ELAPSED TIME TO DISCLOSURE OF BRCA1/2 GENETIC TESTING RESULTS AND PARTICIPANTS’ DISTRESS: PRELIMINARY FINDINGS FROM A RESEARCH SETTING

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OBJECTIVE: It is assumed that genetic testing for breast-ovarian cancer predisposition in the context of peer-reviewed research protocols at academic centers offers protection against test-related distress. However, BRCA1/2 genetic testing under research protocols often implies a significant time delay before the test result can be disclosed, which would not apply to commercially available testing. Using data from our own research setting, we investigated whether delay in getting BRCA1/2 test results was associated with participants’ distress.

METHODS: Participants were 128 women from 26 French Canadian kindreds with a BRCA1/2 germline mutation identified. Genetic counseling was provided in a pre-test education session and a result disclosure session. Of the women tested, 53 (41%) were found to be carriers of the familial mutation and 75 (59%), non-carriers. Mean age at enrollment (48.4 yrs ± 12.1) was similar for the two groups. Test-related distress was assessed by the Impact of Event Scale one month after result disclosure. Time interval between blood sample for testing and result disclosure varied considerably (range: 35 to 756 days), and was similar for carriers (mean = 172 ± 120 days) and non-carriers (mean = 174 ± 174 days).

RESULTS: For FI the average days with 0, 1, 2, 3, ≥4 AEs in a SR was 6.59, 4, 2.56, 0.81, 0.37 and in a NR, 1.59, 1.67, 0.56, 0.11, 0. For P in a SR we had respectively 8.3, 3.8, 2.8, 2.2, 0.125 and in a NR, 2.13, 0.9, 0, 0. Average estimated QoL-score was 81.71 for FI (SD: 3.15, range: 72.54–85.24) and 80.66 for C (SD: 3.01, range: 71.8–84.68) (Mann Witney U test: p = 0.49 but decreased to <0.25 for first hospitalization period). Kaplan-Meier graph demonstrates after day 16 a constant QoL benefit for FI due to earlier hospital discharge (Log rank test: 27.2; p < .001).

CONCLUSION: Filgrastim use 24 hours post-PBPC in high dose treatment of n-HFL patients is associated with QoL improvement due to earlier hospital discharge.

PSYCHOMETRIC PROPERTIES OF THE EORTC QUALITY OF LIFE CORE QUESTIONNAIRE (QLQ-C30) IN EORTC TRIALS

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OBJECTIVE: The EORTC QLQ-C30 is one of the most widely used QL measures in cancer clinical trials. This study aimed to look at the psychometric properties of the QLQ-C30 in 32 countries with a database of 9000 patients.

METHOD: All EORTC studies incorporating the EORTC QLQ-30 were systematically selected for this study. Inclusion criteria for trials were if the trial containing the QLQ-C30 responses had been coded into the EORTC database. One hundred fourteen EORTC studies were reviewed of which 52 met the criteria for being included in the final analysis.

RESULTS: The majority of cancer patients were receiving palliative care for primary cancers including melanoma, prostate, head and neck, breast and lung cancers and 90% of the patients were distributed over 10 out of the 32 countries. At least one item of data was missing in 14 to 17% of patient questionnaires completed, though the average percentage of missing items per patient ranged from 1.1% to 1.5%. Particular items relating to Role Functioning and Financial Difficulties were the most common items missing (3%). Factor analyses for all three versions of the questionnaire are similar, though some
INFECTIONIOUS DISEASE

IMPACT OF INFLUENZA AND TREATMENT WITH OSELTAMIVIR ON INDIVIDUALS’ DAILY ACTIVITIES AND RETURN TO NORMAL ACTIVITY

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OBJECTIVE: Recommendations on the appropriate use of corticosteroids (cort) and HT-3 antagonists (HT3A), alone or in combination with benzodiazepines (benz) and dopamine receptor antagonists (dopA) vary between three and nine different anti-emetic strategies.

METHODS: We retrospectively compared the use of anti-emetics in our clinical practice with the consensus recommendations of Peruggia. We analyzed all patients from a single department unit receiving chemotherapy on an inpatient basis in February 2000.

RESULTS: One hundred thirty five days of chemotherapy in 38 patients (20–78 years old, male/female 1,7/1) suffering from various malignant diseases were included. Five patients (13.1%) received anti-emetic therapy for other reasons than preventing nausea and vomiting (e.g. corticosteroids as comedication with paclitaxel). We grouped the chemotherapy protocols as follows: very low risk, \( n = 5 \); low risk, \( n = 44 \); moderate risk, \( n = 16 \); high risk, \( n = 40 \); and severe risk, \( n = 30 \), according to the Peruggia guidelines. We calculated the total theoretical consensus-guided costs for anti-emetic treatment to be 2079.04 Deutsche Marks (DM) and the real costs to be 2024.93 DM (hospital supplier prices).

CONCLUSION: We found a considerable drug-group-related difference between consensus guidelines for anti-emetic strategies and clinical practice. However, the total expenditures did not vary significantly. We assume, that the differences observed are due to patient-related factors like history of nausea and emesis, tumor stage, tumor location, sex, age, co-morbidity and alcohol consumption rather than to chemotherapy. A computer-assisted anti-emetic decision model (Emeto-Help) will be presented, which includes both the drug-related emetogenic potential and the individual patient’s risk.

QUALITY OF LIFE IN CANCER CLINICAL TRIALS — AN OVERVIEW OF APPROACHES WITHIN THE EORTC

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OBJECTIVE: Quality of life (QOL) is becoming an accepted endpoint in cancer clinical trials. However, reports suggest that fewer than 10% of clinical trials include QOL assessment, it is believed that such reports may be biased by time lag. This paper examines the extent of QOL studies that are conducted within one of the largest academic cancer clinical trial organizations in Europe.

METHOD: Examination of all clinical trials conducted by the EORTC (between 1990 to 2000) was undertaken by reviewing databases, records and publications. Trials were systematically selected if they involved any aspect of QOL assessment. The protocols were then evaluated using criteria that evaluated the quality of trial designs and methodology employed.

RESULTS: In total, 112 clinical trials involving over 10,000 patients were identified as having a QOL component. All trials involved multinational patient recruitment, with the highest recruitment from the Netherlands, France and Germany, and lowest from Malta, Estonia and Slovakia. Approximately 25 disease groups have been actively recruiting patients from disease groups of genito-urinary, breast and lung cancers. A clear linear trend was noted, with increasing numbers of clinical trials involving QOL components over this period. Of these trials, 74 studies were Phase III, 15 Phase II and the remainder were feasibility studies. Presently, 45 trials are ongoing, 19 almost ready for data analysis, 15 published and 10 being analyzed. In the last year, 30 studies involving QOL assessment have been submitted for research, suggesting that QOL is a highly important endpoint in trials throughout Europe

CONCLUSION: While a decade ago QOL was not a major component of EORTC clinical trials, it is now highly integrated into trials, almost a standard secondary end-point. In the European context, this suggests that clinicians and researchers are increasingly seeing the importance of patient-based outcome assessment methods.