

wish to use individual patient data. This is a very important project, whose aim is to prepare and make widely available the most reliable evidence currently obtainable on all aspects of the care of cancer. It will need the cooperation and collaboration of many groups and individuals worldwide and we look forward to being contacted by anyone who would like more information about this major collaborative effort or who would like to participate, either by working on a systematic review; by helping with the process of finding trials; or by providing other support to the Network.

886 **PALLIATIVE EFFECTIVENESS OF RADIATION THERAPY IN THE TREATMENT OF SUPERIOR VENA CAVA SYNDROME**

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A study was made of 34 patients concerning the palliation effect of radiation therapy in the treatment of superior vena cava syndrome (SVC3). They were seen between 1986–1993, at the department of Radiotherapy in Middelheim General Hospital Antwerp. All patients had a syndrome of superior vena cava obstruction secondary to malignancy. The histologic diagnosis delivered an equal distribution of small cell carcinoma (SCLC) and non-small cell carcinoma (NSCLC). All patients with a small cell carcinoma received chemotherapy as initial treatment, but they didn't respond, relapsed or became evolutive during treatment. Each treatment was started with rapid-high dose irradiation, to continue after re-evaluation with rapid high-dose in case of a less good response or with the conventional fractionation of 200 cGy daily in patients with a good relief of symptoms. The initial rapid-high dose schedules depended on the performance status of the patients. Seventy-six percent of the patients with non-small cell lung carcinoma showed a good relief of their symptoms. It was very unexpected but the major part of NSCLC responded more quickly than SCLC, within 3 days after initiating treatment. In SCLC, 94% of the patients responded and this until death. The palliation index which is defined as the ratio of the symptom free period on the total survival and should be 1 in ideal circumstances, was 0.60 in case of NSCLC and 0.95 in case of SCLC. In this last group death was mainly due to disease progression in distant sites. <500>

887 **PROSTHESIS FOR THE TREATMENT OF METASTATIC BONE DISEASE OF THE HIP: EFFECTS OF RADIOTHERAPY**

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Twenty-eight patients with metastatic involvement of the proximal femur were treated by resection and prosthetic replacement. A large femoral prosthetic component was routinely fixed with polymethyl-metacrylate bone cement. Radiotherapy was delivered preoperatively in 2 and post-operatively in 7 patients. Postoperative pain (Habermann) was excellent in 81% and good in 15% of the patients. Hip functions (hip rating scale of Merle d'Aubigné) were rated as excellent in 19%, very good in 22% and good in 22% of the hips. Survival correlated with preoperative Karnofsky performance status ($P < 0.01$) and with the absence of postoperative pulmonary complications ($P < 0.01$). The radiographs of the 18 patients surviving 3 months or longer showed formation of a new bony envelope around the femoral prosthetic component in 11 cases (61%) and bone remodelling of the distal femur in 12 cases (67%). These changes occurred only if no radiotherapy had been delivered to the femur ($P < 0.01$).

888 **NEBULIZED OPIOIDS FOR BREATHLESSNESS IN CANCER PATIENTS: A CHART REVIEW**

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Purpose: The following is a retrospective chart review undertaken on cancer patients to assess the safety and efficacy of nebulized opioids for the treatment of breathlessness. **Patients and Methods:** Charts reviewed included patients over the eighteen month period. Forty patients were treated with nebulized opioids and subjective data was compiled. **Results:** Eleven patients received less than 3 doses. The treatment was

found to be effective, safe and convenient for 86% of the remaining twenty-nine patients. A feeling of claustrophobia while wearing the mask was found to be a major reason given for discontinuing treatment.

Conclusion: Nebulized opioids have been demonstrated as a treatment modality which is effective and safe for management of dyspnea in patients with terminal cancer. It was also found to be feasible for self-administration by the patient at home.

889 **INTRA-ARTERIAL CHEMOTHERAPY IN PATIENTS WITH LOCALLY ADVANCED PANCREATIC CANCER**

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From 8/1989–2/1995 22 patients (13-male, 9-female) with locally advanced pancreatic cancer received palliative intra-arterial chemotherapy (IAC). 20/22 patients had primary surgery, 6/22 pts. were pretreated with systemic 5-FU. All patients were suffering from inoperable local tumor or metastatic disease at the time of IAC.

Using the Seldinger technique and digital subtraction angiography the catheter was placed with its tip in the celiac axis. A total of 54 treatment courses has been performed (2.5 courses/patient). The chemotherapeutic regimen consisted of Mitomycin at 14 mg/m² over 2 hours, Cisplatin at 50 mg/m² over 4 hours, Folinic acid at 120 mg/m² and 5-FU at 2.0 g/m² over 20 hours.

