223 POSTER

The relationship of follow-up tests results with the occurrence of overt metastatic disease

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Aim: To determine the association of blood tests: CA 15-3, GT, alcaline phosphatase, SGOT, total calcium, with the diagnosis of overt metastatic disease.

Methods: 528 patients (all patients had at least total mastectomy and axillary clearance as primary treatment (1985–1990) were analyzed for abnormal or equivocal findings in five routine blood tests obtained every 3 months for the first two years, every six months for years 3–5 and yearly thereafter. Median follow up was 7 years. Test results were evaluated to estimate the yield of different tests for any relapse.

Results: Of the 528 patients analyzed, 396 (75%) had node positive breast cancer. A total of 330 (62.5%) have got cancer relapse (at any site) during 7 year median follow-up. CA 15-3 with positive predictive value of 74% was the most effective indicator of progressive overt metastatic disease, among five blood tests evaluated. Alcaline phosphatase was the second (with positive predictive value of 28%), and other analyzed test were not justified.

Conclusion: CA 15-3 was the most effective blood test to distiguish patients with relapse from those without it; other analyzed tests were not justified.

224 PUBLICATION

Liaison® hCG – An automated chemiluminescent immunoassay for the determination of human chorionic gonadotropin

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An immunoassay utilizing chemiluminescence and paramagnetic particles has been developed for the new fully automated, random access Liaison® immunoanalyzer. The Liaison® hCG assay is a two-site immunoluminometric one-step assay using two highly specific monoclonal antibodies. Total incubation time is only 10 min. A specially designed unique reagent integral contains all specific reagents; the on-board stability of these reagents is given over a very long period (>4 weeks). The assay works with a 2-point calibrated mastercurve. 30 μl sample is added to 200 μl tracer and 20 μl antibody-coated magnetic particles. After 10 min incubation the particles are separated, washed and the chemiluminescent signal is generated. The time to first result is only 15 min. The assay with a unique extended standard range up to 5,000 ng/ml shows no high dose hook effect up to 400,000 mIU/ml (spiked sera). The assay detects both the intact molecule and the free beta subunit. The cross-reactivity to FSH, LH and TSH is less than 0.5%. Precision (within-run <3%; between-run <5%), linearity, recovery and sensitivity (<0.5 mIU/ml) are excellent. The assay shows a very good correlation to the LIA-mat® hCG ($r = 0.995$). In summary the Liaison® hCG assay together with the new Liaison® immunoanalyzer is a very rapid and accurate method for the quantitative determination of hCG/β-hCG in serum.

Supportive care

225 ORAL

Pain management in cancer patients at home: The role and views of patients and professionals

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Purpose: Pain in cancer patients at home is still treated inadequately, caused by, among other things, the organization of care. The purpose of this study is to make an inventory of how the treatment of pain is organized. The study gives insight in how the cancer patient experiences pain and the management of pain. It also gives insight in the role, tasks, and expertise of the health care professionals. Special attention will be given to aspects on cooperation and communication between involved professionals. The results will offer a lead for working out interventions, directed to organizational aspects of care, to improve cancer pain management at home.

Methods: A random selected group of oncology patients (n = 400), who were diagnosed with cancer between half a year and 3 years ago and treated in a university hospital, filled in a postal questionnaire on pain (MPQ-DLV) and the treatment of pain. Thirty patients who have indicated that they have pain and/or pain treatment are interviewed about pain management and the organization of care (using a semi-structured interview). The health care professionals (e.g. general practioner, specialist) who are involved in the care are also interviewed about these topics.

Results and Conclusion: Preliminary results indicate that the interviewed patients have a mean 'least pain' of 2.6 and a mean 'worst pain' of 6.2 on a VAS (range 1–10). They find the pain bearable but are worried because they think having pain means the cancer is progressing. Most patients use medication, but it is not prescribed at regular intervals. Half of the patients is dissatisfied with the effect of the treatment. All patients are medically supervised by a specialist, the GP has a minor role in pain management. They very rarely get in touch and in most cases the GP is not informed about the patients' pain, though they think this is necessary. The consequence for the organization of cancer pain management will be discussed.

227 ORAL

The patient-generated subjective global assessment of nutritional status: Evaluation in a Swedish setting

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Purpose: To evaluate the Patient-Generated Subjective Global Assessment, PG-SGA, a method for nutritional assessment in oncology patients (Ottery F.D. Sem in Oncol. 6: 770–8, 1994). A Swedish translation was used in the study including patients with gastro-intestinal and urologic tumours.

