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Impact of Operability Bias on Outcomes in Veterans with Muscle Invasive Bladder Cancer Receiving Bladder Preserving Trimodality Therapy

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Abstract
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Abstract

BACKGROUND:

There have been no successful randomized trials comparing radical cystectomy (RC) to trimodality therapy (TMT), consisting of transurethral resection of bladder tumor followed by concurrent chemoradiation, in muscle invasive bladder cancer (MIBC). Observational studies using large registries comparing RC with or without neoadjuvant chemotherapy (NAC) to TMT often cannot distinguish whether patients receiving TMT were eligible for cystectomy but declined or simply ineligible for cystectomy. Therefore, these studies are vulnerable to significant bias. The objective of this study was to compare oncologic outcomes of veterans with MIBC receiving TMT stratified by whether they were cystectomy-eligible to patients receiving RC +/- NAC.

METHODS:

The national Veterans Affairs' (VA) database was used to identify patients diagnosed between 2000-2017 with urothelial histology, MIBC (T2-4a/N0-3/M0) who underwent RC +/- NAC or TMT. Overall mortality (OM) was evaluated with a multivariable Cox proportional hazards model. Bladder cancer-specific mortality (BCSM) was evaluated with a multivariable Fine-Gray regression.

RESULTS:

Overall, 2304 patients with MIBC were included: 1472 (64%) with RC without NAC, 506 (22%) with RC-NAC, 105 (5%) with TMT eligible for RC, 189 (8%) with TMT ineligible for RC, and 32 (1%) with palliative-intent radiation. Median follow-up time was 5 years. Compared to patients receiving TMT, patients receiving RC were on average 10 years younger, more likely to have creatinine clearance greater than 50 (77% vs. 61%, p<0.01), and more likely to have Charlson comorbidity score 0 (73% vs. 57%, p<0.01). Compared to cystectomy-ineligible TMT patients, cystectomy-eligible TMT patients were more likely to receive cisplatin (58% vs. 35%, p<0.01), and have a Charlson comorbidity score of 0 (71% vs. 49%, p<0.01). Cystectomy-eligible and ineligible TMT patients had similar rates of pre-treatment hydronephrosis (26% vs. 35%, p = 0.09), carcinoma in situ (9% vs. 15%, p=0.10), and unifocal disease (65% vs. 69%, p=0.48). On multivariable analysis, compared to RC-NAC, TMT in cystectomy-eligible patients was associated with similar OM (hazard ratio [HR] 0.96; 95% confidence interval [CI] 0.74 - 1.25; p = 0.77) and BCSM (HR 0.97; 95% CI 0.67-1.41; p = 0.89). Compared to RC-NAC, TMT in cystectomy-ineligible patients was associated with inferior OM (HR 1.40; 95% CI 1.13 - 1.74; p<0.01) and BCSM (HR 1.66; 95% CI 1.25 - 2.21; p < 0.01). Among TMT patients, the 5-year cumulative incidence of salvage cystectomy was 3%.

CONCLUSIONS:
Cystectomy-eligible patients receiving TMT likely have similar survival outcomes as those receiving RC. In

the absence of level 1 data, non-randomized comparisons between RC and TMT lacking information regarding operability may be unreliable. TMT is underutilized and should be offered as an alternative to RC for select patients with MIBC.