1101 POSTER

Longitudinal study on posttraumatic stress symptoms in adolescent children of a parent recently diagnosed with cancer

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Background: The diagnosis and treatment of cancer may cause substantial stress for children when a parent has cancer, and may be a traumatic experience for some of them. This study investigated the prevalence of posttraumatic stress symptoms (PTSS) in adolescents (aged 11−18 years) during the first year after the parent's cancer diagnosis, factors affecting PTSS (such as gender, age and cancer-related variables), concurrent associations between PTSS and emotional/behavioural problems, and prospective predictive effects of initial PTSS on later PTSS and emotional/behavioural problems.
Materials and Methods: Forty-nine adolescents (21 sons, 28 daughters, aged 11−18 years), 37 parents with cancer and 37 spouses completed questionnaires within 4 months after the parent's diagnosis (T1), and at six (T2) and twelve months (T3) after the first assessment. Sixty-two percent of the parents with cancer were women, and breast cancer was the most common diagnosis.
Results: Clinically-elevated PTSS were found in 29% of adolescents at T1, 16% at T2, and 14% at T3. Ten percent of the adolescents reported clinically-elevated PTSS at all assessments. Daughters seemed slightly more at risk than sons. Age was not significantly related to PTSS. Adolescent children of a mother with cancer reported similar levels of PTSS to those of a father with cancer. Intensity and length of the parent's treatment did not affect PTSS. Adolescents who suffered more PTSS reported also more emotional/behavioural problems. Parents with cancer and spouses observed fewer problems in adolescents with more PTSS than these adolescents did themselves. Initial PTSS was related to PTSS and emotional problems later on in the year, while behavioural problems were not.
Conclusions: PTSS were highest shortly after the parent's diagnosis and decreased over time. Adolescents with high initial distress were more at risk for later problems. Adolescents' and parents' reports on problems of adolescents with PTSS were discrepant.

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Meta-analysis of randomised comparisons between the effects of warfarin and low molecular weight heparin in thromboprophylaxis and mortality in cancer patients

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Introduction: The role of anticoagulants warfarin and low molecular weight heparin (LMWH) in the prophylaxis of venous thromboembolism (VTE) in cancer patients remains uncertain. A meta-analysis was performed to determine the effects of warfarin and LMWH on primary and secondary VTE rates and mortality.
Methods: Computerised searches in MedLine, NCI Trials Register, ISTH, ASCO and ASH proceedings and reference checks were carried out for papers from 1984 onwards, to October 2006. The inclusion criteria set were: RCTs; medical cancer patients; thromboprophylaxis; warfarin or heparin vs no treatment or placebo or warfarin (oral) vs heparin. Standard meta-analysis methods were utilised and results were presented as ORs and CIs with tests for interaction used to determine heterogeneity of treatment effect.
Results: 27 trials with 6320 patients were found to match the criteria; this included thromboprophylaxis in patients with central venous catheters (CVCs); some cancer data were extracted for patients from all disease trials if possible.
In 6 trials (n = 1667) of warfarin vs not, there was no clear evidence of a decrease in VTEs (OR = 0.72, CI = 0.49−1.06, p = 0.09) A total of 8 trials (n = 2344) had survival data: there was no clear benefit of a decrease in mortality with warfarin (OR = 0.92, CI = 0.82−1.02, p = 0.1)
In 7 trials (n = 2441) of LMWH vs not, VTE was reduced with the anticoagulant (OR = 0.62, CI = 0.44−0.89, p = 0.009) 5 trials (n = 1211) contained survival data and mortality was also reduced with LMWH (OR = 0.78, CI = 0.67−0.91 p = 0.002)
In 8 trials of LMWH vs oral anticoagulation (mainly warfarin), (n = 1179), VTE rates were less with LMWH (OR = 0.49 C = 0.35−0.69, p ⩽ 0001). No significant mortality benefit was observed with LMWH in 10 trials (n = 1100) (OR = 0.95, CI = 0.80−1.14, p = 0.6)
Conclusions: The results of these meta-analyses suggest that LMWH is the preferred form of prophylaxis for VTE in cancer patients and that overall, there may be an anti-tumour effect, leading to a survival benefit.

