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A PHASE II STUDY OF VINORELBINE IN METASTATIC PANCREATIC ADENOCARCINOMA. PL ETIENNE1, JY DOUILLARD2, A ADENIS3, JF BRETAGNE4. 1- CENTRE E MARQUIS 35062 RENNES Cedex.. 2- CENTRE R GAUDUCHEAU 44805 SAINT HERBLAIN. 3- CENTRE O LAMBRET 59020 LILLE Cedex. 4- CHRU PONTCHAILLOU 35033 RENNES Cedex. FRANCE.

Identification of new active drug is necessary to improve the very slim prognosis of metastatic pancreatic carcinoma. Fourteen patients with histologically proven pancreatic adenocarcinoma were included in this phase II study. Median age of these patients was 56 (range 41-68), performans status 0 to 2. Vinorelbine was administred weekly at 25mg/m2. Dose reduction was planed according to neutrophils count (<1000 0%, 1000< <1500 50%, 1500< <2000 75%). Median duration of the treatment was 8 weeks (range 4-20). Toxicity was mild. Hematological toxicity was observed in 9 cases (neutropenia grade II: 7 cases, grade III: 2 cases). Neurological grade 1 toxicity was observed in 2 cases, drug related fever in 1 case. No major objective response was seen but 2 patients had stable disease for 2 and 3 months respectivelly. Vinorelbine do not demonstrate sufficient clinical activity to be asociated with other drug in this disease.

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LIDOCAINE TEST IN CANCER PATIENTS WITH LIVER METASTASES.
Sanz A, Fernández Y, Lorenzo D, Vena C, Palacio I, Vigil E, Dacosta S, Fernández JL, Urréchaga E and Buesa JM.
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The capacity to metabolize lidocaine to monoethyl-glycine xilidide (MEGX), an useful prognostic test in pts with liver cirrhosis, was evaluated in cancer pts with liver metastases. MEGX and lidocaine serum levels were determined (TDX test,Abbott Laboratories) at 15 and 30 min after and IV lidocaine bolus injection (1 mg/Kg). From Jan 93 - March 93, 20 pts were studied (11 with/ 9 without liver metastases). Mean +/- s.d. MEGX and lidocaine values at 15 and 30 min were not different in those two groups:

MEGX (ng/ml)	15 min	30 min
with metastases	90.0 +/- 36	104.3 +/- 42
without metastases	89.0 +/- 25	97.6 +/- 22
Lidocaine (ng/ml)		
with metastases	2.7 +/- 3.2	1.3 +/- 0.9
without metastases	3.9 +/- 3.7	2.5 +/- 2.5

In the whole group there was a correlation between MEGX and cholinesterase or bilirubin values (p 0.05). No untowards side-effects were noted and the study continues.

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VINORELBINE (NAVELBINE®) IS AN ACTIVE DRUG IN METASTATIC EPIDERMOID ESOPHAGEAL CARCINOMA (MEEC).
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Since 01/1990, the EORTC GITCCG conducted a Phase II study in MEEC with Navelbine (NVB) 25 mg/m^2 weekly. 45 patients (pts), with measurable disease, were entered by 12 institutions. 29 pts previously untreated by chemotherapy and 16 pts relapsing after neoadjuvant FU-DDP entered the protocol. 42/45 pts were eligible (93 %) : male 92 % ; median age of 59 years (range : 40-72) ; median ECOG performance status 1 (range : 0-2). 38 pts are evaluable for toxicity and response (4 pts too early). Median NVB courses was 8 (range : 1-27). Main toxicities were : granulocytopenia 85 % : (43 % WHO grade [gr.] 3 ; 12 % gr. 4) ; gr. 3 thrombocytopenia 3 % ; gr. 3 infection 3 % ; gr. 3 constipation 2 %. Gr. 1 peripheral neurotoxicity was observed in 19 % of pts. 15 pts (38 %) complained of fatigue (30 % gr. 1 ; 5 % gr. 2 ; 3 % gr. 3). No toxic death occurred. Among the first 26 pts without prior chemotherapy, 7 achieved a PR (27 % ; 95 % C.I. : 12-48 %). Median response duration was 3+ months. 8 had stabilisation of their disease, including an unconfirmed PR because of pt's refusal of a second CT-scan. 1/12 pts with prior FU-DDP had a CR with a 7 months' time to progression. 8 pts are still on study. Responses occurred in primary tumors, local relapses, pulmonary, hepatic and lymph nodes metastases. Median survival was 6 months.
The high activity and low neurotoxicity of NVB in MEEC will lead to further evaluation in combination chemotherapy with cisplatin.