Results: A PR was achieved in 4/22 pts. (18.2%), NC in 8/22 pts. (36.4%). 45.4% of the patients showed PD. The estimated mean progression-free survival time (Kaplan-Meier) for local disease was 11.6 months (4/12 pts. censored)—18.4 months for PR and 6.7 months for NC. The estimated mean survival time after IAC was 6.9 months (1/22 pts. censored)—22.9 months for PR, 5.7 months for NC and 3.6 months for PD.

Side effects were well tolerated: only moderate myelosuppression and gastrointestinal toxicity. There was only one patient with Grade III thrombopenia/leucopenia and 4 patients with Grade III or IV vomiting.

890 **SIGNIFICANCE OF PALLIATIVE RADIOTHERAPY OF THE METASTATIC BRAIN TUMORS**

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The aims of this study: To evaluate the radiation and combined treatment results of 167 patients with brain metastases: to determine the quality of life.

Methods: Whole brain irradiation of 40 Gy in 20 fractions and total-differential irradiation (20 Gy boost) was applied. Surgery has been performed in 49 (29.3%) patients with single lesion. The quality of life was scored according KPS, WHO status, and a neurological examination was performed.

Results: Management with steroids alone extends the median survival time to 1.67 mos. The overall length of survival was significantly longer in radiotherapy group (median, 8.77 mos., Mantel-Cox $P = 0.01$). Median survival was 10.47 mos. in the surgery + radiation group (Breslow $P < 0.004$). Analysis showed that radiotherapy was associated with a better quality of life ($P < 0.01$).

891 **PALLIATIVE CHEMOTHERAPY FOR MELANOMA PATIENTS: INVERSE RELATIONSHIP BETWEEN TUMOR LOAD AND TREATMENT EFFECTIVENESS**

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Patients (P) selected for phase II trials differ subst. from those who need pall. treatment for sympt. disease. A low PS due to high tumor load is inversely related to ORR. Expectations from the publ. efficacy of any part. treatment are hardly ever met in daily clin. routine, side effects are underestimated and the psych. benefit for the desperate P hardly out-ways the discomfort afflicted by the necessary med. surveillance. In P with dissem. melanoma improvement of 'time without symptoms and toxicity' by system. chemother. still is the exception. This was demonstrated by a multicenter trial of the EORTC, undertaken to confirm the except. high ORR of some 45% reported earlier with FOTEMUSTINE. The ORR in 98 highly selected eligible P was 12% (17% DS), thus sign.

lower than in earlier monoinstit. trials and reached only 5% (12% DS) in 42 non-eligible P. The responsibility of the treating oncologist for his P's quality adjusted life months is stressed.

892 POSTER **TOTALLY IMPLANTABLE VENOUS ACCESS DEVICES (TIVAD) IN CANCEROLOGY. RESULTS OF 141 PERCUTANEOUS CANNULATION**

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Introduction: cytotoxic chemotherapy often requires a central venous access by a catheter or a TIVAD.

Materials: we reviewed a homogenous series of 141 patients: 87 women, 54 men, ranging in age from 20 to 80 years old (mean age 54 years). Each patient had a malignant disease, most frequently being metastasis: breast cancer (41.8%), head and neck cancer (10%), ovary cancer (7.8%), lung cancer (7%), sarcoma (5.6%) colon cancer (4.2%) and others (23.4%). The TIVAD used was the standard model Districath® (Districlass) for 90% cases, joined by a silicon catheter with an internal diameter of 1.10 mm.

Methods: after a prophylactic antibiotherapy, a neuroanalgesia and a local anesthetic, firstly we used the method of percutaneous cannulation of the subclavian vein and then implanted the TIVAD 2 cm under the clavicle. All implantations were made under normal sterile surgical procedures. The treatment started after 4 days and injection of heparin continued every 29 days.

Results: percutaneous venous access was successful 139 times (98.6%) with the puncture 112 times (79.4%) on the right. We regret having punctured the subclavian artery 6 times (4.2%) but this did not cause any after-effects. However we experienced no complications of haematoma, pneumothorax, local infections or septicemia. Unfortunately we had to remove 7 TIVADs due to 3 ruptures of the catheter, 2 septicemias, 1 case of ulcerated skin and 1 for psychological intolerance. The time patients spent in the operating theatre in 68% of the cases ranged between 1.5-2 hours. During this study in 1994 we did not experience any extravasation of the cytotoxic drug and no catheter blockage, nor any TIVAD related deaths.

Conclusion: in our series, the implantation of TIVAD by a percutaneous puncture of the subclavian vein is a quick, reliable method with a low morbidity rate. This operation can lead to many potential complications and should be carried out stringently in surgical conditions. Nevertheless we believe that the percutaneous puncture method provides good venous access and improves the security and the quality of patient life.

