1098 ORAL

The relative risk of secondary tumors in extragonadal germ cell tumors (EGGCT)

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Purpose: The relative risk of secondary tumors associated with EGGCT is unknown. This analysis examines the incidence and frequency of secondary tumors in EGGCT.

Methods: 635 pts treated at 11 centers in the US and Europe during the cisplatin-based chemotherapy era (ctx) were retrospectively evaluated (1975–96).

Results: No treatment-related leukemia was observed in 611 pts treated with ctx. In 7 pts solid tumors were observed resulting in a cumulative incidence of 1.1% ($CI_{95\%}$, 1.1–1.1%) after a median follow-up of 59 mon (42–166). Four solid tumors (57%) developed in pts with primary mediastinal and 3 (43%) in retroperitoneal EGGCT. Three pts had a non- (57%) and 4 (43%) a seminomatous histology, 6 pts had been treated with ctx and 1 with radiotherapy. 6 of 7 (86%) solid tumors had developed within 5 yrs and 7/7 within 10 yrs. Median time period to the occurrence of neoplasia was 47 mon (9–145). Four tumors were melanoma/basalioma, the other included angiosarcoma, NSCLC and colorectal cancer. The risk for developing secondary tumor is not increased compared to the age-matched general population (SMR, 1.49 [$CI_{95\%}$, 0.60–3.06]). An elevated risk was observed for skin tumors and ctx (SMR, 5.33 [$CI_{95\%}$, 1.45–13.65]).

Conclusion: EGGCT are not associated with an increased biological or ctx-induced risk for secondary malignancies which has been demonstrated for primary mediastinal NSGCT and hematological disorders (Hartmann JT, ESMO 98). The risk of secondary solid tumors in EGGCT appears to be comparable to primary testicular cancer (Bokemeyer C, JCO 1995) and does not alter treatment strategies.

1099 ORAL

Space-time clustering patterns in childhood leukaemia suggest a role for infection

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Purpose: To conduct analyses of space-time clustering of cases of leukaemia diagnosed between 1954 and 1985, using Manchester Children's Tumour Registry data.

Methods: Knox tests for space-time interactions between cases were applied with fixed thresholds of close in space, <5 km and close in time <1 year apart. Addresses at birth as well as diagnosis were utilised. Tests were repeated replacing geographical distance with distance to the Nth nearest neighbour. N was chosen such that the mean distance was 5 km. Data were also examined by a second order procedure based on K-functions.

Results: All methods showed highly significant evidence of space-time clustering based on place of birth and time of diagnosis, particularly for: all leukaemias aged 0–14 and 0–4 years, and ALL 0–4 years. Some results based on location at diagnosis were significant but mainly gave larger p-values. The clustering was limited to specific geographic areas and short time periods. There was an excess of male cases over females involved in space-time pairs.

Conclusion: The results are consistent with an infectious hypothesis. We suggest the gender differences may be related to differential genetic susceptibility to infection between males and females.

1100 ORAL

Information and communication in the context of clinical trial

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Background/Methods: When a patient is asked to participate in a clinical trial true informed consent depends on the patient receiving and understanding adequate information for decision-making, and being able to make an independent decision about participation. To address these questions we sent a questionnaire to breast cancer patients who participated in randomized trials of adjuvant therapy.

Results: The questionnaire was returned by 289 (88%) of patients. The information provided was regarded as adequate for decision-making by 74%. Additional questions were asked prior to randomization by 69%. Younger and better educated patients asked questions more often and received satisfactory answers more often. When the effects of age and education on asking questions were examined simultaneously the effect of education proved to be stronger than the effect of age. The method of treatment allocation was unclear to most patients: 47% thought that the doctor chose the treatment, while only 28% knew that they were randomised. Younger and better educated patients had better understanding (p = 0.001). Reasons for participation were to benefit future patients (61%), desire for more efficient follow-up (60%), desire for more effective treatment and better continuity of care (44%). Most would participate again. Factors considered important when offered participation in a trial included: comprehensive information about treatments and their side-effects, treatment alternatives, communication issues such as clarity of explanation, psychological support, unhurried discussion.

Conclusion: While most patients are satisfied with the information received, there is poor understanding of how treatment is allocated. Communication should be modified especially for older and less-educated patients.

