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ORIGINAL ARTICLE

# A role of multimodality bladder-preserving therapy in patients with muscle-invasive bladder cancer plus hydronephrosis with or without pelvic nodal involvement



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## KEYWORDS

bladder cancer;  
chemotherapy;  
cystectomy;  
hydronephrosis;  
radiotherapy

**Background/purpose:** To retrospectively evaluate the failure patterns of multimodality bladder-preserving therapy in patients with muscle-invasive bladder cancer.

**Methods:** Patients with muscle-invasive bladder cancer underwent maximal transurethral resection of bladder tumor and induction chemotherapy, followed by concurrent chemoradiotherapy (CCRT). Radiotherapy was given with 45 Gy to the pelvis, 50.4 Gy to the bladder, and 64.8 Gy to the tumor bed. Three protocols of trimodality treatment were used: Protocol A, three cycles of cisplatin and fluorouracil (CF), followed by CCRT with 6 weekly cisplatin; Protocol B, three cycles of weekly paclitaxel plus CF, followed by CCRT with 6 weekly paclitaxel and cisplatin; Protocol C, three cycles of gemcitabine and cisplatin, followed by CCRT with 6 weekly cisplatin. Interval cystoscopy confirmed complete response (CR) after induction chemotherapy and 40–50 Gy of radiotherapy. Patients without CR were referred for salvage cystectomy.

**Results:** A total of 60 patients were enrolled, including 11 patients with unfavorable factors defined as hydronephrosis and/or pelvic nodal involvement. After a median follow-up of 86.7 months, the 5-year overall, progression-free, and bladder preservation-specific survival rates were 76.3%, 62.9%, and 71.5%, respectively. Three patients underwent salvage cystectomy for invasive bladder recurrence. Of 45 surviving patients, 42 patients (93.3%) retained

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functioning bladders. Patients with unfavorable factors had significantly lower metastasis-free survival ( $p = 0.002$ ), but not bladder preservation-specific survival ( $p = 0.25$ ).

**Conclusion:** With trimodality treatment involving visually complete transurethral resection of bladder tumor, cisplatin-based induction chemotherapy, and CCRT, patients with unfavorable factors maintained satisfactory bladder preservation but not systemic control.

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## Introduction

Radical cystectomy remains widely accepted as the standard treatment for muscle-invasive bladder cancer and yields a 5-year overall survival (OS) ranging from 45% to 66%.<sup>1–4</sup> Nevertheless, removal of the bladder may lead to significant morbidity and affect patients' quality of life. Several bladder-preservation options exist.<sup>5–9</sup> A multimodality therapy approach, including visually complete transurethral resection of bladder tumor (TURBT) followed by chemotherapy and radiotherapy, is the most studied bladder-sparing strategy. Long-term follow-up from several institutions have shown that this multimodality treatment leads to an excellent chance for long-term survival ranging from 50% to 60% with the preserved bladder.<sup>10–15</sup>

A previous trimodality series indicated that T2 disease and complete tumor resection are favorable prognostic factors, whereas hydronephrosis is an unfavorable one.<sup>11</sup> Hydronephrosis and pelvic lymph node involvement are considered by some experts to be contraindications for bladder preservation protocol.<sup>1</sup> We have previously reported the early satisfactory outcome of 30 patients undergoing bladder preservation with visually completed TURBT and cisplatin-based induction chemotherapy, followed by cisplatin-based concurrent chemoradiotherapy (CCRT).<sup>16</sup> In the following years, we also used the other two bladder-preserving protocols including the additional paclitaxel or gemcitabine as induction chemotherapy in hope of enhancing treatment response while maintaining acceptable side effects.<sup>17,18</sup> In this work, we evaluated the failure pattern of trimodality treatment with more muscle-invasive bladder cancer patients who have favorable or unfavorable prognostic factors with a longer follow-up. The impact of unfavorable factors on the bladder preservation and oncologic outcomes was investigated.

## Methods

### Patients

From September 2002 to January 2015, 60 eligible patients were retrospectively reviewed and included in this study. The diagnosis of muscle-invasive bladder cancer had to be histologically confirmed. Patients were staged by the seventh edition of the American Joint Committee on Cancer as T2-T4aN0-1M0. A well-functioning bladder following visually completed TURBT was required. Patients with pelvic lymph node involvement, with the prostatic urethra

involvement limited to the mucosa without stromal invasion and completely excised, as well as with hydronephrosis/hydroureter, which had been treated with internal ureteral stents or percutaneous nephrostomy, were included in the analysis. Radical cystectomy remained the standard of care in this subgroup of patients unless they insisted on bladder preservation and understood the possible consequence. Karnofsky Performance Scale score was registered on patient admission. At inclusion, all patients were subjected to the following diagnostic work-up: physical examination, radiologic evaluation including chest radiograph, abdominal and pelvic computed tomography (CT) scan, and intravenous (IV) pyelography when CT evidence of hydronephrosis or hydroureter was found. Pelvic lymphadenopathy was defined as lymph nodes greater than 15 mm in the short axis on CT scan. All patients received cystoscopic evaluation including examinations under anesthesia and postresection biopsy from the tumor base/prostatic urethra tissue samples. The study protocol was approved by the Research Ethical Committee of National Taiwan University Hospital (201407038RINC).

### Induction chemotherapy

Patients began induction chemotherapy within 1 week after TURBT. Three protocols were used (Protocols A–C). Protocol A was cisplatin and fluorouracil (CF) regimen (cisplatin 35 mg/m<sup>2</sup> IV for 24 hours on Days 1 and 8; 5-fluorouracil 2000 mg/m<sup>2</sup>, and leucovorin 300 mg/m<sup>2</sup> IV for 24 hours on Days 1 and 8; repeated every 21 days) for three cycles.<sup>16,19</sup> Protocol B was CF regimen plus weekly paclitaxel (paclitaxel 70 mg/m<sup>2</sup> IV for 1 hour on Days 1 and 8; cisplatin 35 mg/m<sup>2</sup> IV for 24 hours on Days 2 and 9; 5-fluorouracil 2000 mg/m<sup>2</sup> and leucovorin 300 mg/m<sup>2</sup> IV for 24 hours on Days 1 and 8; repeated every 21 days).<sup>16,17</sup> The third protocol (Protocol C) was gemcitabine regimen (gemcitabine 1000 mg/m<sup>2</sup> for 30 minutes on Days 1, 8, and 15; cisplatin 70 mg/m<sup>2</sup> for 2 hours on Day 2; repeated every 28 days).<sup>18</sup>

### Concurrent chemoradiotherapy

Patients underwent CCRT within 6 weeks after induction chemotherapy and interval cystoscopy. Radiotherapy consisted of once daily treatment with 1.8 Gy/d, five fractions/wk. Radiotherapy was given with 45 Gy to the pelvis (25 fractions), 50.4 Gy to the bladder (3 fractions), and 64.8 Gy to the tumor bed (8 fractions). Linear accelerators with beam energy of 10 MV were used. All patients underwent CT-based planning. The small pelvis field included four

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