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5 FLUOROURACIL, ETOPOSIDE, EPIRUBICIN, CISPLATIN IN TREATMENT OF ADVANCED GASTRIC CANCER.
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Between january 1989 and july 1992, 25 patients with previously untreated adenocarcinoma of the stomach have been treated with FEAP which consists in 5FU 500 mg/m2/d by continuous infusion d1-5, VP16 100 mg/m2/d d2-4, Epirubicin 50 mg/m2 day 3, CDDP 25 mg/m2/d d1-5 and repeated every 3 weeks. The median age was 56 years (38-70) with 17 males and 7 females. Median performance status was 90 (range 70-100). 1 patient had locally advanced disease alone, 18 patients had liver metastases, 6 had metastases in other sites. All patients were evaluable for toxicity and response. The mean number of cycles was 8 (range 1-15), the total number of cycles was 206.
Incidence of WHO toxicity grade 3-4 were -neutrophils:6; -platelets:1; anemia:10; -vomiting:3; -stomatitis:3; -diarrhea:1; -neurological toxicity:3.Toxic death 1 pt. due to septic shock. All patients had alopecia after 2 cycles of treatment.
20 patients (80 %) showed objective response, always associated with clinical improvement with median response duration of 9 months (3- 22). There was no complete responder. The overall survival was 10 months (2-22).
Conclusion: FEAP is active against advanced gastric carcinoma but can be associated with substential toxicity without evident impact on survival.

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TRANSCATHETER ARTERIAL CHEMOEMBOLIZATION (TACE) WITH CARBOPLATIN (C), LIPIODOL (L) AND GELATIN SPONGE (S) IN HEPATOCELLULAR CARCINOMA
Marmiroli L, Ausili-Cefaro G, Grieco A[1], Castellano R[1], Marcoccia S[1], Nuzzo G[2], Salvi G, Alsayyad SMS, Cotroneo AR - Depts of Radiology, [1]Internal Medicine and [2]Geriatric Surgery - Catholic University, Rome, Italy
TACE represents an effective means in prolonging survival in inoperable HCC and is also a useful procedure in resectable tumors for its high diagnostic accuracy in detecting daughter nodules missed at standard imaging (US, CT). Oily chemoembolization allows for retention of a higher concentration of anticancer agents within the tumor and for a longer contact to enhance effects of chemotherapy. In this study a mixture of L 10-15 ml and C 150 mg/m^2 was injected into the hepatic artery; S particles were used with a superselective tecnique for segmental TACE. Therapy was repeated 2-3 times with a 3 months rest. Selection criteria for TACE: Child A or B, PS I-II, absence of bleeding esofageal varices or portal vein thrombosis. From 01/92 26 pts with pathologically diagnosed HCC were treated; M:F 21:5; Okuda I 19, II 7; average age 64.3 y (range 46-84). 34 TACE were performed. Side effects were always non-hematologic: in most cases nausea and vomiting, fever and abdominal pain occurred. There was one treatment-related death due to upper GI hemorrhage. Response (R) was recorded according to the following criteria: percentage of L accumulation, decrease in size and number of the nodules, decrease of α-Fetoprotein levels. 13 pts had a major R, 6 a minor R or stable disease, 7 a progression. In 2 pts, who underwent TACE in neoadjuvant setting, surgical specimens revealed total necrosis of the tumor. We conclude that TACE with C is relatively well tollerated and can be considered the therapy of choice for palliative and preoperative treatment.

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QUANTITATIVE ESTIMATION OF TUMOUR-PENETRATING LYMPHOCYTES IN GASTRIC ADENOCARCINOMA.
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Study of tumor-penetrating lymphocytes (TPL) has been performed in 25 patients with gastric adenocarcinoma within the fields of continuous tumour growth. Identification and quantification of TPL in one square millimeter was done with the use of standard monoclonal antibodies on cryostat sections in immunofluorescent method. The level of tumor infiltration by CD45+ cells determined the quantity of both CD3+,CD7+ T-TPL and their subpopulations (CD4, CD8). Activation of TPL (CD25+) was not dependent on the level of lymphocytic infiltration of tumor. Quantity of TPL increased in the cases of prominent expression of transferrine receptor (CD71) on tumor cells and decreased in poorly differentiated adenocarcinomas. Statistically higher number of CD7+ CD3+ CD4+ CD8+ CD25+ TPL was found in II clinical stage in comparison to III stage of gastric cancer. Peak intensity of local immune reactions fell down on Ib, II, IIIa stages. The types of TPL subpopulation changes indicate on the correlation between morphological,clinical features and immunophenotype of gastric adenocarcinoma. So, the quantification of TPL may be a useful parameter in immunobiological studies of gastric cancer.