



ONCOLOGY/RECONSTRUCTION

ORIGINAL ARTICLE

The effect of preoperative clinical variables on the 30- and 90-day morbidity and mortality after radical cystectomy: A single-centre study

Khaled Mursi *, Hany ElFayoumy, Ismail Saad, Ahmed Tawakol, Hesham Badawy

Urology Department, Faculty of Medicine, Cairo University, Cairo, Egypt

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ABBREVIATIONS

RC, radical cystectomy;
BMI, body mass index;
CCI, charlson comorbidity index;

Abstract Objective: To analyse the effect of preoperative clinical variables and comorbidity on the early, late and cumulative 90-day morbidity and mortality rates, as well as hospital re-admissions, after radical cystectomy (RC), in one centre.

Patients and methods: All patients undergoing RC over a period of 3 months were included. Preoperative investigations included measurements of serum albumin, a complete blood analysis, body mass index (BMI), Charlson comorbidity index (CCI) and the age-adjusted CCI (ACCI). We recorded the length of hospital stay (LOS) and all postoperative events for 90 days, and graded them according to the five-grade modification of the original Clavien system.

Results: In all there were 31 patients undergoing RC (mean age 58.4 years). The mean preoperative serum albumin and haemoglobin level, BMI, CCI and ACCI were 3.82 g/dL, 12.53 g/dL, 29.29 kg/m², 3.0 and 4.58, respectively. The mean LOS was 20.03 days; seven patients needed re-admission and three died within the 90 days. There were postoperative complications in 20 patients. The age, CCI and

* Corresponding author. Address: 5 El-Sheikh Al-Khodary St., Heliopolis, 11341 Cairo, Egypt. Tel.: +20 12 222 35 232; fax: +20 2 2419 6314.

E-mail addresses: khaledmursi@hotmail.com, khaledmursi@kasralainy.edu.eg (K. Mursi).

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ACCI, age-adjusted CCI;
LOS, length of hospital stay;
IQR, interquartile range;
Hb, haemoglobin

ACCI were significantly associated with complications ($P = 0.009$, 0.001 and < 0.001 , respectively). Preoperative haemoglobin, BMI and smoking had no effect on the morbidity or mortality rate. The LOS increased in older patients ($P = 0.031$) and those with a higher ACCI ($P = 0.042$). Postoperative mortality increased among patients with a lower serum albumin level ($P = 0.048$).

Conclusions: Age, CCI and ACCI are related to early postoperative complications. Older patients and patients with a higher ACCI have a longer LOS. A low preoperative albumin level needs to be evaluated more thoroughly.

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Introduction

Bladder cancer is the ninth most common cancer diagnosed worldwide, with $> 330,000$ new cases diagnosed annually and estimated deaths per year at $> 130,000$ [1].

Since Bernhard Bardenheuer first performed a radical cystectomy (RC) in Germany in 1887, the procedure has become the standard treatment for patients with muscle-invasive bladder cancer. Complications often occur after this extensive procedure and it is necessary to consider the full range of complications, including perioperative mortality, when evaluating new treatments or surgical techniques, and most importantly, when counselling individual patients [2].

It was previously common to use the 30-day or in-hospital mortality rates for comparison, but improvements in postoperative care have further postponed surgery-related deaths, and currently surgeons usually report the 90-day mortality rates [3].

The Charlson comorbidity index (CCI), developed in 1987, includes 19 medical conditions scored as 1–6 with a calculated total sum score of 0–37, yielding a total comorbidity score. Reviews of the CCI suggest it has good reliability, an excellent correlation with the mortality and progression-free survival outcomes. Advantages of the CCI are that it is easily extractable from other variables, has widespread use and is easily handled [4]. In the phase of CCI validation, researchers found that age is an independent risk factor for death, so they adapted the CCI to account for the increase in age, i.e. an age-adjusted CCI (ACCI). From the combined score, an estimate of 10-year survival is given [5]. Thus we analysed the effect of preoperative clinical variables and comorbidity on morbidity and mortality rates, and on hospital re-admissions, after RC at our centre.

