tolerability of the 5HT3-antagonist tropisetron in chemotherapy-induced emesis (CIE) based on a large patient population.

Methods: 1506 patients (41% male, 59% female, mean age 52 years) with diverse malignancies received at least one course of emetogenic chemotherapy (cisplatin/non-cisplatin) and were given prophylactically tropisetron 5 mg once daily i.v. or p.o from day 1 until 2 days after end of chemotherapy. Nausea and emesis were recorded by the patients in diary cards.

Results: (course 1): Total control of emesis on day 1–9 was achieved in 74, 73, 76, 76, 76, 79, 82, 84, 83 and 85% of pts. In the "worst day analysis" 65% (38%) of patients had complete protection from emesis (nausea) during the whole study course. Tropisetron was well tolerated; in 91% of patients tolerability was rated as "good" or "very good".

Conclusion: Our results confirm the good efficacy and tolerability of tropisetron observed in former trials. No decrease in efficacy due to delayed symptoms was observed. 5 mg tropisetron o.a.d. is a simple and convenient means for prophylaxis of CIE in daily practice.

249 PUBLICATION

Totally implantable central venous access ports connected to Groshong catheter for chemotherapy of solid tumours: Long-term results of 270 cases

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Purpose: To examine the early and late complications rate of central venous access ports connected to Groshang catheter for long-term chemotherapy delivering.

Methods: All the patients suffering from a variety of solid neoplastic diseases requiring long-term chemotherapy and undergoing the placement of implantable ports during a 27-month period (October 1, 1994 to December 31, 1996) have been prospectively studied for device-related and overall complications.

Results: 270 devices, comprising a total of 59,943 days in situ, were placed in 267 patients. 3 patients received a second device after the removal of the first. Adequate follow-up was obtained in all the cases (median: 222 days, range: 4–732). Early complications included 9 pneumothoraxes (3.3%) and 3 revisions for port and/or catheter malfunction (overall early complications = 12, 4.4%). Late complications were 4 cases of catheter rupture and embolization (1.4%, 0.066 episodes/1000 days of use), 2 cases of venous thrombosis (0.7%, 0.033), 1 case of pocket infection (0.35%, 0.017), and 4 cases of port-related bacteremias (1.4%, 0.066). Infections were caused by coagulase-negative *Staphylococcus aureus* (4 cases) and *Bacillus subtilis* (one case); they required the port removal in 3 out of 5 cases.

Conclusion: Totally implantable access ports connected Groshong catheter have resulted a good option for long-term access to central veins and delivery of chemotherapeutic regimens.

250 PUBLICATION

Quality of life after radical prostatectomy

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Introduction and Objectives: In recent studies tumor specific moduls were developed according to the guidelines of the EORTC. These tumor modules were used together with the QLQ C-30 core questionnaire of the EORTC. Our group developed a prostate specific module for radical prostatectomy which was tested in a retrospective study.

Methods: In a retrospective study 130 patients with localized prostate cancer were interviewed with questionnaires between 1 and 3 years after radical prostatectomy. They received the EORTC QLQ C-30, the new developed tumor specific module and the IPSS score. The quality of life data were analyzed together with the clinical data of the patient. Statistical analysis was done with SPSS programm.

Results: Regarding to the problems concerning sexuality and incontinence after radical prostatectomy more detailed information was possible due to the new developed tumor specific module. All patients answered the questions dealing with sexuality, partnership and incontinence. 58% of the patients admitted severe limitation of their sexuality with high problems in partnership.

Conclusion: The present retrospective study help to increase the reliability and validity of the new instruments. In the future it is necessary to test this instrument in a prospective trial with baseline quality of life data.

251 PUBLICATION

Acute and delayed emesis in patients with solid tumors undergoing high-dose chemotherapy with autologous stem cell support (ASCS)

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Purpose: High-dose chemotherapy regimens with ASCS are higly emetogenic and adequate prevention of nausea and vomiting is requested. We have therefore evaluated the efficacy of 5-HT3 antagonists plus steroids in preventing emesis in pts with solid tumors undergoing high-dose chemotherapy with ASCS.

Methods: Antiemetic treatment: dexamethasone 20 mg i.v + ondansetron 48 mg i.v. (32 mg 8.00 a.m. + 16 mg 20.00 p.m.) each day of chemotherapy was administered in 12 pts (11 F, 1 M; median age 44 years; range 30–52 years) with breast (7), ovarian (4) and testis cancer (1) treated with a high dose regimen including cyclophosphamide 4 g/sqm i.v. + Paclitaxel 200 mg/sqm i.v.(4 pts), Vp16 2 g/sqm i.v. over 10 hrs (1 pt), melphalan 120 mg/sqm i.v. over 3 hrs on day 1 + thiotepa 600 mg/sqm i.v. over 3 hrs on day 3 (7 pts), carboplatin 1.800 mg/sqm i.v. over 6 hrs die 1 to 3 + mitoxantrone 60 mg/sqm i.v. over 1 hr die 1 to 3 (1 pt). Incidence, intensity and duration of acute and delayed nausea and vomiting were assessed for 5 days.

Results: Complete-major protection of acute and delayed vomiting was achieved by 10 pts (83.3%) and 8 pts (66.6%) and minor protection by 2 pts (16.6%) and 3 pts (25.0%) respectively. Acute nausea was absent or mild in 11 pts (91.6%) and moderate in 1 pt (8.3%); delayed moderate-severe nausea was observed in only 3 pts (25.0%).

Conclusion: These data show that the antiemetic regimen with 5-HT3 antagonists, at these doses and with this scheduling, improve significantly the complete control of vomiting in pts treated with high-dose chemotherapy.

252 PUBLICATION

Phase II multicentric trial of the use of intravenous clodronate by single fifteen day interval infusions in patients with bone osteolysis

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Purpose: Refractory bone pain remains a major clinical problem in the management of patients with metastatic bone disease. Clodronate inhibits normal bone resorption and has proven to be an useful treatment for osteolytic bone metastasis. However the best dose and administration schedule remain to be determined.

Methods: Twenty-nine normocalcemic patients (16 male and 13 female) with bone metastases and intractable bone pain by traditional therapy were studied in this phase II single arm open trial. Primary tumors: breast (44.8%), prostate (27%), myeloma (13.8%), renal (7%), lung (3.5%) and colon (3.5%). 50% of the patients presented with more than 10 metastatic bone sites. Pain medication: NSAIDs (62%), morphine (37.9%), corticosteroids (31%), other non-opioid analgesics (68.9%). The patients were treated with clodronate – 600 mg by 3-hour i.v. infusion every fifteen days.

Results: It was observed the decrease of pain through the reduction of the analogic non-visual scale score, with statistical significance from 30 days (the third visit) in relation to the first visit ($p < 0.05$). It was also observed statistical significant reduction of the amount of analgesic drugs used at the beginning as well as at the end of the treatment ($p < 0.005$). There was a very good tolerability to the medication. Mild nausea, vomiting and headache were the main side effects observed.

Conclusion: Useful palliation can be achieved with single fifteen-day intravenous infusion of clodronate.