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

Ph. Maillart, G. Lorimier, E. Gamelin, R. Delva, A. Lortholary, V. Meyer, J. Guerin, C. Giraud, F. Larra
Centre Paul Papin, 2 rue Moll, 49033 Angers Cedex 01, France

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 subsclavian artery 6 times (4.2%) but this did not cause any after-affects. However we experienced no complications of haematoma, pneumothoracis, local infections or septicaemia. Unfortunately we had to remove 7 TIVADs due to 3 ruptures of the catheter, 2 septicaemias, 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 ANALIZING DATA OF CHEMOTHERAPY TRIALS

Z. Ristović[1], S. Jelić[1], V. Kovčin[1], S. Vučković[2], B. Ribarić[1], L. Vuletić-Mitrović[1]
[1] Institute of Oncology and Radiology, Belgrade
[2] Institute of Pharmacology and Toxicology, Medical Falculty, Belgrade

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 group. 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 then 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

G. Šimonová, J. Novotný Jr, R. Liščák, V. Vladyka, Oldřich Šubrt
Hospital Na Homolce, Stereotactic and Radiation Neurosurgery Department, Roentgenova 2, 151 19 Prague 5, Czech Republic

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 cm^3, 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

J.-P. Terrey[1,5], M. Aapro[2,3,4,5], V. Kirchner[2], P. Alberto[2,5]
[1] SmithKline Beecham AG, 3174-Thörishaus
[2] Hopital Cantonal Universitaire. 1211, Geneva
[3] Clinique de Genolier, 1261, Genolier
[4] European Institute for Oncology, IT20141, Milan, Italy
[5] Denotes present address

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	NP
Sequence: cycle 1/cycle 2.			
G + Dex/G+ Plac	13	8	18
G + Plac/ G + Dex	16	6	11
Combined	29	14	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

A. De Rosa, A. Di Luccia[1], A. Rizzo[2]
Oncologist USL 30 Napoli, Italy
[1] CNR Napoli, Italy
[2] Istituto di Microbiologia, I Facoltà di Medicina, Napoli, Italy

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