shown that the survival time of DOX-treated mice receiving CaG was nearly 2.5-fold longer as compared to no CaG. LD_{100} DOX injected with CaG was about LD_{50} as compared to no CaG. The manifistation of DOX intestinal toxicity were lower after the DOX+CaG injection. In chronic experiments CaG caused a two-fold increase in mean survival time of DOX-treated mice and maximum total DOX dose. It was shown also that CaG does not influence on specific therapeutic activity of DOX in tumor-bearing animals. In experiments on the MOPS-406 plasmocytoma-bearing mice we have shown that therapeutic effect of small doses of DOX with CaG was the same as DOX alone. The antitoxic effect of CaG was clearly evident when toxic DOX doses were injected. All DOX-treated mice died earlier than the control tumor-bearing animals. In contrast there were no early deaths in DOX+CaG group and significantly higher DOX efficacy was achieved. Besides, there were cured animals in groups receiving high doses of DOX with CaG· 20 or 40% of mice with 15 or 20 mg/kg DOX+CaG respectively. Comparable results were obtained on hemoblastosis La-bearing mice. We conclude that CaG is perspective modifier which can be used in cancer patients and can increase the efficacy of anticancer DOX therapy by decreasing drug toxicity. Supported: the Russian Foundation for Basic Researches (Grant N 48796).

71 POSTER

Clinical evaluation of azasetron tablets in prevention of cisplatin-induced acute emesis – Multicenter double blind test with ondansetron tablets as control

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Purpose: To evaluate the effectiveness, safety and usefulness of azasetron tablets (Group A) in prevention of cisplatin-induced acute emesis, a double blind test was conducted with ondansetron tablets (Group O) as control.

Materials and Methods: Subjects were inpatients with malignancy receiving cisplatin (≥50 mg/m^2) alone or in combination chemotherapy with cisplatin. Tablets were orally administered before start of cisplatin. Antiemetic efficacy and adverse effects of antiemetic drugs were evaluated. Antiemetic efficacy were evaluated according to the degree of nausea and the number of vomiting episodes.

Results: 245 patients were entered, of whom 232 patients (121 in Group A, 111 in Group O) were accepted for analysis of effectiveness and usefulness, and 245 patients for analysis of safety. The rate of efficacy on acute emesis was 78% (94/121) in Group A and 73% (81/111) in Group O. The equivalence in effectiveness between ondansetron and azasetron tablets was verified. The rate of safety was 94% (120/127) in Group A and 88% (104/118) in Group O (p = 0.074). Adverse reactions were observed in 3 patients in Group A (headache, fever) and in 7 patients in Group O (headache, dull headache, diarrhea, fever and defective colulour vision) with the incidence being 2% and 6%, respectively. The rate of usefulness was 78% (94/121) in Group A and 72% (80/111) in Group O (p = 0.067). Group A was slightly better than Group O about the rate of safety and usefulness, with no significant difference between the two groups.

Conclusion: Group A were as effective as Group O, and slightly better than Group O in safety and usefulness, with no significant differences between two groups. We therefore consider that azasetron tablets is a useful drug in prevention of cisplatin-induce emesis.

72 POSTER

Effect of the perioperative selective bowel decontamination in abdominothoracal resections of the esophagus

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Purpose: The study was designed to evaluate the efficiency of the perioperative selective decontamination of the bowel in patients with abdominothoracal resections of a carcinoma of the cardia or the esophagus.

Method: 73 patients were included in a prospective randomized study. Loss of body weight </> 10% and carcinomas of the esophagus/cardia were stratified. The treatment group (n = 28) orally received 80 mg Gentamycin, 100 mg Polymyxin B and 200 mg Amphotericin B four-times a day starting 4 days prior to surgery. Postoperatively, the drugs were applied by a gastrointestinal tube.

Results are shown in the table.