Methods: The patients, 61 men and 26 women, completed the first four sections. The remaining sections were completed by the physician and the dietitian, independent of each other. The validity was assessed with Serum-Albumin, P-Prealbumin (Transthyretin) and mononuclear leukocytes.

Results: The interobserver agreement was complete in 87%. There were significant differences between means of S-Albumin and P-Prealbumin for the SGA-classes. Weight loss during the last 6 and 12 months was most frequent in patients classified as either moderate/suspected of being malnourished or severely malnourished (SGA classes B and C). The patients had no difficulties in answering the questions. The sensitivity for those questions was 46–70% and the specificity 82–95%

Conclusion: The Patient-Generated Subjective Global Assessment is useful in the assessment of nutritional status in oncology patients. Weight loss has a great influence on the nutritional classification.

228 ORAL

Corticosteroids in acute vomiting – The more the better?

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Purpose: Corticosteroids enhance the antiemetic effects of 5-HT_3 receptor antagonists. Twenty milligrams of dexamethasone (DEX) or an equivalent seem to be the gold standard dose. The importance of corticosteroid dosage in acute antiemetic prophylaxis has not yet been studied.

Methods: Patients assigned to receive cisplatinum-containing combination-chemotherapy upon histologically confirmed ovarian cancer were enrolled to this single-blind, prospective randomized trial. For prophylaxis of acute nausea and vomiting patients received either DEX 20 mg or 8 mg both plus tropisetron 5 mg (Navoban®) 30 minutes prior to chemotherapy. Before chemotherapy and the following days we assessed endogenous cortisol levels, subjective well-being and objective parameters in 125 courses of 60 patients. During the days 2 to 4 patients received alizapride (Vergentan®) (3 × 100 mg).

Results: 20 mg DEX induce significantly lower cortisol levels during the day following chemotherapy. In the 8 mg DEX group 41.8% of the patients were free from nausea compared to 24.1% in the 20 mg DEX group ($p < 0.05$). Also for vomiting, bowel movement, and food intake superiority of the 20 mg medication could not be proven on any of the following days.

Conclusion: There is strong evidence that lower doses of corticosteroids are sufficient for the enhancement of 5-HT_3 antagonists in the prophylaxis of

acute nausea and vomiting and have a lower negative influence on delayed symptoms due to a less suppressive effect on endogenous corticosteroid levels.

229 ORAL

The efficacy of the NMDA receptor antagonist amantadine in the treatment of neuropathic cancer pain: A double blind, randomized, placebo-controlled trial

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Purpose: Neuropathic pain is present in about 25% of advanced cancer patients and remains a major clinical challenge. This pain is often associated with significant suffering and impaired quality of life. Recent evidence indicate that NMDA receptor antagonists can block pain transmission in spinal cord neurons, and reduce experimental pain in animals. However, their use in humans is limited due to high toxicity level. Amantadine (A) is a clinically available drug for chronic use in humans which was recently shown to be an NMDA receptor antagonist. The present study was aimed to test the analgesic efficacy of A in neuropathic cancer pain.

Methods: Fourteen cancer patients suffering from neuropathic pain were blindly assigned to receive I.V. infusions of either A (200 mg) or placebo, over a 3 hour period. Treatments were given 1 week apart, in a random order. Spontaneous pain (VAS), mechanical and thermal allodynia, as well as thresholds to thermal (TSA) and mechanical (Von Frey filaments) sensation and pain, were measured on an hourly basis during treatments.

Results: Amantadine produced around 60% reduction in spontaneous pain ($P < 0.01$) whereas placebo produced a much smaller, insignificant effect. No adverse effects were reported as a result of A treatment.

Conclusion: The clinically available NMDA receptor antagonist A reduces neuropathic pain in cancer patients. Further studies are needed to establish its long-term efficacy.

230 ORAL

Oral itasetron hydrochloride (DAU 6215Cl) versus ondansetron (OND): Comparable efficacy at a lower dose

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Purpose: Experimental and early clinical studies show that itasetron hydrochloride (ITA) has higher potency (~10 times), a longer half-life (~12 h) and potentially higher bioavailability than OND. These features may result in improved prophylactic control of the acute emesis caused by moderately emetogenic (doxorubicin/cyclophosphamide-based) chemotherapy (MECT). This multicentre, double-blind, parallel-group trial investigates the efficacy and tolerability of 5 oral doses of ITA with the label dose of OND for this indication.

