MTX and VBL is as effective as M-VAC in advanced bladder cancer with long-term survival and can be safely given in an outpatient basis and in pts with impaired renal function. We designed a multicentric study, randomizing pts to receive NCT followed by cistectomy (branch A) or cistectomy alone (branch B). We present the results of pts treated in one institution.

Patients and methods: The inclusion criteria were transitional IBC T3b–4aN0M0, T2–3aN0M0 with obstructive uropathy or presence of diffuse Tis, and creatinine $<130 \times 1.25$ μmol/L. The schedule of NCT was: MTX 30 mg/m^2 and VBL 4 mg/m^2 (d +1, +8) and CBDCA 350 mg/m^2 (d +2); 3 cycles, every 4 weeks. All surgical specimens were reviewed by one pathologist*. The minimum follow-up was 2 years. Sixty-six pts were analyzed: 33 pts in branch A, 33 pts in branch B.

Results: Postoperatory mortality was 3%. Response rates were: pCR and pPR 20% and 23% in branch A, and 3% and 12% in branch B. The pCR differences (17%, CI 2–32%) and the pCR + pPR differences (28%, CI 7–50%) were statistically significant with $p < 0.04$ and $p < 0.02$ respectively. There were no survival differences between the two branches. Five-year survival was 50%.

Conclusions: It's the first time that NCT in IBC has demonstrated more pathological responses than the transuretral resection alone. More pts and more trials are needed to confirm these results. The absence of survival differences could be due to chemotherapy selection of pts with a good prognosis in branch A.

1156 PUBLICATION

TREATING UROTHELIAL TRANSITIONAL CELL CANCER (TCC) WITH METHOTREXATE (M), CARBOPLATIN (C), NOVANTRONE (N) AND VINCRISTINE (O)

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Cisplatin combination chemotherapy (CT) is considered as standard therapy for TCC and MVAC as the mostly tested regime in this condition. The aim of this study was to test efficacy and toxicity of a combination by substituting the drugs of MVAC (except for M that was given in increased dose) by their analogues (MCNO) in pts with TCC. We administered M 300 mg/m^2 as a 4 h infusion (with fol.acid rescue), C 300 mg/m^2, N 12 mg/m^2 and O 1 mg/m^2, all given on d. 1, q 3w. 47 consecutive and CT-naive pts aged 65 y. (43–74) received MCNO as follows: 16 pts as postsurgical adjuvant CT with 10 NED for 6^+ ($4–16^+$) mos, 5 relapsed/dead and 1 relapsed/alive on CT. 20 pts as neoadjuvant CT with 3 cCR (0 pCR), 7 cPR and 10 SD. 9 pts were operated (0 pCR/8 sCR), 5 of them are NED for 5^+ ($2–28^+$) mos, 6 survive on CT and 9 died. And 11 pts with metastatic disease and with 2 cCR/NED for 9^+ and 23^+ mos, 1 cPR, 4 SD and 4 PD. Alive off CT 2, alive on CT 3, dead 6. Toxicity gr. >2: Hb 21 (45%) pts, ANC 32 (68%), thrombocytopenia 20 (43%), G.I 14 (30%) with no toxic death. Our conclusion is that MCNO does not differ from other similar regimes in terms of efficacy/toxicity.

1157 PUBLICATION

CMV AND CAMV IN THE TREATMENT OF ADVANCED BLADDER CANCER

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From June 1992 to March 1995, 28 patients (pts) with advanced bladder cancer were treated with CMV cytostatic regimen (14 pts; day 1: methotrexate 40 mg/m^2 e.v., vinblastine 4 mg/m^2 e.v.; day 2: cisplatin 90 mg/m^2 e.v.; day 8 = day 1; every 21 days) or with CaMV schedule, if serum creatinine was > 1.5 mg/dl (14 pts; cisplatin substituted by carboplatin, according to renal function, following Calvert formula; every 28 days).

Pts' characteristics were: 23 males, 5 females; median age: 62.5 (range 49–76) median performance status (ECOG): 1 (range 0–2). Sites of disease involvement: locoregional spreading in 13 pts; nodal metastases (mts) in 15 pts; pulmonary mts in 4 pts; hepatic mts in 3 pts; bone mts in 1 patient (pt).

