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

J.T. Hartmann, C.R. Nichols, J.P. Droz, A. Horwich, A. Gerl, S.D. Fossa, J. Beyer, J. Pont, L. Kanz, C. Bokemeyer. *The International Extragonadal Germ Cell Tumor Study Group; Tuebingen/Hannover/Munich/Berlin, Germany, Indianapolis/Portland, United States, Lyon, France, Sutton, United Kingdom, Oslo, Norway, Vienna, Linz, Austria*

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.

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

R.J.Q. McNally[1], J.M. Birch[1], F.E. Alexander[2], V. Blair[1], O.B. Eden[1], G.M. Taylor[3]. [1]*The Royal Manchester Children's Hospital, Manchester;* [2]*The University of Edinburgh, Edinburgh;* [3]*St. Mary's Hospital, Manchester, United Kingdom*

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.

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Information and communication in the context of clinical trial

P. Hietanen[1], A.R. Aro[2], K. Holli[3], P. Absetz[2]. [1]*Dept. of Oncology, University Hosp. of Helsinki;* [3]*Tampere,* [2]*Dept. of Epidemiology, National Public Health Institute, Helsinki, Finland*

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.

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

R. Thomas[1,2], M. Daly[3], F. Delorenzo[4]. [1]*Addenbrooke's Hospital Cambridge University NHS Trust, Oncology, Cambridge;* [2]*Primrose Oncology Unit, Oncology, Bedford;* [3]*Queen Elizabeths Hospital, Oncology, Kings Lyn, United Kingdom;* [4]*Aimac, Roma, Italy*

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.

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

V.A. Jenkins, L.J. Fallowfield. *CRC Psychosocial Oncology Group, UCLMS, London, United Kingdom*

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