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# *Cystectomy in the ninth decade: operative results and long-term survival outcomes*

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**Introduction:** Radical cystectomy (RC) with urinary diversion remains as one of the more complex urological procedures despite considerable progress in surgical technique. Increasing patient age, along with associated age-related comorbidities, may portend a poor outcome in those undergoing such complicated surgical procedures. Herein, we report our experience with radical cystectomy in the elderly population.

**Methods:** We retrospectively reviewed our RC results from 1995 to 2003. Patients  $\geq 80$  years old were included in this analysis. Perioperative outcomes, as well as overall and disease-free survival were evaluated.

**Results:** A total of 517 patients underwent RC with urinary diversion during this time period. Forty-nine (9.5%) patients were  $\geq 80$  years old. Mean age and BMI were 83.4 years (range 80-94) and 27.1kg/m<sup>2</sup> (range 17.4-39.0), respectively. Eighty-three percent of the patients had  $\geq 1$  comorbidities and 67% had a

significant smoking history. Mean operative time and estimated blood loss were 279 minutes and 985 ml, respectively. Thirty-two patients (76%) required blood transfusion in the perioperative period. Among patients found to have urothelial cancer a pathological analysis (36), 21 patients (58%) had  $\leq$  pT3a while 15 patients (42%) had  $\geq$  pT3b or  $\geq$  N1. Intraoperative complications (5%) included one large bowel injury and hypogastric artery laceration. Thirty- and 90-day mortality rates were 9.5% and 11%, respectively. Early and late postoperative complications were 57% and 17% and 5-year overall and disease-free survival were 44% and 36%, respectively.

**Conclusions:** Radical cystectomy with urinary diversion in patients  $\geq 80$  years old is related with significant short-term and long-term morbidity. Proper patient selection assessing performance status and psychosocial parameters appear to optimize survival outcomes. However, regardless of age, timely surgical management for localized disease control is essential for ultimate sustained disease-free survival.

**Key Words:** urothelial carcinoma, urinary bladder, elderly

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## Introduction

Urothelial carcinoma (UC) of the urinary bladder is a disease of the elderly population with a peak incidence in the seventh decade of life.<sup>1</sup> Due to

advancements in surgical technique and better perioperative management, survival outcomes in elderly patients have improved over the years as more patients are being treated with curative intent.<sup>2</sup> Despite the fact that this age group is associated with significant comorbidities, more patients are being subjected to definitive surgery for curative intent and improved palliative care.<sup>2</sup>

Radical cystectomy (RC) with urinary diversion has been the mainstay treatment of patients with muscle-invasive carcinoma of the bladder since the early 1960's.<sup>3</sup>

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During recent years, the indications for the procedure have increased to include a wider spectrum of bladder cancer disease stages.<sup>3</sup> This is due to the fact that clinical under- and over-staging have continued to be an unresolved problem,<sup>4</sup> and the significant morbidity associated with untreated or inadequately treated bladder cancer has led to deterioration of the remaining quality of life in most patients.

Although RC remains the standard of care for the treatment of muscle invasive bladder cancer, it is associated with significant short and long-term morbidity. As a result, many clinicians remain reluctant to offer this treatment to elderly patients presumed to have a lower tolerance to perioperative complications. Thus, older patients may potentially be guided toward alternative therapies such as radiation therapy with or without chemotherapy, or transurethral resection simply because of age. This practice may result in substandard age.<sup>5</sup>

Several authors have shown that radical cystectomy with urinary diversion can be performed safely in carefully selected elderly patients<sup>6-8</sup> with early complication rates of 12%-32% and mortality rates of 0%-3%.<sup>8,9</sup> Unfortunately, these reported outcome studies, particularly in the octogenarian population include a small number of patients.<sup>10-13</sup> In our study, we sought to review our experience with RC in patients  $\geq$  80 years old with associated medical comorbidities, particularly evaluating perioperative results and subsequent long-term survival outcomes.

