group A were treated from October 1, 1992 to October 1, 1994 (51/T3, 4/T4, 4/N+, all Mo). Group B included 38 patients (28/T3, 2/T4, 8/N+, all Mo). In both groups radiotherapy was applied on LINAC (10 MV) with locoregional technique to a dose 65 Gy by conventional fractionation. Patients in group A received carboplatin weekly at daily dose of 150 mg, every fifth day, one hour prior to irradiation, up to total dose of 900 mg. Achieved response rates were in group A: CR = 89%, PR = 4%, PD = 7% and in group B: CR = 63%, PR = 11%, SD = 21%, PD = 5%). Hematological toxicity grade I and II (by WHO criteria), predominant leucopenia and thrombocytopenia, was registrated in majority of patients in group A. Mean follow-up time was 20 months (range 3–26). Two-year overall survival as 86% and 70%, disease free survival as 69% and 50% in group A and in group B; respectively. Invasive local relaps occurred in 5/59 patients in group A and 6/38 patients in group B. Metastatic disease with local control confirmed in 7/59 patients in group A. Local relaps with disseminated disease had 5/38 patients in group B. Results showed that addition of carboplatin to radiotherapy increased complete response rate, local control and early survival in patients with locally advanced bladder cancer, but short follow-up, not permit definitive conclusion concerning long-term survival and bladder preservation.

1151 POSTER

NEOADJUVANT MVAC CHEMOTHERAPY IN BLADDER CANCER: THE CENTRE FRANCOIS BACLESSE (CFB) EXPERIENCE

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The efficiency of MVAC (Methotrexate 30 mg/m^2 J_1–J_{15}–J_{J22}, Vinblastine 3 mg/m^2 J_1, Doxorubicine 40 mg/m^2 J_1, Cisplatin 70 mg/m$_2$ J_1) given as neoadjuvant chemotherapy (CT), was evaluated in a series of newly diagnosed patients treated at a single institution. From April 1988 to March 1993, 71 patients were referred to CFB of whom 40 were given MVAC as neoadjuvant CT. Initial patients' characteristics were: male/female ratio 4.7; mean age 57 years (range 31 to 75); there were 9 T_0T_1 with grade III, 16 T_2T_3, 7 T_4 and 8 T_x; 19 patients were N_0, 4 N_+, and 17 N_x. CT consisted of 3 to 4 courses of MVAC (35 patients); 5 patients were only administered 2 courses because of toxicity. Surgery was performed after CT in 30 patients (21 radical cystectomy); in 10 patients, secondary treatment consisted of irradiation.

After surgery, residual disease was present at histological examination in 20 patients; in the other 10 patients no tumour was microscopically found (objective and complete responses respectively 55% and 33%). Globally, at the end of therapy, 15 patients were in complete remission, 15 in partial remission, 7 had progressive disease, and 3 were not evaluable.

Toxicity (grade 2 to 4): CT induced haematological toxicity in 24 patients, renal toxicity in 5, cardiac toxicity in 3, and 3 patients died during CT.

With a median follow-up of 56 months, the 4 year overall survival rate from first CT course was 67%; the 4-year freedom from progression rate was 63%.

1152 POSTER

GEMCITABINE IN THE TREATMENT OF PATIENTS WITH ADVANCED TRANSITIONAL CELL CARCINOMA: A PHASE II STUDY

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Gemcitabine is a nucleoside analogue with broad-spectrum activity in several solid tumours. In a Phase I trial, responses were seen in patients with MVAC-refractory bladder cancer. Currently 21 patients with no prior chemotherapy for metastatic transitional cell cancer have been entered on a Phase II trial of gemcitabine at 1200 mg/m^2 weekly × 3 every 4 weeks. Patient characteristics include: 14 males, 7 females; median age 71 (range 42–88), median Karnofsky performance status 80 (range 60–100); 20 metastatic, 1 locally advanced disease; 2 prior adjuvant or neoadjuvant chemotherapy and 2 with prior radiation therapy. Currently 18 patients are evaluable for response with 3 too early. There have been 11 partial responses among the 18 evaluable patients. Sites of response have included pelvic and periaortic lymph nodes, liver and lung metastases. Toxicity has been modest in this study with no Grade 4 drug-related side effects. Grade 3 nausea and vomiting have been encountered as have Grade 1 and 2 leukopenia, myalgias, skin rash and fever. One patient with a partial response developed pneumocystis pneumonia with lowered T-4 counts and was removed from study. When he subsequently progressed (approximately 5 months later) he was retreated with gemcitabine (and trim-sulfa prophylaxis) and again has had a partial response. These data suggest that gemcitabine has promising activity in patients with transitional cell cancer and merits combination studies with other active agents in this disease such as cisplatin (with which preclinical synergy has been demonstrated) and paclitaxel.

1153 POSTER

TRANSURETHRAL RESECTION (TUR) AND CHEMOTHERAPY FOR MUSCLE-INVASIVE BLADDER CANCER: LONG-TERM RESULTS

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116 patients with muscle-invasive bladder cancer (15 T2, 94 T3, 7 T4: 23 G2, 91 G3, 2 GX, 115 Nx, 1 N1) were treated by "extensive" TUR and chemotherapy, either with high dose methotrexate (HDMTX) or cisplatin combinations. Follow-up is 3.9 to 15.2 years (median 11.6 years). The median age was 67 (range 37–88) and tumour size ranged from less than 2 to 7 cms. The median disease-specific survival is 7 years for the entire group, 4 years for HDMTX and has not been reached at 10+ years for the cisplatin combination group. T category and tumour size, but not histological grade, predict for outcome.

The results indicate that, for selected patients, this approach offers an excellent chance of bladder conservation without compromising cure rates. Results, in terms of local control and survival, are comparable with more conventional treatment approaches.

1154 POSTER

PRESERVATION OF THE ORGAN IN THE THERAPY OF INFILTRATING BLADDER TUMOURS

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From 1986 to 1994, in the II Clinic of Urology, 109 patients affected by invasive bladder carcinoma, without any random schedule, have been subjected to 3 different treatments: (1) Radical cystectomy; (2) Neoadjuvant chemotherapy (N.C.) + radical cistectomy; (3) N. C. + conservative surgical therapy. The difference of survival between group 1 and group 2 and 3 is important from the statistic point of view, and is respectively $P = 0.0209$ and $P = 0.0190$ after adjustment for age, stage, lymph node status (cox model). In the patients of group 3 (13 patients) we have considered it possible to carry out a conservative surgical treatment, in relation to the clinical-pathological response after N. C. In 9 cases, in which we have obtained 7 complete responses and 2 partial responses > than 90%, the conservative surgical therapy consisted of bladder TUR; in the remaining 4 patients for whom we have obtained a partial response > than 50% the therapy consisted of a bladder resection. These results seem to suggest that some patients affected by infiltrating bladder tumour, with a good response to N.C. and well selected, may be evaluated for a conservative treatment.

1155 POSTER

A PHASE III TRIAL OF NEOADJUVANT CHEMOTHERAPY (NCT) IN PATIENTS (PTS) WITH INVASIVE BLADDER CANCER (IBC). PRELIMINARY RESULTS: NCT IMPROVES PATHOLOGICAL COMPLETE RESPONSE RATE

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Introduction: As we reported previously (Eur J Cancer 1991;27(S12):107; Ann Oncol 1994;5(S8):66) treatment with CBDCA,