1101 ORAL

Preparatory information on video cassette significantly reduces treatment related anxiety & depression – A randomised multicentre trial

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Purpose: Too much emphasis is placed on information provision in the hospital setting whilst the benefits of continuing the learning process at home with videocassettes has been undervalued.

Methods: We established a panel of patients, doctors, nurses and radiographers and made an information film with the help of experienced TV personalities and documentary film makers. 220 patients entered this prospective study immediately after their consultation with the oncologist in three hospitals between Jan '97–Sept '98. Patients were randomised to receive either oral information supported by written booklets or the same plus an educational video which they took home. Patients completed a HAD score and an ad hoc questionnaire before randomisation and 3 weeks into either radiotherapy or chemotherapy. Statistical analysis was independently performed at the Institute of Public Health, Cambridge University.

Results: Between the video group and non video group there was a 25% difference in treatment associated anxiety ($p < 0.001$) and 29% difference in treatment associated depression ($p < 0.001$). Of the 110 patients randomised to the video group 94% were satisfied with the information they received, 87% felt the video contained just the right amount of information, 13% not enough and no patient felt it was misleading.

Conclusion: Although other information sources have improved patient satisfaction, no other information video has been shown to lead to such a definite reduction in treatment related anxiety and depression. We highly recommend an copy of this video is given to every patient to take home before chemotherapy or radiotherapy, in addition to verbal information and other strategies with proven effectiveness. The film has been translated into Italian, in association with the charity AiMac (info@aimac.it), and we plan to evaluate its effectiveness in Italy and other countries where cultural attitudes to cancer may differ. Further information on the film is available from the publishers (HEP) Tel: (44) 1222 403022, health.education@btinternet.com.

1102 ORAL

Reasons why patients accept or decline entry to randomised clinical trials of cancer therapy

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Purpose: As part of a larger study designed to improve doctor-patient communication in randomised clinical trials (RCT), we examined the reasons why patients agreed to or declined entry into trials.

Method: Patients completed a 16 item questionnaire following the consultation which examined whether or not they had agreed or declined to enter a RCT of cancer therapy. For each item the patient indicated the degree to which he or she agreed or disagreed with the statement. Also they indicated which statement most influenced their decision concerning trial participation.

Results: 200 patients completed the questionnaire, of these 110 (55%) were women with breast cancer. Overall results showed that 143 (71.5%) patients accepted entry to a RCT. The main reasons nominated for participating in a trial were that "*others will benefit*" (23.1%) and "*trust in the doctor*" (20.3%). One of the main reasons for declining trial entry was that patients were "*worried about randomisation*" (19.6%). Results were analysed according to the type of trial on offer, e.g. trials that examine a new versus standard treatment for cancer. Acceptance rates differed significantly, with a high acceptance rate for trials with an active treatment arm 80 (79.2%) compared with those with no treatment arm 41 (54.7%), p = 0.0004.

Conclusion: The study outlines a number of factors that appear to influence a patient's decision to accept or decline entry into an RCT of cancer therapy. An important factor is whether or not the trial offers active treatment in all arms of the study. Communication that promotes trust and confidence in the doctor is also a powerful motivating influence.

1103 POSTER DISCUSSION

Communication about sex between health care professionals and patients with ovarian cancer: Attitudes and beliefs versus reality

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Purpose: It is not known to what extent health care professionals (HCPs) talk to patients with ovarian cancer about the impact that the diagnosis and the treatment have on sexual functioning, nor whether patients think this kind of information is important. A study was performed in Leeds to investigate these issues.

Methods: Interviews were carried out with 16 clinicians and 27 nurses to investigate the importance that HCPs place on discussions about sexual problems, and views on lines of responsibility for such discussions. In-depth interviews were carried out with 16 ovarian cancer patients to determine the incidence of sexual problems, the underlying causes of sexual problems, the relative importance of sexual functioning to patients, and patients' views about whether sexual matters should be discussed.

Results: Although the vast majority (95%) of HCPs believe that sexual issues should be discussed with patients, only 4/16 (25%) of clinicians and 5/27 (19%) of nurses actually discuss sex with patients. Patients with ovarian cancer do find that their sex life is affected and feel that they would benefit from talking to someone about sex.

Conclusion: There is a need to improve communication with patients about sex, by encouraging and training HCPs to feel comfortable initiating discussions about sexual matters and/or by employing a psychosexual counsellor.