## Materials and methods

### Patient selection

A retrospective review of our bladder cancer database from February 1995-November 2005 was carried out after Institutional Review Board approval. A total of 517 patients underwent RC and urinary diversion, of which 49 patients (9.5%) were  $\geq$  80 years old. All surgeries were performed by a single surgeon (GDS). All patients underwent a thorough preoperative physical examination and medical screening (cardiology consultation with cardiac stress test, preoperative anesthesia evaluation) to ensure adequate cardiac and physical performance status. Patients were excluded from perioperative and survival analysis if they underwent simple cystectomy for non-oncological indications or had other concomitant surgery. Patients with non-urothelial carcinoma were excluded from survival analysis. All patients underwent RC with urinary diversion in a standard fashion with particular attention given to appropriate anesthetic and perioperative monitoring in a step-down care unit.

### Statistical analysis

Patients with UC were divided into two pathological subgroups according to the 1997 modification of the TNM staging system. In brief, patients were categorized into two groups: those with organ-confined disease ( $\leq$  pT3a/N0) and with extravesical disease extension (T3b or  $\geq$  N1). Overall and disease recurrence-free survival were analyzed using Kaplan-Meier survival estimates and log rank tests were utilized to compare survival outcomes between pathological stage groups.

## Results

Patient demographic data and perioperative outcomes are summarized in Table 1. Of the 517 patients who underwent RC with urinary diversion, 49 patients were  $\geq$  80 years old. Mean patient age was 83.4 years (range 80-94). The majority of patients were either current or previous smokers (67%) and most had two or more associated comorbidities (63%). The most common comorbidities were hypertension, coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD) and diabetes mellitus.

TABLE 1. Demographics data and perioperative outcomes in patients aged > 80 years

	Mean (range)
Total patients	49
Mean age (yrs)	83.4 (80-94)
Mean BMI (kg/m <sup>2</sup> )	27.1 (17.4-39.0)
Sex (%)	
Male	36 (73)
Female	13 (27)
Smoking history (%)	33 (67)
Comorbidities (%)	
None	8 (16)
1	10 (20)
> 2	31 (64)
Mean operative time (min)*	278.6 (208-465)
Mean estimated blood loss (ml)*	985 (400-2000)
Transfusion rate*	32 (76)
Urinary diversion technique (%)*	
Ileal conduit	39 (93)
Orthotopic neobladder	3 (7)
Length of hospital stay (days)	12.9 (5-73)

\*Excludes patients with non-oncological indications for surgery or who had concomitant surgery

**TABLE 2. Intraoperative and postoperative complications in elderly population**

Complication	Rate
<b>Intraoperative complications (%)</b>	2 (4.7)
Hypogastric artery laceration	1
Rectal enterotomy	1
<b>Early postoperative complications (&lt; 90 days) (%)</b>	24 (57)
Postoperative hemorrhage	1
Ileal conduit or bowel leak/fistula	8
Aspiration pneumonia	1
ARDS	1
Atrial fibrillation	1
Duodenal ulcer	1
Postoperative ileus	9
Wound infection	2
<b>Late post-operative complications (&gt; 90 days) (%)</b>	7 (17)
Ureteral stricture	3
Parastomal hernia	1
Bladder neck contracture	1
Vesico-ureteral reflux	1
Deep venous thrombosis	1
<b>Mortality (%)</b>	
< 30 days	4 (9.5)
< 90 days	5 (11)

