ oncologists in Germany. METHODS: With a target population of 500 MM patients, the registry prospectively collects data on the treatment of MM patients, including patient characteristics. In addition, data on tumour history, response rates, adverse drug reactions and concomitant diseases are documented. MM patients older than 18 years receiving a 1st- or 2nd-line therapy which has started no longer than 4 weeks before patient enrolment can be recruited into the registry if informed written consent is present. Currently, 114 sites in Germany are participating. RESULTS: The registry started in May 2009. By February 2011, 353 patients with MM have been enrolled. Mean age of MM registry population is 70 years at the onset of the systemic 1st-line therapy. Bortezomib/Melphalan/Prednisone is most often used as 1st-line treatment (28%), whereas the Bortezomib/Dexamethasone combination (16%), the Lenalidomide/Dexamethasone combination (14%) or the Bortezomib monotherapy (13%) is most often used as 2nd-line treatment, regardless if stem cell transplantation was reported. On average, MM patients receiving Bortezomib/Melphalan/Prednisone are older than patients who are treated with Bortezomib/Dexamethasone in both 1st- and 2nd-line treatment. CONCLUSIONS: The registry provides an overview of the current treatment of patients with MM treated by office-based oncologists in Germany. Furthermore, the registry shows how fast research results concerning the treatment of MM patients are transferred into current medical practice.

SYSTEMATIC REVIEW OF CLINICAL EFFICACY AND SAFETY OUTCOMES OF ANTI-ANGIOGENIC THERAPIES FOR METASTATIC COLORECTAL CANCER

<u>Aggarwal S</u> Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Anti-angiogenic therapy has become an integral component of treatment for metastatic colorectal cancer patients. During last 10 years several studies were conducted to test the safety and efficacy of anti-angiogenic therapies in mCRC patients. This study reviewed the results of randomized controlled trials published in peer-reviewed journals. **METHODS:** We searched the MEDLINE, and abstracts from ECCO, ESMO and ASCO until May 2011. Studies were selected for randomized controlled trials on targeted anti-angiogenic drugs in mCRC. Primary endpoints reviewed were progression-free (PFS) and overall survival (OS). Response rates, toxicity and secondary resectability were secondary endpoints. Aggregated data were further analyzed to understand comparative safety and efficacy. RESULTS: Until May 2011, eligible mCRC randomized clinical trials for this review were available for bevacizumab (5 trials including 3101 patients) and vatalanib (2 trial including 2033 patients). Overall, anti-angiogensis therapy for mCRC shows significant OS and PFS benefit versus comparators. The median OS and PFS benefit for regimens containing Bevacizumab were 3 and 3.15 months, versus background chemotherapy. The median OS and PFS benefit for vatalanib containing regimens were statistically insignificant versus background chemotherapy. CONCLUSIONS: Anti-angiogensis therapy with Bevacizumab for mCRC shows significant OS and PFS benefit versus comparators.

DANCE AS PHYSIOTHERAPY IN THE REHABILITATION OF WOMEN SUFFERING FROM TUMOUR

¹University of Pécs, Pécs, Hungary, ²ELTE PPK, Budapest, Hungary

OBJECTIVES: In Hungary annually 35,000 people die because of malignant cancer. The main characteristics of the treatment of cancer are multidisciplinary and complex approach. The aim of our examination was to measure the effectiveness of dance rehabilitation group of female patients suffering from malignant tumours, and the changes of lifestyle and social support of patients. METHODS: Our exam-

ination is descriptive, prospective and quantitative. Female patients suffering from malignant cancer illnesses were examined with random sampling method between 2005-2009. Follow-up was implemented a year later. Data was collected with standardised (F-SoZu, EORTC-QLQ-C30, Campbell) and own-designed questionnaires. Data of 175 patients were processed. Statistical analysis was made with SPSS 17. RESULTS: The average age of patients in the dance group was 48.87 years (SD:8,87) and 51,13 in the control group (SD:11,06). The degree of social support in the dance group was 65,22 at the first, 67,55 at second time. In case of the control group the rate was firstly 57,41 then 53,88. The change in the degree of social support was significant in both groups between the two measures (p<0.01). Patients attending in the dance group had less corporal and psychic symptoms at both measures than the members of the control group. In case of the questionnaire $\,$ of Campbell the scores in the dance group was higher in both measures than in the control group. The two groups differ in the degree of change: the dance group had more significant change in case of complacency with life compared to the other group. CONCLUSIONS: Dance as a rehabilitation method need less investment form the state and it does not charge the Social Insurance Fund. These arguments cannot be neglected in the current economic status. Care system would get a rehabilitation which may help women to return actively to society.