	Treatment group (n = 28)	Control group (n = 45)
Artificial respiration	3.6 ± 5.0 days*	5.3 ± 9.5 days*
Stay in the ICU	9.1 ± 7.1 days*	11 6 ± 13.7 days*
Hospitalization	33.1 ± 16.1 days*	40.4 ± 27.3 days*
Pneumonia	36%	40%
Sepsis	11%	13%
Mortality	3 6%	8.9%

*[med ± SD]

Conclusion: No statistically significant differences were observed between both groups. The analysis of the postoperative course, however, shows that patients with a delayed postoperative weaning may profit from a perioperative selective bowel decontamination. This therapy should be focussed on this high risk patients.

73 POSTER

Risk factors and reversibility of neurotoxicity induced by high-dose paclitaxel

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Peripheral neuropathy (PN) is the main side effect with repetitive cycles of paclitaxel at standard doses. High-dose paclitaxel (HDP) with peripheral blood stem cell (PBSC) rescue is a novel treatment of patients (pts) with advanced cancer. No systematic evaluation of the neurotoxicity of HDP is available. Neurotoxicity of HDP was evaluated during a Phase I trial of HDP (500–800 mg/m^2 by 24-hour infusion, on day 1) followed by high-dose cyclophosphamide, thiotepa and carboplatin (Antman et al, J Clin Oncol, 1992, 10, 102) + PBSC rescue. Eighteen pts with metastatic cancer were treated with escalating doses of HDP (500 mg/m2, 3 pts; 600 mg/m2, 3 pts; 650 mg/m2, 3 pts; 700 mg/m2, 6 pts; 800 mg/m2, 3 pts) plus CTCb and evaluated before, during and after treatment with neurological examination (Neuropathy Symptom Score (NDS) and NCI common toxicity criteria (NCI-CTC), nerve conduction study (NCS) and evaluation of autonomic function. Four pts had been previously treated with neurotoxic chemotherapy (NC) (cisplatin, 3 pts; vinorelbine, 1 pt; paclitaxel, 1 pt). Pts with prior PN (grade, 2, NCI-CTC) were excluded. All pts had distal paresthesias and 5 had distal motor symptoms. None had vegetative symptoms and 2 had abnormalities on vegetative evaluation. Symptoms started 2.9 ± 0.3 days after HDP, worsened for 9 ± 0.8 days and improved by day 15.2 ± 0.4. Nerve conduction studies showed axonal neuropathy predominantly in the legs. Dose escalation correlated with duration of symptoms and delayed improvement (p = 0.013, Spearman). Previous NC but not dose escalation, was associated with more severe PN (p = 0.005, M-W). PN resolved within 2–4 months. PN induced by HDP is reversible and not dose limiting. Increasing dose is associated with more prolonged PN but not with severity. Neurotoxicity of HDP is moderate except in pts with prior NC.

74 PUBLICATION

Protective action of EHF electromagnetic irradiation on cisplatin-suppressed functional activity of immune system cells

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The question addressed in this study was how low-intensity non-ionizing electromagnetic irradiation (EMI) of extremely high frequency (EHF) range would modulate suppressive action of anticancer drug cisplatin (DDP) on specific activities of immune system cells, in particular, rosette-forming activity of T-lymphocytes (RFA) and phagocytic activity of neutrophils (PCA). G-protein inhibitor pertussis toxin (PT) was used to evaluate the role of cell signaling systems in the effects of DDP and EMI. Mice blood cells were exposed in vitro to DDP, PT and EMI, and assayed for functional responses as described in (A. Luik et al., Exp. Oncol., 1994, v. 16, p. 71–75).

DDP and PT inhibited RFA by 35 and 25%, respectively. Their joint effect was multiplicative (decrease by 55%), suggesting G-protein-independent route of DDP action. EMI did not affect normal or PT-suppressed RFA but completely reversed the effects of DDP, applied either alone or with PT.

Individual effects of DDP, EMI and PT on PCA were similar to their effects on RFA. However, joint effect of DDP and PT on RFA was synergistic rather than multiplicative (decrease by 75%). EMI did not reverse PT effect, activated by 20% PCA suppressed by DDP, and activated by 100% PCA suppressed by DDP+PT.