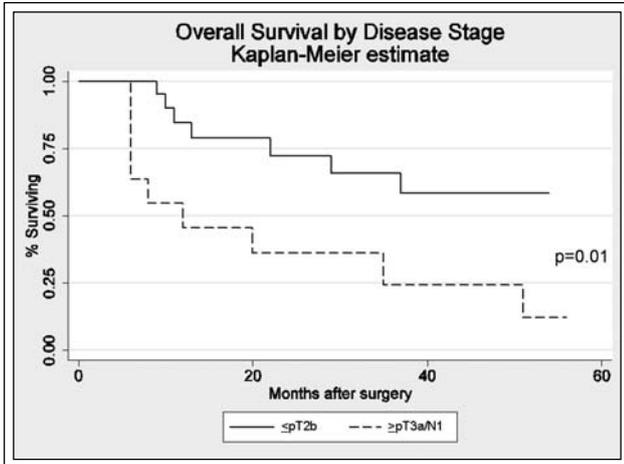
A total of 7 patients were excluded both in the perioperative and survival analysis due to a non-oncological indication for surgery (3) or other concomitant surgery (4). The remaining 42 RC patients available for perioperative analysis had a mean operative time of 279 minutes (range 208-465) and mean estimated blood loss of 985 ml (range 400-2000). Thirty-two patients (76%) received blood transfusion in the perioperative period. Ninety-three percent of patients had an ileal conduit as a form of urinary diversion. Mean length of hospital stay was 12.9 days (range 5-73) with one patient having a prolonged hospital stay of 73 days. This particular case was complicated by acute respiratory distress syndrome (ARDS) that necessitated prolonged intubation and subsequent tracheostomy placement. This patient was an 83-year old male who was previously diagnosed with COPD secondary to severe smoking and a previous myocardial infarct (ejection fraction of 25%). He was eventually discharged to a nursing facility but died within 6 months after surgery of other medical complications.

Details related to perioperative complications are summarized in Table 2. Major intraoperative complications were observed in 5% (2/42), namely hypogastric artery laceration and a rectal enterotomy, both of which were recognized and repaired intraoperatively without sequelae. A total of 4 (9.5%) patients died within 30 days following surgery. Three of these patients (75%) had locally advanced disease and died of surgical complications (2 from sepsis due to anastomotic breakdown and 1 from severe post-operative hemorrhage). The remaining patient was a 94-year old male who died of aspiration pneumonia on post-operative day 13. Early post-operative (< 90 days after surgery) complication rates were noted in 67% and the majority of which were diversion-related, namely postoperative ileus and conduit leak or fistula. Late postoperative complications (> 90 days after surgery) occurred in 7 (17%) patients, most of which were also diversion-related and required hospitalization and subsequent surgical repair (86%).

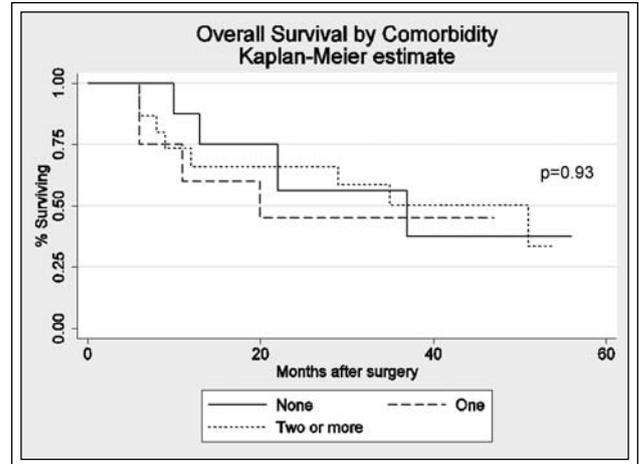
Surgical pathology details are summarized in Table 3. As expected, the most common pathological diagnosis was urothelial carcinoma (86%). Non-urothelial carcinoma consisted of squamous cell (7%), adenocarcinoma (2%), primary malignant melanoma (2%) and small cell carcinoma (2%), all of which were excluded from survival analysis due to the relative aggressiveness of their tumor variety compared with UC. Of the 36 patients with urothelial tumors available for pathologic staging, 21 (58%) were noted to be organ-confined ( $\leq$  pT3a/N0) and 15 (42%) were noted to have extravesical disease extension ( $\geq$  pT3b or  $\geq$  N1).