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Invasive acupuncture for radiotherapy-induced nausea and vomiting is not more effective than placebo acupuncture

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Treatment with acupuncture is, despite sometimes unclear evidence, increasing in curative and palliative cancer care. Acupuncture is used for indications such as pain and nausea, but for radiotherapy (RT) induced nausea it is still an unexplored treatment. For evaluation of the method, the use of sham acupuncture as a control treatment provides a tool resembling placebo for drugs.
Aim: To investigate whether acupuncture reduces nausea caused by radiotherapy in a patient group with a >50% risk of experiencing the symptoms (abdominal or pelvic region).
Method: 237 patients were randomised to invasive acupuncture (IA) or placebo acupuncture (PA) 30 min, 2−3 times/week during the whole RT period; md 5 weeks. IA was administered bilaterally to the point PC6 using an invasive needle and PA with a needle, which looks identical but is not pointed and is not fixed in its handle. When this comes into contact with the surface of the skin and gives a feeling of penetration it glides upwards in its handle and is therefore shortened, which gives an illusion that the needle has entered the tissue. Nausea and vomiting was documented in diaries and questionnaires under the entire treatment period as well as two and four weeks after radiotherapy.
Results: Of 215 evaluable patients, 110 received IA and 105 PA. Both groups stated that they believed that the treatment had been invasive and effective in reducing nausea. In group IA, 68% experienced nausea during radiotherapy for a mean number of 19 days. In group PA, 61% experienced nausea, for a mean number of 17 days. 24% and 28% of patients in the IA and PA groups experienced vomiting during the treatment period. Fifty eight patients received RT combined with chemotherapy (CT). Of those 23 (82%) in group IA and 24 (80%) in group PA experienced nausea, for a mean number of 19 and 13 days, respectively. There were no statistical significant differences between IA and PA in number of days with nausea or vomiting or in intensity of nausea, neither in those receiving RT alone or RT combined with CT. Both IA (66%) and PA (71%) groups stated a high interest in receiving acupuncture treatment if future RT would be needed.
Conclusion: This large, randomized study shows that manual invasive acupuncture 2−3 times/week is not more effective than placebo acupuncture in preventing radiotherapy-induced nausea. However, due to treatment satisfaction both groups were highly interested in receiving further treatment with acupuncture.

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Patient-level integrated analysis of data from 6 randomized, double-blind, placebo-controlled trials of darbepoetin alfa (DA) in patients (pts) with chemotherapy-induced anemia (CIA)

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Background: Individual multicenter, randomized, controlled trials (RCTs) have provided repeated evidence of efficacy and tolerability of erythropoiesis-stimulating agents (ESAs) in treating pts with CIA.
Materials and Methods: Pt-level data from 6 Amgen-sponsored, placebo (PBO)-controlled, RCTs of DA to treat CIA in pts with screening hemoglobin (Hb) ⩽11 g/dL, nonmyeloid malignancies, ⩾1 prior chemotherapy (CTX) cycle, and additional planned CTX cycles. Data for individual pts who received ⩾1 dose were combined into pooled analysis sets according to randomized group. To account for differences in study durations,

efficacy endpoints were evaluated up to wk 13. Efficacy was evaluated by transfusions (weeks 5 to 13) and hematologic response at week 13. Safety analyses included hazard ratio (HR) estimates of events from a Cox regression analyses (stratified by study). Events were identified as follows: deaths based on reasons given for drug or study discontinuation, or fatal AE; progressive disease (PD) if given as reason for drug or study termination or end-of-study disease status; progression-free survival (PFS) as time until death or PD, whichever earlier; and thromboembolic events (TEs). To consistently define TEs, adverse events (AEs) across trials were mapped to a common reporting dictionary (MedDRA v.9).
Results: Analyses included 1515 pts (901 DA, 614 PBO). Demography was similar between DA and PBO groups: %women (54.6% and 52.0%, respectively) and mean (SD) ages (62.3 [12.3] and 62.3 [11.8] yrs). Results are presented in the table. The difference between groups in the rates of transfusions and hematologic response favored DA. Risk for a TE was 50% higher in DA group. Risks of death, DP, and PFS were similar between groups.
Conclusions: This analysis reconfirms data from DA RCTs, demonstrating a decrease in transfusions, improvement in hematologic response, and an increased risk of TE. Risks of PFS and death did not differ between groups.

	Difference* or HR (95% CI) [DA vs PBO]
Transfusion wk 5−13, Diff. in KM rate	−19.2* (−21.4, −16.9)
Hematologic response at wk 13, Diff. in KM rate	39.8* (37.1−42.5)
TEs	1.50 (0.97−2.33)
Death – On-study (OS)/OS+FU	1.14 (0.76−1.70)/0.99 (0.82−1.19)
Disease progression – OS	0.87 (0.70−1.09)
PFS – OS/OS+FU	0.91 (0.74−1.12)/0.88 (0.76−1.01)

OS = on-study; FU = follow-up; KM = Kaplan–Meier; HR = hazard ratio; Diff = difference (DA–PBO). HR < 1 favors DA. Hematologic response = Hb increase by ⩾2 g/dL or Hb ⩾12.0 g/dL.

