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MODELLING THE EFFECT OF A NOVEL THERAPEUTIC AGENT ON THE EVOLUTION OF UTILITY IN REFRACTORY MULTIPLE MYELOMA PATIENTS

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OBJECTIVES: To estimate the effect of Bortezomib on utility values in multiple myeloma patients. METHODS: A Phase III trial (APEX) compared Bortezomib with High Dose Dexamethasone. Utility scores (EuroQol-5D) were collected together with a comprehensive range of clinical and serological outcomes. Changes in utility scores were analysed separately for survivors and non-survivors using non-parametric regression methods. A maximum likelihood method that adjusts for the underlying risk of death as a utility-driver was employed to take account of unobservable effects of declining health on utility scores. RESULTS: Data for 655 out of a total of 669 patients in APEX were included in the analysis, including 129 patients for whom information was available on time to death. Mean utility scores before progression were similar between Responders (0.65) and Non-responders (0.61; mean diff. 0.045, 95% CI –0.01, 0.10); the respective estimates for the after-progression phase (0.67 vs. 0.58) had a mean difference of 0.10 (95% CI –0.00, 0.19). No differences were found between treatment groups. A steep decline in utility over time, following a stable period, began approximately 100 days before death. Estimates from a two-step regression model of utility scores are consistent with informative censoring or sample selection bias in the estimating sample; adjusting for such bias reduced the estimated post-progression difference between responders and non-responders. CONCLUSIONS: The last days of life in patients with multiple myeloma are associated with a steep decline in health related quality of life. Evaluations of utility outcomes conducted alongside clinical trials of salvage therapies in hematology and cancer are likely to require adjustment for the unavailability of representative samples for assessment as a result of early trial termination. We propose an approach commonly used in other fields to deal with this issue and discuss its advantages and limitations.

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CRITICAL APPRAISAL OF SCIENTIFIC POSTERS COMPARING ANEMIA TREATMENTS IN CANCER PATIENTS: APPLYING ISPOR TASK FORCE GUIDELINES ON METHODOLOGICAL QUALITY OF RETROSPECTIVE STUDIES

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OBJECTIVE: Lack of space may prevent research posters from fully disclosing methodological details. Nevertheless they are increasingly used as scientific evidence in communications with health care professionals and as references in review articles, although they are not subject to extensive peer-review. The objective of this study was to assess the methodological quality of posters with results from retrospective database studies on the use of erythropoiesis-stimulating proteins [epoetin alfa (Eprex®), epoetin beta (Neorecormon®), or darbepoetin alfa (Aranesp®)] in the management of anemia in cancer patients. METHODS: We evaluated the quality of research posters in anemia, presented at European congresses since 2004 by using the methodological criteria published by the ISPOR Task Force on Retrospective Database. Two reviewers assessed all posters independently. In total 21 criteria were applied: 3 on data sources, 3 on research design, 8 on study population, 5 on statistical analyses and 2 on conclusions. RESULTS: Four posters were assessed (Persson, ISPOR 2004; Reichardt, OGHO 2004; Malonne, BHS 2005; Pujaide-Lauraine, ECCO 2004). Three presented a retrospective cost-minimization analysis and one a retrospective efficacy evaluation. Overall, the quality of the analyses was poor to very poor satisfying from 14% to 38% of the criteria. Very low scores were observed regarding the quality of the data sources and the research design (scoring 0/3 each in the 3 cost-minimization studies). Key elements such as selection bias were not considered. Cost data were mostly limited to specific categories, such as drug costs, without including other costs associated with the condition and its treatment. CONCLUSIONS: The ISPOR guidelines for the evaluation of retrospective analyses are a useful tool for quality assessment of scientific posters. When assessed against these guidelines, all posters revealed serious methodological shortcomings. These findings caution against the use of posters without appropriate assessment of their methodological quality.

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HEALTH RELATED QUALITY OF LIFE EVALUATIONS IN PROSTATE CANCER: WHO’S BEING STUDIED?

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OBJECTIVES: The issue of health-related quality-of-life (HRQOL) of prostate cancer patients has gained prominence.