**TABLE 3. Histopathologic outcomes of patients undergoing radical cystectomy aged > 80**

<b>Histological subtype (%)</b>	
Urothelial carcinoma	36 (86)
Squamous cell carcinoma	3 (7)
Adenocarcinoma	1 (2)
Primary malignant melanoma	1 (2)
Small cell carcinoma	1 (2)
<b>Pathologic stage (%)</b>	
Organ-confined disease	21 (58)
pT0/Tis/T1N0	11 (30)
pT2a/bN0	4 (11)
pT3aN0	6 (17)
Non organ-confined disease	15 (42)
pT3b/4N0	9 (25)
> N1	6 (17)



**Figure 1.** Log-rank test indicates that overall survival between organ confined and extra-vesical disease stages are significantly different ( $p = 0.01$ ).

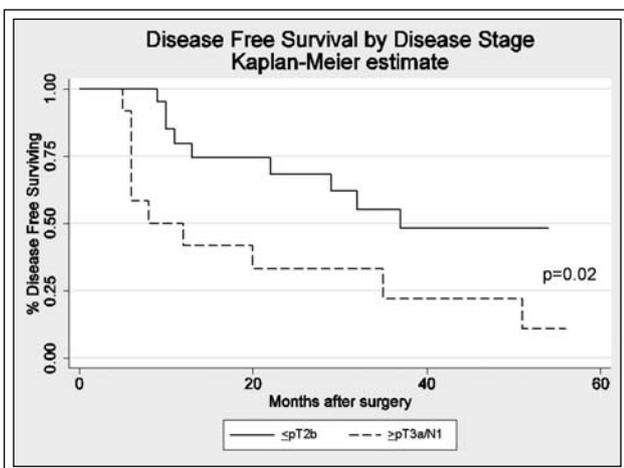


**Figure 3.** Log-rank test indicates that overall survival among comorbidity groups are not significantly different ( $p = 0.93$ ).

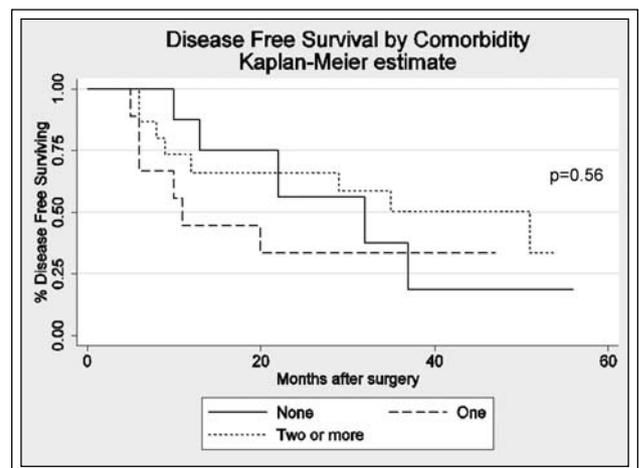
The mean follow-up for the patients who were alive was 38 months (range 5-103) with the majority being disease free (82%). Mean time to death for expired patients was 19.5 months (range 6-51). When these patients were classified into disease stage ( $\leq pT3a/N0$  versus  $\geq pT3b$  or  $\geq N1$ ), patients with organ confined disease had a significantly better overall and disease recurrence free survival of 62% and 52%, respectively compared to 20% and 13% in the patients with extravesical disease ( $p = 0.01$  and  $p = 0.01$ , respectively). The majority of patients with extravesical disease ( $\geq pT3b$  or  $\geq N1$ ) died of disease progression (43%, 9/21) with a mean time to death of 15 months (6-51). There were

3/21 (14%) patients with extravesical disease who are still alive with disease recurrence undergoing salvage chemotherapy at a mean follow-up of 16 months (5-32).