DISEASE BURDEN AND TREATMENT OUTCOMES IN SECOND-LINE THERAPY OF PATIENTS WITH ESTROGEN-RECEPTOR POSITIVE (ER+) ADVANCED BREAST CANCER: A REVIEW OF THE LITERATURE

Boswell KA¹, Wang X², Shah MV¹, Aapro MS³

¹Xcenda, Palm Harbor, FL, USA, ²Novartis Pharmaceuticals Corporation, Florham Park, NJ, USA, ³Multidisciplinary Oncology Institute, Genolier, Switzerland

OBJECTIVES: To determine the variable burden of disease of patients with advanced ER+ breast cancer and assess the current treatment landscape after failure of ER+ first-line therapy. **METHODS:** A comprehensive literature review was performed (2000-2011) by searching Medline via PubMed and Embase and Cochrane databases to assess disease burden (ie, societal, humanistic and/or economic burden) and treatment landscape for second-line therapy of ER+ advanced breast cancer in postmenopausal women. RESULTS: Only 1 study was identified that evaluated burden of disease based on ER status (ER+, ER-, or ER-unknown), which was a subgroup analysis assessing the impact of recurrence over 10 years. The investigators reported that only minor differences in survival and medical costs were noted according to ER status. Regardless of ER status, patients with breast cancer recurrence consumed more health care resources and were associated with more costly care than those without recurrence. A total of 7 studies were identified related to treatment outcomes of ER+ second-line therapy. A combined international population totaled >3,800 patients who had progressed on prior hormonal therapy, including tamoxifen and aromatase inhibitors. Three trials performed a comparative efficacy/safety assessment of ER antagonist vs aromatase inhibitor and 1 trial each for aromatase inhibitor versus megestrol acetate and aromatase inhibitor versus aromatase inhibitor. Among each of the studies evaluated, no significant differences were observed in the primary efficacy endpoint, and the safety profiles were similar. Two additional studies, both dosing evaluations, demonstrated that lower doses had a similar or better efficacy and safety profile. CONCLUSIONS: Currently, there is insufficient evidence on the economic and humanistic burden associated with ER status, and this gap warrants further research. With increasing drug resistance and greater economic burden associated with breast cancer recurrence, there is an unmet medical need for improved treatment in this patient population.

PCN17

CORRELATIONS BETWEEN SURROGATE END POINTS AND OVERALL SURVIVAL IN ADVANCED OR METASTATIC BREAST CANCER

<u>Abdel-kader L</u>¹, Castillo MA¹, Lacalle JR², Flores S¹

¹Andalusian Agency for Health and Technology Assessment, Seville, Andalucia, Spain, ²Seville University, Seville, Andalucia, Spain

OBJECTIVES: To determine whether surrogate end points [progression free survival (PFS), time to progression (TTP) and response rate (RR)] are correlated with overall survival (OS) in the first-line treatment of advanced or metastatic breast cancer (BC). METHODS: A systematic review of the literature was conducted to indentify randomized clinical trials (RCTs) that evaluate the efficacy of chemotherapy in first-line treatment of advanced or metastatic BC. Searches were realized in MED-LINE and EMBASE databases from 1995 to April 2010. The nonparametric Spearman rank correlation coefficient (rs) was used as a measure of correlation between the difference (Δ) in surrogate outcomes (Δ PFS, Δ TTP and Δ RR) and the difference in OS (ΔOS). Correlation coefficients were compared using the normal approximation to the z-transformation of rs and its standard deviation. Linear regression analysis, through the origin of the plot, evaluating ΔOS as a function of differences in each surrogate outcomes was used to determine the proportion of variability explained (R2). Statistical analyses were performed using STATA software v.10. RESULTS: Thirty-four RCTs were included in the analysis, with a total of 11,398 patients evaluated. In the first-line therapy of advanced or metastatic BC, there was a weak significant association between ΔPFS and ΔOS [rs: 0.43 (Confidence Interval (CI) 95%: 0.04-0.71)]. When the analysis was performed including only RCTs in the metastatic stage, the rs data between ΔPFS and ΔOS increased statistically significant to 0.59 (CI95% 0.17 to 0.83). The surrogate outcomes that correlated better with the ΔOS, were ΔTTP [rs: 0,79 (CI95%: 0,43-0,94); R2:62%], and ΔRR [rs: 0,73 (CI95%: 0,55-0,85); R2: 53%]. CONCLUSIONS: In the first-line treatment of advanced or metastatic BC, TTP and RR may be appropriate surrogate end points for OS, although it is important to consider the magnitude of their variations.