Patients and methods

We analysed the effect of different preoperative variables and comorbidity on the early (≤ 30 days), late (31–90 days) and cumulative 90-day morbidity and mortality, and hospital re-admissions, after RC. We recruited all patients with bladder cancer who underwent RC in the urology department of Kasr Al-Einy Hospital

over a period of 3 months. All patients signed an informed consent for inclusion in the study.

Before RC all patients provided a full history, and had a complete clinical examination, routine laboratory investigations, including serum albumin and a complete blood count. Radiological investigations were also used, in the form of abdomino-pelvic ultrasonography and CT of the abdomen and pelvis with contrast medium. For each patient we measured the body mass index (BMI) and calculated the CCI and the ACCI.

In addition to recording the routine intra- and postoperative data, we recorded the length of hospital stay (LOS) and all postoperative events for 90 days, and graded them according to the established five-grade modification of the original Clavien system [6].

RC was performed with the patients supine, being conventional in male and with an anterior pelvic exenteration in female patients. All patients had a standard lymphadenectomy.

Data were described statistically using the mean (SD) or range and percentages when appropriate. Numerical variables between the study groups were compared using the Mann–Whitney U -test for independent samples when comparing two groups, and the Kruskal–Wallis test when comparing more than two groups. We used Student's t -test, ANOVA single-factor test and the Chi-squared test where appropriate, with $P < 0.05$ considered to indicate statistical significance.

Results

Within the 3-month period, 31 patients underwent RC, comprising 22 men (71%) and nine women (29%) with 21 smokers (68%) and 10 non-smokers (32%). The mean (SD, range) age of the patients was 58.4 (8.89, 30–72) years.

We subgrouped the patients according to age into three groups, i.e. 14 (45%) aged < 60 years, 14 (45%) aged 60–69 years and three (10%) aged ≥ 70 years.

The mean (SD, range) BMI was 29.3 (6.52, 20.8–48.0) kg/m^2 , subgrouped into four groups, i.e. 12 (39%) with a normal BMI, seven (23%) as overweight, seven (23%) as obese and five (16%) as very obese.

The mean (SD, range) preoperative serum albumin level was 3.82 (0.37, 3.0–4.6) g/dL. Again we subgrouped the patients into two groups, seven (23%) with a level of < 3.5 g/dL and 24 (77%) with a level of \geq 3.5 g/dL.

The mean (SD, range) preoperative haemoglobin (Hb) level was 12.5 (1.61, 9.80–15.60) g/dL, and the patients were subgrouped into four groups, 11 men (36%) with a level of \geq 13 g/dL, 11 men (36%) of < 13 g/dL, six women (19%) of \geq 12 g/dL and three (10%) of < 12 g/dL.

Considering the comorbid conditions, 12 of the 31 patients (39%) reported no comorbid conditions, 11 (36%) had one and eight (26%) had two or more comorbid conditions. The comorbid conditions were hypertension in 10 patients (32%), liver disease in five (16%), chronic renal failure in four (13%), diabetes mellitus in four (13%), pulmonary disorder in three (10%), coronary artery disease in two (7%) and a neurological disorder in one (3%).

The mean (SD, range) preoperative CCI was 3 (1.0, 2.0–6.0), and patients were subgrouped as CCI \leq 2 in 12 (39%), 3–4 in 18 (58%) and > 4 in one (3%). The mean (SD, range) ACCI was 4.58 (1.54, 2.0–8.0), and subgrouped as < 3 in 11 (36%), 4–5 in 11 (36%) and > 5 in nine (29%).

The median (interquartile range, IQR) expected 10-year survival for the patients weighted against the existing comorbid conditions was 21% (75%).

Operative data

The RC procedures were performed by different surgeons with different levels of experience, including trainees, MSc and PhD students. Two types of urinary reconstruction were used, i.e. an orthotopic neobladder in 16 (52%) and an ileal conduit in 15 (48%).

