243 POSTER

Protocolized administration of naso-gastric tube feeding in children with cancer: Effects on nutritional status

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Purpose: Without nutritional intervention, children with cancer are at high risk for developing a poor nutritional status due to the presence of a tumor and the aggressive oncologic treatment. From a retrospective study in our department it is known that non protocolized administration of naso-gastric tube feeding does not lead to a satisfactory improvement of nutritional status. Therefore a prospective study was set up in which children with cancer received naso-gastric tube feeding according to a protocol.

Methods: 20 pediatric cancer patients received naso-gastric tube feeding for a period of 16 weeks. Amount of tube feeding covered ≥100% of the child's total daily energy requirements. Changes in nutritional status were assessed weekly using anthropometric measurements (weight, height, skinfold and, mid-upper arm circumference) and bioelectrical impedance data. Biochemical variables reflecting nutritional status were also determined.

Results: There was a significant increase of bioelectrical impedance, body weight, skinfold thicknesses and mid-upper arm circumference. The increase in body weight could be contributed to both an increase of body fat and lean body mass. Within 16 weeks all children reached their ideal weight (= weight before clinical manifestation of illness). Biochemical variables showed a positive trend.

Conclusion: Protocolized administration of naso-gastric tube feeding significantly improves the nutritional status of a child with cancer. Covering the child's total daily energy requirements, regular monitoring of nutritional status and involvement of parents is crucial in achieving a good nutritional status in a child with cancer.

244 POSTER

Multicenter comparison of intravenous granisetron (G) alone or in combination with dexamethasone (GD) in the prevention of nausea and vomiting associated with moderate and highly emetogenic chemotherapy (CH) – The Hungarian experience

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Purpose: To compare the efficacy and safety of **G** (3 Mg i.v.) alone or in combination (**G** + 8 mg dexamethasone i.v.) in repeated cycles of **CH** administered over 24 hours in each course (day 0).

Methods: 147 **CH** naive patients (pts) were recruited in an open randomised multicenter two arms study. 145 pts were suitable for detailed analysis. All together 624 cycles (**C**) were followed (C_1: 145, C_2: 135, C_3: 109, C_4: 99, C_5: 71, C_6: 65). During the cisplatin 50–70 mg/m^2) containing (**CC**) and the nonciplatin containing (**NCC**) **CH** the acute and delayed emesis and nausea were compared between groups and an overall analysis was done.

Results: There were no significant differences in the complete and major responses between the two arms (**G** or **GD**) in the **NCC-CH** group by cycle and day (0–6 days). In the **CC-CH** group we observed a trend of the total responses in favour of the **GD** but the total and major control together did not differed significantly. The side effects (5.3%) were similar and well tolerated.

Conclusion: We recommend **GD** as a first choice in case of **CC-CH** for high risk pts or as second choice for those pts who did not respond well for **NCC-** or **CC-CH** since **G** is highly effectivite in monotherapy.

245 POSTER

Assessment of quality of life in incurable cancer patients in the First Moscow Hospice

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The purpose of the work was to evaluate the quality of life of the patients with the advanced cancers. The work was performed in the First Moscow Hospice (founded in September, 1994) – one of the first establishments of that type in Russia. The quality of life was assessed from the point of view of the patient and of the care-giver. The investigation was performed in 137 patients. For that special questionnaires were designed, taking into account the specific features of the disease and the conditions for the palliative care in Russia. In spite of the economic difficulties good results were achieved. 61% of patients noted considerable improvement of the quality of life. In 70% of patients pains decreased from 7–10 grades to 0–2 grades according to the 10-grades scale. In 55% of patients effective analgesia was achieved without narcotic analgetics.

Control of pain, of other symptoms, solution of the psychological, social and spiritual problems improve the quality of life in incurable cancer patients.

246 PUBLICATION

Rehabilitation of Oncological patients' in Lithuania

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Purpose: Rehabilitation of Oncological patients' is a novelty in the Lithuanian's medicine, because still 5 years ago the rehabilitation treatment of oncological patients' was strictly contraindicated. Since 1993 oncological patients have been sent to Palanga Health Centre "Energetikas". The aim of this study was to evaluate the structure of diseases of the treated patients' and the volume of rehabilitation.

Methods: 958 records of disease have been analysed using a personal computer. Part of the patients have been questioned by mail questionnaire.

Results: The majority of the patients (41.4%) have been directed for rehabilitation during first 4 months after diagnostic of oncological disease. The female patients after breast cancer operations made 29.2%, after oncogynecological diseases – 28.5%. Patients after abdominal cancer surgical treatment, ablation of larynx and chemotherapy courses made 12.9%, 9.2% and 11.1% of all treated patients respectively. The rehabilitation team in treating oncological patients was formed of a doctor, a psychologist, a kinesitherapeutist, a masseur, a logopaedist and a specialist of social care. Rehabilitation treatment complex included physiotherapy, balneotherapy, kinesitherapy, massage, phytotherapy, psychological, social and professional methods of rehabilitation.

Conclusion: The changed attitude of Lithuanian's oncologists' to the rehabilitation of oncological patients' and the use of rehabilitation methods restore oncological patients to full-valued life.

247 PUBLICATION

ECG and blood pressure changes during the 6-hours paclitaxel infusion

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Purpose: To determine the cardiac effects, ECG and blood pressure (BP) changes during the 6-hours paclitaxel (P) infusion in 33 pts were evaluated.

Methods: A total of 141 cycles of paclitaxel (P) was infused to 24 ovarian, 8 breast, and 1 lung cancer pts in 1000 cc 5% Dextrose solution. The standard premedication consisted of prednisolone and H1–2 antagonists were administered to all pts. Sixteen pts received 135 mg/sqm, 7 pts 150 mg/sqm and 10 pts 175 mg/sqm of paclitaxel. Pre and post infusion ECGs and hourly BP and pulse rate during infusion period were recorded in all pts. Twelve pts were pretreated with anthracycline based combination chemotherapy.

Results: ECG changes were determined only in 4 (12%) pts and 4 (3%) cycles. The changes were: ST depression in two, ventricular premature beats in 1, asymptomatic bradicardia (<60/min) in 1. These 4 pts had not used anthracyclines previously but 2 of them had a history of cardiac disease (coronary by-pass and mitral valve disease respectively). No persistent ECG changes occurred during the P infusions. Although the total body volume was increased at the end of the infusion, no significant change in blood pressures were recorded. In 65% of the cycles pulse rate decreased during the therapy.

Conclusion: There is no need in ECG and BP monitoring during P infusion in pts with no history of cardiac disease.

248 PUBLICATION

Tropisetron for prophylaxis of chemotherapy-induced emesis. Results of a German multicenter study

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Purpose: We performed a multicenter trial to evaluate the efficacy and

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.