

Documents

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Abstract

Purpose: Gemcitabine plus cisplatin (GC) and methotrexate, vinblastine, doxorubicin, and cisplatin (MVAC) were compared in patients with locally advanced or metastatic transitional-cell carcinoma (TCC) of the urothelium. **Patients and Methods:** Patients with stage IV TCC and no prior systemic chemotherapy were randomized to GC (gemcitabine 1,000 mg/m² days 1, 8, and 15; cisplatin 70 mg/m² day 2) or standard MVAC every 28 days for a maximum of six cycles. **Results:** Four hundred five patients were randomized (GC, n = 203; MVAC, n = 202). The groups were well-balanced with respect to prognostic factors. Overall survival was similar on both arms (hazards ratio [HR], 1.04; 95% confidence interval [CI], 0.82 to 1.32; P = .75), as were time to progressive disease (HR, 1.05; 95% CI, 0.85 to 1.30), time to treatment failure (HR, 0.89; 95% CI, 0.72 to 1.10), and response rate (GC, 49%; MVAC, 46%). More GC patients completed six cycles of therapy, with fewer dose adjustments. The toxic death rate was 1 % on the GC arm and 3% on the MVAC arm. More GC than MVAC patients had grade 3/4 anemia (27% v 18%, respectively) and thrombocytopenia (57% v 21 %, respectively). On both arms, the RBC transfusion rate was 13 of 100 cycles and grade 3/4 hemorrhage or hematuria was 2%; the platelet transfusion rate was four patients per 100 cycles and two patients per 100 cycles on GC and MVAC, respectively. More MVAC patients, compared with GC patients, had grade 3/4 neutropenia (82% v 71 %, respectively), neutropenic fever (14% v 2 %, respectively), neutropenic sepsis (12% v 1 %, respectively), and grade 3/4 mucositis (22% v 1 %, respectively) and alopecia (55% v 11 %, respectively). Quality of life was maintained during treatment on both arms; however, more patients on GC fared better regarding weight, performance status, and fatigue. **Conclusion:** GC provides a similar survival advantage to MVAC with a better safety profile and tolerability. This better-risk benefit ratio should change the standard of care for patients with locally advanced and metastatic TCC from MVAC to GC.   2000 by American Society of Clinical Oncology.

Index Keywords

alkaline phosphatase, analgesic agent, antibiotic agent, antiemetic agent, antifungal agent, antiviral agent, cisplatin, doxorubicin, folinic acid, gemcitabine, granulocyte colony stimulating factor, methotrexate, vinblastine; absolute neutrophil count, adult, advanced cancer, alkaline phosphatase blood level, alopecia, altered state of consciousness, anemia, Article, bladder metastasis, bleeding, cancer combination chemotherapy, cancer patient, cancer staging, cancer survival, comparative effectiveness, constipation, controlled study, cystectomy, diagnostic error, diarrhea, febrile neutropenia, female, fever, follow up, hematuria, hospital admission, human, infection, lung disease, major clinical study, male, middle aged, mortality rate, mucosa inflammation, multicenter study, multiple cycle treatment, nausea and vomiting, neutropenia, open study, overall response rate, overall survival, phase 3 clinical trial, randomized controlled trial, skin toxicity, thrombocyte transfusion, thrombocytopenia, time to treatment, transitional cell carcinoma of the bladder, tumor volume

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