Nineteen patients (61%) required an intraoperative blood transfusion, in four of 10 uncomplicated patients and in 15 of 21 (71%) who had complications. We de-

finied intraoperative bleeding as the need for \geq 4 units of blood and accordingly, six patients had intraoperative bleeding (19%).

Postoperative data and complications

The median (IQR) LOS was 16 (15) days, with two patients (6%) omitted in the follow-up period. Seven patients (23%) needed a re-admission, the cause being urinary retention and elevated chemistry in two, a pouch-vaginal fistula in two, and a suprapubic fistula, a deep venous thrombosis and a wound infection in one each.

There were postoperative complications in 21 patients (68%), the commonest being a wound complication in 12 (30%), followed by urinary leakage, pulmonary complications and haematological complications in five each (13%). There were gastrointestinal complications in four patients in the form of ileus in three and diarrhoea in one (Table 1).

The complications are subgrouped according to the five-grade modification of the original Clavien system. The commonest was Grade II in 10 patients, followed by Grade IIIb in five and Grade V in three (Table 1).

According to the type of urinary diversion, there were postoperative complications in 10/16 patients with an orthotopic neobladder diversion and 11/15 with an ileal conduit. Grouping the complications according to the Clavien system, the most frequent highest grade in those patients with an orthotopic neobladder was Grade IIIb and Grade II (three each), followed by Grade IIIa and Grade V (two each). In the ileal conduit group, the most frequent highest grade was Grade II (seven patients), followed by Grade IIIb (two) and Grades IVa and V (one each). There was no statistical significance between the types of diversion in the occurrence of postoperative complications ($P = 0.535$).

None of the 10 patients who had no complications had intraoperative bleeding, but six of the 21 who had complications had intraoperative bleeding (29%). The mean (SD) estimated blood loss for the complicated

Table 1 Postoperative complications and Clavien grade.

Complication type	Complication grade, <i>n</i>							Total, <i>n</i> (%)
	I	II	IIIa	IIIb	IVa	IVb	V	
Patients	0	10	2	5	1	0	3	21 (100)
Wound	0	6	0	3	1	0	2	12 (30)
Urinary leakage	0	0	1	2	0	0	2	5 (13)
Pulmonary	0	3	0	1	0	0	1	5 (13)
Gastrointestinal	0	4	0	0	0	0	0	4 (10)
Cardiac	0	0	0	0	1	0	0	1 (3)
Haematological	0	4	0	0	0	0	1	5 (13)
Urinary retention	0	1	1	0	0	0	0	2 (5)
Fistula	0	0	0	2	0	0	0	2 (5)
Bleeding	0	0	0	1	0	0	0	1 (3)
Death	0	0	0	0	0	0	3	3 (8)
Total, <i>n</i> (%)	0	18 (45)	2 (5)	9 (23)	2 (5)	0	9 (23)	40 (100)

vs. uncomplicated patient group was 1014.3 (420.16) vs. 715.0 (272.90) mL, respectively. The blood loss was significantly related to the occurrence of postoperative complications ($P = 0.025$).

The mean (range) postoperative Hb and Hb deficit were 10.3 (8.1–12.1) and 2.3 (0.1–5.6) g/dL, respectively. The mean postoperative Hb for the complicated vs. uncomplicated patients was 9.97 vs. 10.86 g/dL, respectively, and the mean deficit was 2.30 vs. 2.22 g/dL, respectively. Although the postoperative Hb level was significantly related to the occurrence of postoperative complications ($P = 0.027$), the deficit was not significantly related ($P = 0.870$).

Three patients died (10%) during the 90 days after RC, two in the first 30-days, and the third at 30–60 days. The cause of death was septicaemia in one patient, pulmonary embolus in one, and of uncertain cause in the remaining patient.

Analytical results

We analysed the effect of age, smoking, preoperative serum albumin and Hb levels, BMI, CCI and ACCI on the postoperative outcome.

There was a statistically significant difference between the three age subgroups for the postoperative complication rate and LOS. Older patients had a higher incidence of complications ($P = 0.009$) and a longer LOS ($P = 0.031$) (Table 2).