Kaplan-Meier survival estimates, Figures 1 and 2, further demonstrate that patients with organ-confined disease had a significantly longer mean overall and disease recurrence-free survival compared to patients with extravesical disease ( $p \leq 0.01$  and  $p = 0.002$ , respectively). Comparing three groups according to number of associated comorbidities (no comorbidity, one comorbidity and two or more comorbidities), no significant differences on subsequent overall and disease recurrence free survival were noted, Figures 3 and 4.



**Figure 2.** Log-rank test indicates that disease-free survival between organ confined and extra-vesical disease stages are significantly different ( $p = 0.02$ ).



**Figure 4.** Log-rank test indicates that disease-free survival among comorbidity groups are not significantly different ( $p = 0.56$ ).

## Discussion

Several contemporary studies have been done to assess the feasibility of performing RC in the elderly population with well-recognized medical co-morbidities.<sup>6-8</sup> The majority of such studies have shown favorable results. Clark et al observed similar operative mortality rates in 1054 patients when stratified into four age groups (< 60, 60-69, 70-79, and ≥ 80 years) treated with RC, although patients older than 70 had a higher rate of early complications ( $p = 0.002$ ).<sup>14</sup> Farnham et al reported a mean overall and disease-specific survival rate of 29% and 33%, respectively in higher risk, elderly patients with more significant co-morbidities.<sup>15</sup> Their group specifically assessed a group of elderly, high perioperative risk patients (≥ 75 years and American Society of Anesthesiologists (ASA) classification ≥ 3) and demonstrated comparable results with other series in lower risk patients. Even in high risk cystectomy population of 44 patients aged >75 years, with an ASA of 3 or 4, Chang et al observed no perioperative deaths and a 30% complication rate, which is similar to the expected rate of complications for all individuals undergoing RC.<sup>9</sup> Despite its apparent risks, RC should be advocated in the elderly population because it provides a disease specific survival benefit compared to alternative treatments.<sup>2,5</sup>

Though data from multiple small surgical series have demonstrated that well-selected older patients fare comparably with their younger counterparts in terms of early and late complications and perioperative outcomes, there are also data suggesting that age may be independently associated with adverse oncological and overall survival outcomes.<sup>14,16,17</sup> In a recent article by Nielsen et al evaluating 888 consecutive patients who underwent RC for UC, higher age was associated with extravesical disease and pathological upstaging (all  $p < 0.02$ ).<sup>16</sup> In multivariate models, higher age at RC as a categorical variable was associated with disease-specific survival ( $p < 0.05$ ). Furthermore, patients > 80 years old had a significantly greater risk of disease recurrence than patients aged ≤ 60. Moreover, through the use of more rigorous tools to evaluate comorbidities, Weizer et al have recently described the impact of the Karnofsky performance status (KPS) on overall survival of elderly patients with muscle invasive bladder cancer.<sup>5</sup> In a multivariate analysis, patients with a KPS < 80 had 1.8 times the risk of death compared to patients with a KPS ≥ 90 (95% CI 1.0-3.2,  $p = 0.05$ ). The authors conclude that the majority of elderly patients are able to undergo definitive treatment. More important, due to the value of KPS in predicting risk of death from any cause after RC, KPS may be a valuable tool for treatment planning.

