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

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## 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.

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## 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.

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## 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.

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## 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.

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## 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,