Age had no effect on either the intraoperative complications ($P > 0.05$), postoperative complication grade ($P = 0.273$), postoperative mortality ($P = 0.682$), or the re-admission rate ($P = 0.529$).

Smoking had no effect on either the intra- or postoperative complications ($P = 0.548$ and 0.660), postoperative complication grade ($P = 0.292$), postoperative mortality ($P = 0.967$), re-admission rate ($P = 0.593$), or the LOS ($P = 0.611$).

For the preoperative serum albumin level, there was a statistically significant difference between the two subgroups in postoperative mortality rate, being higher among patients with a lower serum albumin level (< 3.5 g/dL, $P = 0.048$; Table 3). However, because

Table 3 Preoperative albumin and postoperative mortality.

Variable, n(%)	Preoperative serum albumin, g/dL		Total	P
	< 3.5	≥ 3.5		
Yes	5	23 (96)	28 (90)	0.048
No	2	1 (4)	3 (10)	
Total	7	24	31	

there were very few deaths (three patients) and only two in those with a low serum albumin level, it is difficult to assign any valid and reliable significance. Although a low preoperative albumin level was associated with a high re-admission rate, it was not quite statistically significant ($P = 0.087$). The preoperative serum albumin level had no effect on the intra- or postoperative complication rate ($P > 0.05$ and 0.183), the postoperative complication grade ($P = 0.258$) or the LOS ($P = 0.740$).

There was no statistically significant difference among the four subgroups of preoperative Hb level in intra- or postoperative complication rate ($P > 0.05$ and 0.292), the postoperative complication grade ($P = 0.445$), the postoperative mortality ($P = 0.462$), the re-admission rate ($P = 0.638$) or the LOS ($P = 0.450$).

Although a high BMI was associated with a high postoperative complication grade, it was not quite statistically significant ($P = 0.058$; Table 4). There was no statistically significant difference between the four BMI subgroups in intra- or postoperative complication rates ($P > 0.05$ and 0.118), postoperative mortality ($P = 0.427$), readmission rate ($P = 0.322$), and the LOS ($P = 0.307$).

Patients with a high CCI had a statistically significantly higher incidence of postoperative complications ($P = 0.001$; Table 5). There was no statistically significant difference between the three subgroups in the intraoperative complication rates ($P > 0.05$), the postoperative complication grade ($P = 0.628$), the postoperative mortality ($P = 0.301$), the re-admission rate ($P = 0.848$), or the LOS ($P = 0.205$).

There was a statistically significant difference in the postoperative complication rate and LOS for the ACCI, patients with a high ACCI having a higher incidence of postoperative complications ($P < 0.001$) and a longer LOS ($P = 0.043$; Table 5). There was no statistically significant difference between the three subgroups for the intraoperative complication rate ($P > 0.05$), the postoperative complication grade ($P = 0.971$), postoperative mortality ($P = 0.382$), or the re-admission rate ($P = 0.414$).

Discussion

RC is the standard management for muscle-invasive bladder cancer and for non-muscle-invasive tumours for which intravesical therapy has failed. Thus we analysed the effect of preoperative variables (age, history

Table 2 Age groups and complications.

Variable, n (%)	Age group (years)			Total	P
	< 60	60–69	≥ 70		
<i>Complications</i>					
Yes	5 (36)	12 (86)	3	20 (65)	0.009
No	9 (64)	2 (14)	0	11 (36)	
Total	14	14	3	31	
<i>LOS, days</i>					
≤ 15	10 (71)	4 (29)	1	15 (48)	0.057
16–25	3 (21)	5 (36)	1	9 (29)	
> 25	1 (7)	5 (36)	1	7 (23)	
Total	14	14	3	31	

Table 4 BMI subgroups and the complication grade.