Nevertheless, the technical complexity of this procedure has caused reluctance among community urologists to perform this procedure, particularly in elderly patients. In a population based study by Prout et al in 2005, older patients were less likely to undergo radical cystectomy compared to younger age groups.<sup>18</sup> Cystectomy rates, defined as the percentage of patients with muscle invasive disease who underwent radical cystectomy compared with other treatment modalities, were noted to be very low (4%) in patients ≥ 85 y/o compared with 55% in the 55-59 y/o age group. This trend persisted despite recent reports that extirpative surgery still offers the greatest risk reduction from death among the primary treatment modalities in ≥ 80 years old patients with bladder cancer.<sup>2</sup> The belief that elderly patients will generally tolerate surgery poorly and have a shorter remaining life expectancy has resulted in older patients receiving less definitive therapy such as repeated transurethral bladder tumor resection with or without intravesical chemotherapy, partial cystectomy, radiation therapy, systemic chemotherapy and combined therapeutic modality, all of which were reported to have limited curability with a high incidence of treatment toxicity in elderly, frail patients.<sup>2</sup> Furthermore, if left untreated or inadequately treated, most muscle-invasive bladder cancer will progress with significant morbidities such as renal insufficiency related to urinary obstruction, recurrent hematuria and anemia, local pain and irritative symptoms with most patients eventually dying of disease progression within 2 years from diagnosis.<sup>19</sup> Such conditions impact significantly on the individual's quality of life.

In the current series, a high percentage of patients (42%) having extravesical disease on final histopathology was noted. This demonstrates the evolution in our management of muscle-invasive UC as indications for RC have expanded to include older patients with relatively advanced disease. Several studies support the fact that a significant delay in cystectomy (≥ 3 months) undermines patient survival and an early intervention in bladder cancer is essential to better survival outcomes.<sup>9,20,21</sup>

With regards to perioperative outcomes, the current mean EBL and mean operative times were comparable with other contemporary series.<sup>22</sup> Furthermore, intraoperative complication rates in this series (5%) were lower, however, early (57%) and late (17%) postoperative complication rates were higher compared to other reported series.<sup>7,8,23</sup> Thirty-day and 90-day mortality rates in this cohort were high (9.5% and 11%, respectively) compared to reported outcomes of other high-volume RC centers (0%-4%).<sup>24,25</sup> Three of the four

early postoperative mortalities had extremely advanced disease and died of surgical complications rather than medical disease. All such patients however had ASA scores  $\geq 3$ , significant cardiopulmonary disease and poor preoperative performance status.

Historical operative mortality rates have ranged from 14%-20%, but with refinements in surgical techniques and perioperative management, rates have decreased to  $< 3\%$  in most contemporary series.<sup>24</sup> It is evident though that the inherent inability to recuperate from major complications has led to higher operative mortality in this elderly age group. Therefore, meticulous surgical technique and better perioperative monitoring is essential to prevent complications and improve survival in this patient cohort. Patient selection based on overall medical status and performance status should also be stressed to optimize perioperative outcomes.

Our overall and disease-free survival rate of 44% and 36%, respectively, are favorable when compared to other reported series.<sup>14</sup> As expected, a statistically significant disease-specific survival advantage was noted for organ-confined compared to non organ-confined disease (52% versus 13%,  $p = 0.01$ ). Miller et al demonstrated an association between comorbid illness and adverse pathological and survival outcomes following radical cystectomy.<sup>26</sup> In this cohort of patients, a high percentage of patients with extra-vesicle disease were subjected to radical cystectomy although the association of the pathological stage and patient age were not clearly defined.

The limitation of this study is its retrospective nature. A randomized, prospective study with age, medical comorbidity and stage stratification, would better assess the effect of these independent factors to subsequent long-term survival after RC. Our present data though may help assist urologists counsel elderly patients with UC of the bladder prior to undergoing complex surgery. With the continuous rise in average life expectancy in this patient cohort, a chance for cure and better palliative care is becoming a more valuable outcome. Moreover, with the recent reported data on robotic-assisted radical cystectomy,<sup>27,28</sup> minimally invasive surgical approaches will continue to develop for the treatment of bladder cancer. Such technical advances may allow further reduced morbidity related to the RC procedure.

## Conclusion

Radical cystectomy with urinary diversion in patients  $\geq 80$  years old with significant comorbidities is related to significant short-and long-term morbidity. The chance for local control and long term survival heavily depends on the stage of disease rather than patient age. As such,

timely surgical management for local disease control, for well-selected elderly patients, is essential for ultimate sustained disease-free survival.  $\square$

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