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Results: Both health status and HRQL improved between pre-and post-test. Cantril's then-test was lower than the pre-test both in child- and parent-report, indicating a negative response shift for overall HRQL. Corrected for response shift, the improvement in overall HRQL was greater than based on the conventional pre-test versus post-test design. However, no differences were found between the PedsQL then- and pre-tests.

The response shift of child and parent was moderately related (Spearman's rho 0.55 p < 0.01), where children experienced a greater negative response shift than parents.

Conclusions: Three months after diagnosis children and parents were more negative about the HRQL (Cantril) at diagnosis than at the moment itself. This response shift threatened the interpretability of the change in overall HRQL over time. No response shift was demonstrated in the more specific domains of HRQL (PedsQL) despite the improved health status. By explicitly measuring response shift, changes in the perceived overall HRQL of childhood cancer patients will be assessed more validly.

3043 POSTER

Measurement Properties and Equivalence of the English and Chinese Versions of the New 5-level EQ-5D in Asian Breast Cancer Patients

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Background: Recently, a new, 5-level version of the EuroQoL Group's – 5 Dimensions (EQ-5D) questionnaire has been released. This study aimed to examine the measurement properties and equivalence of the English and Chinese versions of the new EQ-5D in assessing self reported outcomes in Asian breast cancer patients.

Materials and Methods: This is an observational validation study of ethnic Chinese breast cancer patients in Singapore. The patients answered either the English or Chinese version of the EQ-5D according to their language preference and another cancer-specific questionnaire at baseline and at follow-up two weeks later. Demographics, performance status and other clinical variables were also obtained. Multivariable regression analysis with adjustment for differences in demographic and clinical background was used to assess measurement equivalence of the two language versions.

Results: The EQ-5D showed known group validity in distinguishing differences in performance status, evidence of disease and treatment status, and the two language versions had similar performance. The utility index and the 5 classifiers showed convergent and divergent validity in relation to the domains of the cancer-specific questionnaire. Based on patients who expressed no change in quality of life and performance status at follow-up, the test-retest reliability of the EQ-5D was high, and comparable between the two language versions.

**Conclusions:** The new, 5-level EQ-5D is a valid questionnaire in assessing breast cancer patients' self reported outcomes. The English and Chinese versions of the EQ-5D performed similarly in terms of discriminative ability and test-retest reliability.

3044 POSTEF

## Bone Marker Patterns During Long-term Bisphosphonate Therapy for Patients With Bone Metastases

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Background: Patients (pts) with bone metastases (mets) from breast cancer (BC), prostate cancer (PC), and other solid tumours are routinely treated with bisphosphonates (BPs) to reduce their risk of potentially debilitating skeletal-related events (SREs). Prior studies have shown that zoledronic acid (ZOL) effectively lowers levels of the osteolytic marker N-telopeptide of type I collagen (NTX) in pts with bone mets (Coleman, JCO, 2005), and NTX effects are generally observed within 3 mo (Lipton, Cancer, 2008). However, long-term NTX effects, especially beyond 2 yr, have not been studied in the clinical practice setting.

Material and Methods: Urinary NTX assessments were performed for pts with bone mets treated at Hospital de Santa Maria in Lisbon. For ZOL-treated pts, NTX levels were assessed at baseline and annually and categorized as elevated (E) if >100, moderate (M) if 50–100, and normal (N) if <50 nmol/mmol creatinine. Medical records were evaluated for SREs and drug safety.

Results: Fifty-eight ZOL-treated pts with a median follow-up of 36 mo were evaluated, mostly with BC (n = 43) or PC (n = 13), but lung, renal, and

liver cancer cases were also included. At baseline, mean NTX was 131 (median, 87) overall and 150 (median, 95) nmol/mmol creatinine for BC. With ZOL, most pts transitioned to lower-NTX categories during treatment (table). Median time to first SRE was 31 mo overall; 22 pts (38%) remained SRE-free at last follow-up, 20 of whom were treated for >2 yr. Three pts had serum creatinine elevations (none >3 mg/dL). A total of 4 pts had ONJ; each was treated for a total of  $\geqslant 2$  yr. One case of ONJ healed to normal; 3 persisted.

NTX parameter	Baseline	1 yr	2 yr	>2 yr
Evaluable, n	58	54	41	30
E/M/N distribution, n	24/23/11	11/6/37	1/4/36	3/3/24
Median NTX, % of baseline	(= 100%)	32%	28%	26%

**Conclusions:** These analyses illustrate that ZOL produces long-term normalization of NTX levels and in pts with bone mets. Therapy with ZOL produces SRE rates that compare favorably with prior reports in bone mets settings; ZOL therapy for 2 or more years was generally well tolerated.

3045 POSTER

Febrile Neutropenic Patients Admitted for Intravenous Antibiotics – Analysis of 213 Episodes in 201 Patients With Solid Tumours

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**Background:** Febrile neutropenia (FN) is a serious adverse event of chemotherapy, but a fraction of patients (pts) diagnosed with solid tumours develops serious complications related to a FN episode. We aimed to characterize FN episodes in patients diagnosed with solid tumours admitted for intravenous antibiotics in our institute, and to identify those pts prone to develop serious clinical complications.

Materials and Methods: It is a retrospective study of 213 episodes of FN in 201 pts admitted in our institution from Jan/2009 to Dec/2010 for intravenous antibiotics after a diagnosis of FN. Antibiotics were selected following the current recommendations. Relevant information were collected at admission, and were correlated to selected clinical complications as outcomes (admission at ICU, hypotension, altered mental state, respiratory failure, renal failure, rapid intravenous fluids administration, dialysis, congestive cardiac failure, arrhythmias, bleeding, disseminated intravascular coagulation, death). Exploratory analyses were performed using chi-square test or Fisher exact test, when appropriate, and the optimal cutoff value for differentiation of patient's categories was defined by ROC analysis for each continuous variable.

Results: 213 episodes of FN in 201 pts were analyzed: 51% male, median age 55 y (16-88 y). Most frequent (>5%) primary tumour sites included soft tissue/bone (21%), breast (13%), lung (12%), colorectal (10%), stomach (7%) and testis (6%). 96 (50%) presented stage IV disease. At admission, the median neutrophil count was 300 cells/microliter, and the median MASCC score at admission was 18 (7–26). Cultures were positive in 90 FN (42%) episodes and Gram negative bacilli were identified in 51% of them. Following current recommendations, piperacillin-tazobactam or cefepime, alone or in combination with vancomycin were prescribed in 193 out of the 213 FN episodes. Serious clinical complications were observed in 139 pts and were more frequently observed in those pts aged >40 y (p = 0.003), in pts diagnosed with primary tumours located in esophagus, stomach, lung and colo-rectum (p = 0.002), previously diagnosed with COPD (p = 0.009) and presenting with dehydration at admission (p = 0.002). Conclusion: FN patients is a heterogeneous group and the identification of selected patients with higher risk allows us to better tailoring their supportive care, and clinical parameters remain as important determinants of serious clinical complications.