Clavien grade	BMI group, <i>n</i>				Total, <i>n</i> (%)	<i>P</i>
	Normal	Overweight	Obese	Very obese		
II	5	1	2	1	9 (45)	0.058
IIIa	1	0	0	1	2 (10)	
IIIb	0	0	4	1	5 (25)	
IVa	0	1	0	0	1 (5)	
V	2	0	0	1	3 (15)	
Total	8	2	6	4	20	

Table 5 CCI and ACCI groups and complications.

Complications	CCI group, <i>n</i> or <i>n</i> (%)			Total	<i>P</i>	ACCI group, <i>n</i> or <i>n</i> (%)			Total	<i>P</i>
	≤2	3–4	>4			≤3	4–5	>5		
Yes	3	16 (89)	1	20 (65)	0.001	2	7	12	21 (68)	<0.001
No	9	2 (11)	0	11 (36)		9	1	0	10 (32)	
Total	12	18	1	31		11	8	12	31	
<i>LOS, days</i>										
≤15	–	–	–	–	–	7	6	2	15 (48)	0.043
16–25	–	–	–	–	–	3	0	6	9 (29)	
>25	–	–	–	–	–	1	2	4	7 (23)	
Total	–	–	–	–	–	11	8	12	31	

of smoking, BMI, serum albumin, blood Hb, CCI, and ACCI) on the postoperative outcome of RC in our department over a 3-month period, using different statistical methods.

Evaluating complications over the 90-day, rather than the traditional inpatient or 30-day postoperative period, allows an analysis of the natural evolution of complications over time. We recorded all complications within 90 days of RC and graded them according to an established five-grade modification of the original Clavien system.

Comparing the highest grade found in the present patients with those of Shabsigh et al. [7] the highest grade was 0–5 in 10 (32%), none, 10 (32%), seven (23%), one (3%) and three (10%) patients, respectively, compared to 36%, 11%, 40%, 12%, 0.2% and 2% in the study of Shabsigh et al., respectively.

There was a significant association between both the preoperative CCI and ACCI scores and the occurrence of early complications after RC. Similarly in 2012, Fan et al. [8] reported that ACCI is a significant risk factor related to the in-hospital complications of RC, and in 2010, Hautmann et al. [9] reported that CCI is a significant predictor of the postoperative complication rate and severity.

We found no significant difference between the different CCI groups in postoperative mortality. In the retrospective cohort study conducted by Morgan et al. [10] they found no association between the CCI and the 90-day mortality rate. Earlier, in a multivariate analysis conducted by Koppie et al. in 2008 [11], they reported a significantly increased risk of death with higher ACCI scores.

There was no significant difference between the ACCI groups in the re-admission rate. This is contrary to the findings of Stimson et al. [12], who stated that the ACCI was an independent predictor providing preoperative information that identified patients more likely to require re-admission.

In the current study there was a significant association between both age and preoperative ACCI score and the LOS. Older patients and those with higher ACCI scores had a longer stay. This association might be attributed to the higher incidence of complications among this group of patients. As the incidence of bladder carcinoma increases with age, this means it occurs primarily in older patients and this age group is more likely to have pre-existing diseases. Also, as patients with bladder carcinoma are more likely to be present or former smokers, this in turn results in an increased incidence of comorbidities.

Analysing the results of the current study shows an association between the age of the patients and the rate of early postoperative complications, but not with the early postoperative mortality or the re-admission rate. This is similar to results of Bostrom et al. [13] who, in their retrospective study, reported that age has no association with mortality but it is a significant predictor of in-hospital morbidity. In contrast, Morgan et al. [10] reported that age is a strong predictor of mortality in the early period after RC.

Comparing the clinical outcomes after RC between younger and older patients, Clark et al. [14] reported that the elderly had a similar mortality rate but higher early complication rate, which is probably related to the higher rate of comorbidities in the elderly.

We found no statistically significant difference between the BMI subgroups and either the rate or grade of early postoperative complications, early postoperative mortality, or re-admission rate. Although the analysis of the complication grades showed that a high BMI was associated with higher grade of complication, it was not quite statistically significant ($P = 0.058$). This is contrary to the results of Lee et al. [15] who reported a retrospective cohort study of 498 patients and stated that the complication rate after RC was associated with the increase in the BMI.