1104 POSTER DISCUSSION

Awareness of disease: A cross-sectional study on Italian cancer patients

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Purpose: Today, in Italy, there is a no uniform physician attitude and practice in regard to revealing the diagnosis of cancer, and, therefore, many cancer patients are not fully informed about the nature of their illness, its severity and curability. Because of the impossibility to directly obtain information on the lack of insight of disease, a cross-sectional study of cancer patients was carried out.

Methods: Two visual analogue scales evaluating curability and severity of disease were submitted to 6,098 consecutive cancer patients enrolled in 79 oncologic centers. Patients were asked to mark a point in a 100 mm long horizontal line with the extremes labeled with 0 (very easy to cure, not severe disease) and 100 (very difficult to cure, quite severe disease). Individual responses were classified in "easy to cure‰ and "not severe disease‰ if a point in 0–30 mm interval was chosen on the respective scales; "difficult to cure‰ and "severe disease‰ if a point in 70–100 mm interval was marked. Multifactorial analyses were performed using logistic models, for each of the 4 responses ("easy/difficult to cure‰; "not severe/severe disease‰), assuming as explanatory variables type and staging of cancer, patient characteristics, response to chemotherapy, and presence of 19 problems related to the patient, conditions.

Results: Disease was considered easy/difficult to cure by 3,020 (49.5%)/1,149 (18.8%) and not severe/severe by 1,810 (29.7%)/2,256 (37.0%) patients. Among patients who felt their disease was severe (2,256), only 863 (38.3%) considered it difficult to cure and 897 (39.8%) easy to cure; instead, among those who felt it as not severe (1,810), only 147 (8.1%) considered it difficult to cure and 1,479 (81.7%) easy to cure. The highest percentages of patients who believed their disease was severe were found among those affected by ovarian (48.7%) and lung (47.0%) cancer, while the lowest in those affected by uterine cancer (27.1%), lymphomas (27.4%), colon-rectal (33.0%) and breast cancer (35.3%). Also the staging was important in explaining the variability of the perceived severity: disease was considered severe/not severe by 29.2/36.2% of patients with NED, 38.8/29.0% of patients with localized disease, and 46.6/21.1% of patients with disseminated disease. Moreover, the percentages of patients who considered their disease severe/not severe were different among those who had a Karnofsky performance status 80 (47.0/22.8%) and among those with the highest values (32.1/33.1%). Finally, problems such as lack of optimism, difficulties in daily or working activities, anxiety about follow-up results, body change due to the illness more frequently led the patients to feel the severity of their disease. Similar results were obtained in analyzing curability.

Conclusions: Among Italian cancer patients the insight about the nature and prognosis of their disease is scarce. For example, only less than one half of the patients with disseminated disease felt it as severe and one fourth as difficult to cure. Therefore, some doubts arise regarding the validity of both a fully informed consent to therapy and the utility measurements, based on patient preferences.

1105 POSTER DISCUSSION

Predicting anxiety and depression among cancer patients

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Purpose: To investigate the possibility to predict anxiety and depression 6 months after the cancer diagnosis on the basis of measures of anxiety, depression (Hospital Anxiety and Depression, HAD scale), subjective distress (Impact of Event, IES scale) and some aspects of social support in connection to the diagnosis. To attempt identification close to the diagnosis of individual patients at risk for prolonged psychological distress.

Methods: A consecutive series of 527 newly diagnosed patients with various diagnoses were interviewed in connection to the diagnosis and 6 months later.

Results: Anxiety and depression close to the diagnosis explained 39% of the variance in anxiety and depression 6 months later. Patients scoring as doubtful cases/cases for HAD anxiety and/or depression were above 11 times more likely to score as doubtful cases/cases at 6 months. Additional risk factors for elevated anxiety and/or depression were having an advanced disease and nobody in addition to the family to rely on in case of difficulties.

Conclusion: Levels of anxiety and depression at diagnosis predict a similar status 6 months later. Having an advanced disease and nobody besides the family to rely on in case of difficulties are additional risk factors.

1106 POSTER DISCUSSION

A comprehensive assessment of satisfaction with care: Preliminary psychometric testing in oncology settings from France, Poland and Italy

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Purpose: Satisfaction with care may be closely related to quality of life in cancer patients. International clinical research might thus find valuable information in patients' satisfaction with care assessment. This study was aimed at testing whether equivalent factor structure and scales demonstrating adequate internal consistency and convergent-discriminant validity estimates could be found in a Comprehensive Assessment of Satisfac-