metastasis before cystoscopy could be performed. The 3-year overall survival was 24% and distant metastasis-free survival rate was 27%. The 3-year local-regional control rate was 78%. All patients who achieved local control maintained functioning bladders. No CTCAE v4.0 late grade 3 genitourinary or gastrointestinal toxicity occurred.

Conclusions: Primary chemoradiation provides reasonable rates of local-regional control with a functioning bladder even for patients with locally advanced small cell carcinoma of the bladder. It is an effective alternative to cystectomy for patients who desire bladder conservation. Novel induction chemotherapy regimens are needed to help reduce the rate of distant metastases because distant failure is common and leads to the majority of patient mortality.

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Conservative Trimodality Treatment for Invasive Bladder Cancer: A Comparative Nonrandomized Study of 2 Chemoradiation Therapy Schedules

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Purpose/Objective(s): To compare the outcome of patients (pts) with invasive bladder carcinoma treated by transurethral resection of the bladder (TURB) and two different concomitant chemoradiation therapy (CRT) schedules.

Materials/Methods: From 1995 to 2011, 27 pts (inoperable or refusing radical cystectomy) with node-negative invasive bladder carcinoma underwent TURB followed by curative CRT. Based on TURB histopathology and computerized tomography 24 (89%) pts had stage T2, and 3 (11%) pts had stage T3-T4. Male:female ratio was 3.5. Median age was 74 years (range, 48-85 years). Patient demographics and tumor characteristics between the two groups were comparable. Fifteen pts were treated with an accelerated CRT schedule, delivering 40 Gy to the whole pelvis over 4 weeks with a concomitant 20 Gy boost to the bladder over the last two weeks (total dose of 60 Gy), and daily cisplatin (6 mg/m^2) (Schedule 1, S1). Schedule 2 (S2) consisted of 12 pts treated with a median dose of 60 Gy (range, 54-65 Gy) delivered to the bladder only ($n = 9$) or whole pelvis ($n = 3$) and weekly gemcitabine (median 200 mg/m^2, 112-200). Median follow-up time for the whole population was 21 months (range, 4-164 months), with no difference between the two groups. Acute toxicity was assessed according to the RTOG criteria. Actuarial survival rates were calculated using the Kaplan-Meier method.

Results: Clinical (age, hydronephrosis) and pathological (T-stage, histological grade, LVSI) factors were comparable between groups. Actuarial 2- and 5-year survival rates for the whole population were, respectively, 65% and 45% for loco-regional relapse-free survival (LR-RFS); 55% and 49% for distant-metastasis free survival (DMFS); 45% and 33% for overall survival (OS); and 58% and 45% for cancer-specific survival (CSS). No difference was observed in the 2-year LR-RFS between S1 and S2 (71% vs 61%, $p = 0.523$). As compared to pts treated with S1, S2 pts showed a statistically better 2-years DMFS (79% vs 37%, $p = 0.034$), OS (61% vs 33%, $p = 0.026$) and CSS (86% vs 34%, $p = 0.003$). Grade ≤ 2 genitourinary (GU) and gastro-intestinal acute toxicity was comparable in the two groups. There was only one patient (S1) with grade 3 GU toxicity.

Conclusions: Recent phase I/II studies have demonstrated favorable clinical activity and toxicity profiles using gemcitabine in this setting. Along this line, the present non-randomized study with CRT using gemcitabine confirmed its feasibility and its role as a promising conservative regimen for pts with invasive bladder cancer.

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Neoadjuvant Radiation Therapy Improves Survival in Patients With T2b/T3 Invasive Bladder Cancer

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Purpose/Objective(s): Neoadjuvant radiation therapy (NART) for the treatment of muscle-invasive bladder cancer (BC) has been out of vogue for over the last 2 decades. However, outcomes for BC remain suboptimal. We have reported encouraging results for preoperative radiation therapy in the past and sought here to determine if there was supportive evidence in the SEER Database. We investigate here the relationship of NART to cause specific survival (CSS) and overall survival (OS).

Materials/Methods: Patients diagnosed with primary invasive urothelial carcinoma of the bladder between 1983 and 2008 with localized disease (no regional or metastatic extension) were included. Patients older than 90 years of age, diagnosed with stage T1 or T4 BC, or who had no information on tumor grade were excluded from the analysis. Actuarial estimates of CSS and OS were examined and Cox proportional hazards multivariable analyses (MVAs) performed.

Results: There were 10,979 patients in the BC cohort (125 NART and 10,854 surgery alone). Median follow-up was 30 months and age 72 years. There were 33% with T2a, 35% T2b, and 32% T3a/b. Univariate analysis showed T-stage, gender, year of diagnosis, age at diagnosis, NART, race and grade to be predictive factors of CSS; therefore, these variables were included in the MVA. Since NART would not be expected to benefit patients with early muscle-invasive BC, we tested those with T2a, T2b and T3 disease separately initially. There was a clear-cut difference between those with T2a disease and those with T2b/T3 disease. NART did not have an effect on CSS ($p = 0.47$) or OS ($p = 0.14$) on patients with T2a disease, but was associated with a significant improvement in CSS ($p < 0.0001$) and OS ($p = 0.0033$), for T2b patients. Likewise, there was a significant improvement in CSS (5-y rate: 66% NART vs 46% SA [$p < 0.0001$] and OS 5-y rate 54% NART vs 41% SA [$p = 0.0022$]) for T2b/T3 patients who received NART. The MVA for the T2b/T3 cohort revealed age at diagnosis ($p < 0.0001$), year of diagnosis ($p < 0.0001$), grade ($p = 0.0006$), T-stage ($p < 0.0001$), sex ($p = 0.0321$) and NART ($p = 0.0255$) to be significant predictors of CSS. Whereas age at diagnosis ($p < 0.0001$), grade ($p = 0.0018$), T-stage ($p < 0.0005$), and NART ($p = 0.0349$) were significant predictors of OS.

Conclusions: NART was significantly associated with improved CSS and OS in patients with clinical T2b/T3 N0 UCC of the bladder, independent of other covariates; although the greatest benefit was observed in T2b patients. The SEER database has a number of limitations including lack of information on radiation dose and chemotherapy. Nonetheless, the data suggest that NART may be beneficial in those with T2b/T3 disease. In the modern neoadjuvant chemotherapy era, perhaps the greatest utility would be for patients who experience an incomplete response to neoadjuvant chemotherapy or as an adjunct to neoadjuvant chemotherapy to improve complete response rates.

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Hypofractionation IMRT in Combined Modality Treatment for Bladder Preservation in Elderly Patients With Invasive Bladder Cancer

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Purpose/Objective(s): Long-term results of bladder-preserving combined treatment modalities (CMT) for muscle invasive bladder cancer have confirmed that this approach is safe and effective in selected patients. Here