Although we found an association between the albumin level and the early postoperative mortality rate, because there were very few deaths we think this significance is not reliable. There was no association between the albumin level subgroups and the complication rate and grade or re-admission rate.

Few studies have attempted to identify the nutritional factors predictive of postoperative mortality in patients undergoing RC. Notably, in a cohort study of > 2500 patients who had undergone RC, Hollenbeck et al. [16] reported an increased perioperative mortality rate in association with a low preoperative serum albumin level.

In a prospective study of 54,215 surgical patients at 14 academically affiliated Veterans Affairs centres, patients with a 1.0 g/dL decrease in serum albumin level had twice the risk of 30-day mortality [17]. Similarly, Beghetto et al. [18] evaluated 434 medical and surgical inpatients to determine whether nutritional variables (albumin < 3.5 g/dL, weight loss > 5%, BMI < 18.5 kg/m², lymphocyte count < 1500, and Subjective Global Assessment score indicating severe malnutrition) were predictive of in-hospital death and other adverse outcomes. Multivariate analysis showed that albumin was the only nutritional variable predictive of in-hospital mortality.

In the present study a preoperative nutritional deficiency (measured by a low BMI, low serum albumin level and/or preoperative weight loss) was predictive of an increased 90-day mortality and poor overall survival. Secondary analyses using albumin level alone showed that the albumin level might be a sufficient indicator of preoperative nutritional status.

Morgan et al. [10] reported that the preoperative serum albumin level was the variable most strongly associated with 90-day mortality, accounting for a 2.5-fold increase in the risk of 90-day mortality per 0.7 g/dL decrease in the serum albumin level, emphasising the need to evaluate this variable before surgery.

For the preoperative Hb level we found no association between the Hb subgroups and either the complication grade, early postoperative mortality or the re-admission rate. There was an association between the postoperative Hb level and the occurrence of complications. Similarly, Braticevici et al. [19] found no relationship between the preoperative Hb level and the peri- or postoperative complication rates. However, earlier in 1994, Thrasher et al. [20] reported that a lower preoper-

ative Hb level of 12 g/dL vs. > 12 g/dL was predictive of poor cancer-specific survival ($P < 0.001$).

The present study has a few limitations; the sample was relatively small, which precludes drawing firm conclusions, especially when interpreting some outcomes like postoperative mortality (three cases only). Also, the CCI and the ACCI are applied to generate a 10-year survival from existing comorbid conditions. We only analysed the outcome of RC in terms of the early postoperative period, due to the time constraints of the study. Also, being a teaching hospital, our results might be affected by the different levels of the surgeons' experience.

We showed that there was a high complication rate after RC, especially for wound-related complications, which should be considered in our trials to improve the outcome of RC. Despite the efforts made to reduce the mortality rate and prevent complications of RC, the postoperative morbidity rate remains high, partly because of the complexity of the procedures.

We showed a significant association between comorbidity and early complications. This finding highlights the probable value of CCI and ACCI in assessing the overall health of patients before recommending and proceeding with surgery. In their calculation, the CCI and ACCI include a few comorbid conditions that we did not encounter in our patients (i.e. AIDS, lymphoma and leukaemia). This might have affected the CCI and ACCI scores of the present patients. We therefore recommend that future studies could aim at developing a risk index that is more 'bladder cancer specific'. This index would have more weight on the comorbid conditions that are more frequent in these patients.

Finally, the present study was conducted at a tertiary centre (Kasr Al-Einy Hospital). The patients with bladder cancer expected to be seen at this centre are in an advanced stage with many coexisting comorbid conditions.

In conclusion, wound-related complications were the most common complication after RC, followed by genitourinary complications. Age and the CCI and ACCI scores were associated with the occurrence of early complications, but there was no association with complication grade or mortality. Older patients and patients with higher ACCI scores had a longer LOS.

Conflict of interest

None.

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