893 POSTER **ADVANTAGES OF THE COMPUTER PROGRAM "HEM" IN FOLLOWING, PROCESSING AND ANALYZING DATA OF CHEMOTHERAPY TRIALS**

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One of the most difficult stages in clinical drug trials is collecting, selecting and analyzing data. In the past, this was done manually, which took almost 80% of investigation's time, and the possibility of the mistakes was very high. Computer program "HEM" has been developed and used for storage and processing data in clinical trials. Program has three independent parts: data entry, data processing and data entry control. Data entry includes entering: data about patient's illness before the therapy (diagnosis, TNM classification, stage, PH diagnosis, previous therapy, performance status (PS), localization and dimension (L&D) of the primary tumor or local recurrence, L&D of the metastases), during and after the chemotherapy (PS, L&D of the primary tumor or local recurrence, L&D of the metastases and therapy toxicity-WHO classification), as well as the data about patients excluded from the trial. The initial date, data concerning therapy effect, data concerning therapy toxicity and dose intensity were analyzed for each optionally defined groups, by using data processing. All combinations of initial data could be used for defining these groups. Data accuracy is assessed with data entry control. Advantages of "HEM": 1) reduction of the time necessary for data entry and analyzing data—used time is less than 10 min. for all entries per patient, and 30 min. per complete trial data analyzing, 2) logical control minimizes mistakes (incomplete, wrong and missing data), 3) lost data are eliminated with daily "back up", 4) daily follow up is enabled by data

entry control, 5) it improves accessibility of the data. "HEM" was made in Clipper, installed on PC computer and is user friendly oriented program. It was installed in Sept. 1991. Today, about 1200 patient's records in 30 clinical trials are followed with "HEM".

894 POSTER **THE PALLIATIVE TREATMENT OF THE SOLITARY BRAIN METASTASES WITH THE LEKSELL GAMMA KNIFE STEREOTACTIC IRRADIATION**

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From November 1992 to May 1995 there were 75 patients with 112 intracerebral metastases treated in Hospital Na Homolce in Stereotactic and Radiation Neurosurgery Department. The study characterises the most optimal group of solitary brain metastases indicated for Leksell Gamma Knife treatment, which is mainly determined by volumes up to 20 cm³, location in the brain hemispheres, proper histological type, Karnofsky rate 70% and more, age under 60 years and with no other organ generation (except CNS). For evaluation of late effects longer time interval (min. 18 months from the treatment) will be needed. However, the prognostic factors, symptomatic response, local control, acute toxicity and quality of patient's survival can be evaluated. The main advantages of the described method are already apparent now: no operation mortality, minimal morbidity, short hospital stay and nearly no claims to change of patient's way of life. The stereotactic radiosurgery and radiotherapy fulfil the requirements of palliative treatment: maximum benefit with minimal treatment and investigation procedures.

895 POSTER **PATIENT PREFERENCE OF ANTIEMETIC TREATMENT: A PLACEBO CONTROLLED, DOUBLE BLIND COMPARISON OF GRANISETRON WITH GRANISETRON PLUS DEXAMETHASONE**

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The antiemetic efficacy of 3 mg *iv* granisetron (G) was compared with G plus 20 mg *iv* dexamethasone (Dex) in a double blind placebo (Plac) controlled cross over study. Seventy-two patients (pts) undergoing moderate to highly emetogenic chemotherapy (C), received both antiemetic treatments. At the end of the study, before the study was unblinded, all pts were asked to state their preference of antiemetic treatment; either first cycle, second cycle or no preference (NP). The results are shown below.

	Patient Preference (No. Pts)	
	G + Dex	G + Plac
Sequence: cycle 1/cycle 2.		
G + Dex/G+ Plac	13	8
G + Plac/G + Dex	16	6
Combined	29	14
		NP
		18
		11
		29

An analysis of the patient preferences (PP) showed that there was a significant difference ($P < 0.022$, Likelihood Ratio Chi Sq.) between the preferred treatments. The 24 hour complete response rates (no vomiting or retching and only up to mild nausea) for combined cycles were as follows; 80.6%, for G + Dex and 65.3% for G + Plac ($P = 0.015$).

Overall, more pts (29) preferred the antiemetic session where Dex was incorporated with G than with the G + Plac (14 pts). These data show that PP may be an additional sensitive means of evaluating antiemetic efficacy in cross over comparator studies and may be influenced by the level of control of acute emesis.

896 PUBLICATION **PHOTODYNAMIC THERAPY OF TUMOURS: NEW ADVANCES**

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Studies on transport of HpD by high and low density proteins (VLDL, LDL and HDL) have suggested that apparently lipoproteins possess two