OBJECTIVES: To define clinically useful categories for prostate cancer (PC) risk and associated outcomes. Translating relative risk (RR) and cumulative risk (CR) into risk categories is important if studies of PC epidemiology and genetic predisposition are to have clinical utility for education, counseling and decision-making. Individual risk perceptions compared to clinical risk are important for the study of behavioral outcomes. METHODS: Risk categories were determined by an extensive review of the literature. Using RR and CR for specific risk factors, 4 categories were defined from low to very high. The categories were then used to assess PC outcomes in men at increased risk for PC (defined by race and family history). Risk perceptions were assessed by asking men to rate their chance of getting PC on a scale from 0 to 100%. RESULTS: 264 men participated in this study. Mean age was 47.7 years, and 52% were African American, 48% were Caucasian. By nature of study eligibility, only 31% men were in the low risk category. According to study criteria, 52(20%) were in the moderate risk, 129(49%) in the high risk, and 62(24%) in the very high risk categories. Of the 62 men who answered the risk perception item, there was no correlation between risk category and risk perceptions. CONCLUSIONS: Lacking a Gail-like model for PC risk, the search continues for quantifiable risk categories with clinical utility. The extreme categories proposed in this pilot study show a trend toward clinically meaningful categorization of PC risk. A meta-analysis of RR and CR is underway to refine the categories: Mobility, Activities of Daily Living (ADL), Hand/finger use (NOT EuroQoL), Usual Activity, Anxiety/Depression, Ability to think (NOT EuroQoL), and Pain/Discomfort. After the utility scores were obtained, subjects were asked which of the seven variables were most important and second most important to them.

CONCLUSIONS: It appears that both pts and nur anchored mainly on the Self-Care variable. Combining the most important with the next most important variable demonstrates that the Anxiety/Depression variable was also an important anchoring variable for both groups. Pts appear to anchor more on Usual Activity than nur. Nur appear to anchor more on Pain/Discomfort than pts. The results also suggest that the Hand and Finger use variable (NOT a EuroQoL variable) may not be necessary and may actually overburden subjects. Overall, these finding may help explain why metastatic breast cancer patients differ from oncology nurses on utility scores.
with assessing who might benefit from treatments such as prophylactic G-CSF. METHODS: The literature review included publications from 1990–2000 of adults with any tumor type; 121 articles were identified that referenced risk factors or predictors for severe/febrile neutropenia. Study design, patient characteristics, chemotherapy treatment, and incidences of neutropenia were recorded. RESULTS: Twenty-one relevant publications, including prospective, retrospective, and modeling studies, were further analyzed. These articles yielded 27 potential risk factors/predictors in 3 categories: patient (n = 14), treatment-related (n = 8), and disease-related (n = 5) characteristics. Although most of the 27 potential risk factors/predictors were not validated to identify patients at higher risk for severe/febrile neutropenia, the review suggests that several simple-to-use and commonly available risk factors may be reliable predictors of neutropenia. These included low hemoglobin and neutrophil counts in cycle one; depth of the neutrophil nadir; low lymphocyte, monocyte and platelet levels; and a precipitous, early drop in blood cell counts. Several other risk factors, such as serum albumin ≤3.5 g/dL on day 1, serum LDH >1× normal alone or combined with bone marrow involvement, and high dose chemotherapy, also warrant further investigation. CONCLUSIONS: Few studies have explicitly explored risk factors associated with the occurrence of Grade 3–4 neutropenia. However, this literature review identified several common characteristics that may be measured with early and frequent CBC monitoring and may reasonably predict predisposition of patients to severe/febrile neutropenia.

**COMPARING MEAN VERSUS MEDIAN SURVIVAL AS A PRELUDE TO COST-EFFECTIVENESS (C/E) ANALYSES**

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BACKGROUND: In a multinational trial designed to determine the efficacy of epoetin alfa in chemotherapy-induced anemia, patients receiving non-platinum chemotherapy having a hemoglobin 10.5 g/dL or less, or a decline in hemoglobin of 1.5 g/dL or greater were randomized (2:1) to epoetin alfa or placebo. A total of 375 patients (251 epoetin alfa, 124 placebo) were assessed for survival the results from the samples. RESULTS: The average mean survival difference, across the 10,000 samples, showed a 0.212-year survival benefit for epoetin alfa. The probability that the difference in mean survival favors epoetin alfa was 0.963. CONCLUSIONS: Comparing differences in median and mean survival may lead to different conclusions about the value of a therapy. Given that mean survival is the appropriate effectiveness endpoint for survival-based C/E analyses, a non-significant difference in median survival does not preclude full C/E analyses. Specifically, the mean survival results from this trial warrant a full C/E analysis of epoetin alfa in treating anemia for patients receiving non-platinum chemotherapy.

**DOCETAXEL/DOXORRUBICIN (DD) AS FIRST LINE CHEMOTHERAPY: QUALITY OF LIFE (QOL) IN PATIENTS (PTS) WITH METASTATIC BREAST CANCER (MBC)**

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OBJECTIVE: In spite of initial treatment of MBC with DD showed high level of efficacy expressed as improved disease-free interval, time to relapse and overall response, it remains as a palliative one. Because of there is some evidence that QOL is improved with this treatment, we designed the study to investigate the impact and changes on QOL in patients (pts) with MBC treated with DD, and its relationship with clinical parameter of response. Material and METHODS: Between July 1999 and July 2000, we treated 42 MBC pts with doxorubicin 50mg/m2 and docetaxel 75 mg/m2, i.v., day 1. Inclusion criteria: female between 18–75 years old, ECOG PS 0-2, and stage IV of MBC histologically confirmed. QOL was assessed at baseline and prior to the first, third and fifth cycle of chemotherapy with the EORTC QLQ-C30 version 2.0, an integrated measurement system to evaluate QOL of cancer pts. RESULTS: To date, 33 pts (median age = 51.7; range: 40–67) with available data, have completed 5 cycles of chemotherapy. Repeated measures analysis of variance (MANOVA) showed time effects statistically significant (p < 0.5) for Emotional Functioning (EF; p = .001), and Cognitive Functioning (EF; p = .001) scales, and pain (p = .000), insomnia (p = .05) and constipation (p = .02) symptom scales. When baseline QOL was compared with that after 5 cycles (paired t-test), it was observed significant improved in EF (p = .003), pain (p = .005) and Insomnia (p = .04). We grouped pts with CR and PR (n = 14) for comparing with SD pts (n = 19) and we observed significantly improve in the first group after the fifth cycle, in physical functioning (p = .05) and social functioning (p = .005). CONCLUSION: These preliminary data suggest that pts with MBC undergoing DD chemotherapy experience improvement in several QOL pa-