Methods: Histologically-confirmed cancer (excluding head and neck) patients (pts) (n = 104) due to receive MECT were given escalating b.i.d. doses of 0.5 (n = 16), 1 (n = 17), 2 (n = 18), 4 (n = 17) or 8 mg ITA (n = 16) or 8 mg b.i.d. OND (n = 20) for 3 consecutive days.

Results: Complete response (no emetic episode within 24 h of CT) rates were: ITA = 56% (0.5 mg), 88% (1 mg), 71% (2 mg), 71% (4 mg), 88% (8 mg); OND = 65% (differences not significant $p > 0.05$). Pts given 1 mg b.i.d. ITA had the longest times to first nausea (median 33 h:45 m) or emesis (21 h:00 m). Median times for OND were 6 h:45 m and 9 h:30 m. The tolerability of all treatments was assessed as "very" or "rather" good by over 80% of pts and physicians.

Conclusion: Oral doses ≥1 mg b.i.d. ITA have comparable efficacy and tolerability to 8 mg b.i.d. OND in pts receiving MECT. ITA may offer advantages over OND by delaying the onset of nausea and/or emesis. This warrants further investigation.

231 POSTER

Scalp hypothermia for 2 hours prevents alopecia after adriamycin based chemotherapy

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Purpose: For many patients hair loss is the most disturbing side effect of chemotherapy. We have investigated scalp hypothermia as a measure to prevent alopecia using a new technique.

Methods: 23 patients received adriamycin (≥50 mg/m²) or cyclophosphamide based combination chemotherapy like EC, ACO or CY + CDDP which results normally in a complete alopecia in >80%. Scalp hypothermia of 15°C was maintained for 2 hours starting 30 min. before chemotherapy which was administered up to 60 min. The alopecia preventing effect was quantified using a score from 0–8.

Results: 20/23 of the patients (87%) accepted scalp cooling which can result in a transient headache. *Satisfactory hair preservation was obtained in 90% of the patients* receiving a median of 4 cycles. No hair loss was observed in 55%, a mild alopecia WHO grade I in 35%. Only 10% showed a alopecia grade II. No complete alopecia was observed. In patients treated with CPT-11 ($T_{1/2}$ 10.6 h) scalp cooling was ineffective.

Conclusions: Scalp hypothermia to 15°C over a 2 hour period is in our hands a very effective measure in preventing alopecia following chemotherapy. A wig was not required in 90% of the patients. Adjuvant chemotherapy in breast cancer is feasible without hair loss.

232 POSTER

An evaluation of etiology and risk factors of bacteremia in patients with hematological malignancies

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Objective: To ascertain the risk factors, etiology and outcome of bacteremia in patients with hematological malignancies.

Material and Methods: We undertake a retrospective case-control study, conducted over a 10-years period (1986–1995). The study included 106 patients grouped as follow: 53 patients with bacteremia and hematological malignancies (group A, i.e. the cases) and 53 patients, randomly selected in the same ward of the cases in the study period, with hematological malignancies and without bacteremia (Group B, i.e. the controls).

Results: A total of 63 episodes of bacteremia in 53 patients of Group A, namely 21 AML, 15 NHL, 6 ALL, 5 HD, 3 MM, 3 other malignancies. The most frequently etiologic agents were: coagulase-negative Staphylococci (36%), Pseudomonas aeruginosa (10%), Escherichia coli (10%), Staphylococcus aureus (4%). On univariate analysis, the risk factors for bacteremia were neutropenia (neutrophils <0.5' 109/1 for more than 6 days) ($p = 0.03$ Group A vs Group B), CVC usage ($p = 0.04$), absence of antibiotic prophylaxis ($p = 0.03$) and relapsed neoplasms ($p = 0.04$). The response to the specific therapy was favorable in 88 episodes (83%); death occurred in 9 (17%). Recurrences arose in 5 patients (9%).

Conclusions: Our study confirms the observation that in the last years the epidemiology of bacterial sepsis in neutropenic patients has been switched from Gram– to Gram+ microorganisms. This result probably correlates with the increased use of CVC and with the quinolones antibiotic prophylaxis. Although bacteremia in our series have been characterized by a low mortality rate, this condition requires special attention from the physician who must recognize and treat it promptly.

233 POSTER

Intravenous (i.v.) itasetron hydrochloride (DAU 6215Cl): An effective alternative to ondansetron (OND)

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Purpose: This multicentre (n = 20), double-blind, parallel-group study assessed the efficacy and tolerability of i.v. itasetron hydrochloride (ITA) with a maximally effective i.v. dose of OND.

Methods: Histologically-confirmed cancer (excluding head and neck tumours) patients (n = 219) to be given ≥70 mg/m² cisplatin for the first time,