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A randomized trial of written information versus an interactive multimedia CD-ROM for improving informed consent to chemotherapy

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Background: This randomized controlled trial aimed to determine whether an interactive CD-ROM improved cancer patients' recall of chemotherapy treatment information over standard written information, and whether demographic, cognitive, and psychological factors better predicted recall than this mode of delivery.
Materials and Methods: One-hundred-and-one new patients about to commence chemotherapy were randomized to receive written information or a CD-ROM containing treatment information before giving informed consent. Patients' recall, concentration, short-term memory, reading comprehension, anxiety, depression, and coping styles were assessed with standardized measures pre-treatment. Anxiety and depression were also assessed during treatment.
Results: Seventy-seven patients completed tests for recall of treatment information before their second chemotherapy session. Intention-to-treat analyses indicated no significant differences between the written information and CD-ROM groups across recall questions of number of drugs received ($p = 0.43$), treatment length ($p = 0.23$) and treatment goal ($p = 0.69$). Binary logistic regressions indicated that for groups combined different variables predicted each of the recall questions. All three models were significant and although no individual predictors were significant, depression appeared to be the strongest most stable predictor of incorrect recall across models. Furthermore, presenting treatment information in the form of a multimedia CD-ROM was not found to significantly decrease patient anxiety ($p = 0.96$) or depression ($p = 0.65$) during treatment, although anxiety did significantly decrease over treatment time ($p = 0.000$).
Conclusions: An interactive CD-ROM did not improve cancer patients' recall of chemotherapy treatment information enough to warrant changes in informed consent procedures. However, different demographic, cognitive, and psychological variables do appear to predict recall of different aspects of treatment information highlighting the unique and complex nature of recall of chemotherapy information.

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Prevalence, patterns and predictors of mood disorders in early breast cancer: results from 2208 women in the UK Standardisation of Breast Radiotherapy Trial (START)

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Aims: Psychological problems are common after breast cancer treatments. This study measured prevalence, patterns of change and clinical predictors of anxiety (A) and depression (D) over 5 years follow-up, plus the association of mood disorder with body image (BI) and sexual functioning (SEF).
Methods: Women in the quality-of-life (QL) study completed the HADS, Body Image Scale (BIS), and QL measures, at baseline 6, 12, 24 and 60 months. The independent effect of age, time from surgery, type of surgery, chemotherapy (CT) and endocrine therapy (ET) and change over time were tested using the Generalised Estimating Equations model, adjusting for baseline A or D. Associations with body image and sexual function were estimated using correlation analysis.
Results: 2208 women consented to the QL study; mean age 56.9 years, (range 26−87). 17.1% women had mastectomy, 82.9% underwent conservative surgery; 33% had received CT and most had started ET. Median time from surgery was 8.0 weeks (IQR 5.6−19.6). 2181 (99%) women completed baseline QL of whom 32% reported borderline or case A and 12% borderline or case D; overall point prevalence was 33%. There was no significant change in prevalence over time but 42.3% with case A and 33.6% women with case D at baseline had persistent mood disorder over 5 years. Older age, and lower baseline A predicted lower anxiety over time but only lower baseline D predicted subsequent depression. Higher A and D rates were associated with worse BI and SEF, with depression having a greater effect ($p < 0.001$).
Conclusions: Prevalence of A and D was stable over 5 years with increased anxiety compared to population figures. Mood disorders persisted in over one third of women but clinical factors had no predictive effect. Younger age and the interaction between mood disorder with body image and psychosexual problems have implications for clinical care.
Acknowledgments: On behalf of the START Trial Management Group

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Changes in quality of life over time in 701 patients with esophageal cancer and Barrett's esophagus based on marital status

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Background: To evaluate the impact of marital status on changes in QOL over time in patients with esophageal cancer (EC) in comparison to Barrett's esophagus (BE) patients without cancer.
Materials and Methods: The Mayo Clinic Esophageal and Barrett's Esophagus Registry (EABE) is a multi-institutional resource that includes blood, fresh-frozen and formalin-fixed tissue, linked pathologic and clinical data, and serial validated symptom and quality of life (QOL) questionnaires obtained over time. The current investigation was performed using patients from the EABE Registry who had have completed at least 2 QOL assessments (at baseline and 1 year later) with a diagnosis of either BE or EC. Each QOL measurement consisted of the Linear Analogue Self Assessment (LASA) which contained 12 questions relating to overall QOL and sub-components of QOL, which are summarized in Table 1. Kruskal-Wallis tests were performed for the difference in continuous data between groups.
Results: 701 patients (489 BE and 212 EC) met the eligibility criteria. 584 were married and were 113 single at baseline (4 had an unknown marital status). For EC patients, there were significant differences in changes in QOL reporting between marital states for pain frequency, overall physical, and legal QOL subscores over time, with single patients showing higher net QOL changes in comparison to married patients. See Table 1. By comparison, BE patients without cancer showed no statistically significant difference between marital states in any QOL score.
Conclusions: Married patients with EC reported a decrease in overall physical and pain frequency QOL and less improvement in legal related QOL over time in comparison to single patients. BE patients without cancer