Total number of administered cycles was 107 (median number of cycles per pt: 4; range 1–8). Grade 3 toxicity was: nausea and vomiting in 2 pts; anemia in 5 pts; leukopenia in 3 pts; thrombocytopenia in 2 pts; stomatitis in 3 pts. No grade 4 toxicity was reported.

25 pts were evaluable for the response; we observed: 3 (12%) complete remissions (CR), 8 (32%) partial remissions (PR), 4 (16%) stable diseases and 10 (40%) progressive diseases.

Overall response rate was good (CR + PR = 44%) and toxicity was manageable and reversible.

1158 PUBLICATION

ADJUVANT METHOTREXATE, VINBLASTINE, AND CISPLATIN CHEMOTHERAPY FOR INVASIVE TRANSITIONAL CELL CARCINOMA—TAIWAN EXPERIENCE

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We assigned 56 patients with high risk transitional cell carcinoma (vascular or lymphatic invasion in primary tumor, poorly differentiated P2, P3, P4 or N+ and Mo) to adjuvant chemotherapy after radical urological surgery. The chemotherapy was planned as 6 courses at 21-day intervals of methotrexate vinblastine and cisplatin. The median follow up time was 44 months. An average of 4.63 cycles of chemotherapy were administered with a range of 1 to 6 courses. The mean relative chemotherapy dose intensity was 62.1%. The median actural survival was 44 months; the 1 and 3 year survival probability were 92% and 50%, respectively. The median disease free survival was 15.5 months; the 1 and 3 year disease free survival probability were 66% and 28%, respectively. Disease relapse was note in 33 cases which included 19 local regional relapses, 10 distant metastasis and 4 both local regional relapse and distant metastasis. With regard to treatment related toxicity, only 5 (9%) and 1 (2%) patient complicated with grade III and IV leukopenia, respectively and none died of sepsis. Further randomized study with appropriate patient stratification was needed to clarify the role of adjuvant chemotherapy for invasive transitional cell carcinoma.

1159 PUBLICATION

THE CMV REGIMEN WITH CDDP OR CBDCA IN METASTATIC BLADDER CARCINOMA: REPORT OF A SERIES OF 29 PATIENTS

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From June 1986 to December 1994 29 patients (pts) with metastatic bladder carcinoma were treated with CMV regimen as originally reported by Harker *et al., J Clin Oncol* 1985. Eight out of 29 pts were treated with CBDCA instead of CDDP with dose ranging from 200 to 300 mg/m^2 because of a pre-existing nephropaty, primary or due to the neoplasm (e.g. from pelvic masses).

We retrospectively evaluated responses rate, CR duration and survival from the beginning of treatment. Patient's characteristics in CDDP group were: median age 66 yr (48–79), PS ECOG 0–1, median follow-up 69 mos (6–107); in CBDCA group: median age 65 yr (60–71), PS ECOG 0–1, median follow-up 38 mos (26–51). In CDDP group 10 pts (48%) achieved an objective response, with 6 CR (29%) and 4 PR (19%), while in CBDCA group 3 pts (37%) showed an objective response with 2 CR and 1 PR. The median duration of CR was 30.5 mos in CDDP pts and 19 mos in CBDCA group, while the median survivals from the beginning of CT were 12 and 10.5 mos respectively. Two pts who received CDDP are still alive and free front relapse at 67 and 69 months.

Toxicities ≥3 WHO in CDDP group: neutropenia in 3, piastrinopenia in 2, anemia in 2 and gastroenteric toxicity in 4; in CBDCA group: neutropenia in 3, anemia in 1 and gastroenteric toxicity in 1; no piastrinopania G3–G4 was observed.

Conclusions: Our results confirm the previous reports and the efficacy of CMV regimen in metastatic bladder cancer, the regimens containing CBDCA are slightly less effective.

1160 PUBLICATION

RETROSPECTIVE ASSESSMENT OF PERFORMANCE STATUS (PS)—ACCURACY AND RELATION TO SURVIVAL IN PATIENTS (PTS) WITH URINARY TRANSITIONAL CELL CANCER (TCC)

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The aim of the study was to evaluate the reliability and validity of retrospective assessment of PS in pts with TCC. The clinical records of 149 pts with primary and 53 pts with recurrent TCC were scored twice by the two authors according to the WHO PS scale and related to survival. The results were analyzed in a Cox multivariate model together with other potential prognostic factors for survival. The median survival was